As filed with the Securities and Exchange Commission on September 24, 2010.

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Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM F-1 **REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933** 

#### **BIOLINERX LTD.**

(Exact Name of Registrant as Specified in its Charter) 2834

(Primary Standard Industrial Classification Code Number)

**BioLineRx** Ltd. P.O. Box 45158 **19 Hartum Street** Jerusalem 91450, Israel (972) (2) 548-9100

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

> Nir Gamliel BioLineRx USA, Inc. 15400 Calhoun Drive, Suite 125 **Rockville, Maryland 20855** (240) 864-0920

(Name, Address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering, o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

Title of each class of securities to be registered	CALCULATION OF	REGISTRATIC Amount to be registered	ON FEE <sup>(1)</sup> Proposed maximum offering price per unit <sup>(2)</sup>	Proposed maximum aggregate offering price	Amount of registration fee
Ordinary Shares, par value NIS 0.01 per share		U.S.\$	U.S.\$	U.S.\$40,250,000	U.S.\$ 2,870

(1) Unless otherwise indicated, all share amounts and prices assume the consummation of a reverse stock split, at a ratio of : to be effected prior to the effectiveness of the registration statement of which this prospectus is a part.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) of the Securities Act.

State of Israel (State or other jurisdiction of incorporation or organization) Not Applicable (I.R.S. Employer Identification No.)

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED September 24, 2010



**Ordinary Shares** 

We are offering of our ordinary shares. This is our initial public offering in the United States, and no public market currently exists in the United States for our ordinary shares. All of the ordinary shares to be sold in the offering are being sold by us. We have applied to have our ordinary shares listed on The NASDAQ Global Market under the symbol "BLRX." We anticipate that the initial offering price for our ordinary shares will be between \$ and \$ per share.

Our ordinary shares currently trade on the Tel Aviv Stock Exchange under the symbol "BLRX." On September 21, 2010, the last reported sale price of our ordinary shares was NIS 3.46, or \$0.93 per share (based on the exchange rate reported by the Bank of Israel on such date).

Investing in our ordinary shares involves a high degree of risk. See "Risk Factors" beginning on page <u>10</u>.

	Per Share	Total
Public Offering Price	\$	\$
Underwriting Discounts and Commissions	\$	\$
Proceeds, Before Expenses, to Us	\$	\$

Neither the U.S. Securities and Exchange Commission, the Israel Securities Authority nor any state or other foreign securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

We have granted the underwriters a 30-day option to purchase up to an additional ordinary shares to cover over-allotments, if any, at the public offering price per share, less underwriting discounts and commissions.

The underwriters expect to deliver the ordinary shares against payment in New York, New York on or about , 2010.

**JMP Securities** 

**Oppenheimer & Co.** 

The date of this prospectus is \_\_\_\_\_, 2010

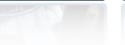


### Bench to Bedside to Partner















You should rely only on the information contained in this prospectus and any free writing prospectus prepared by or on our behalf. We have not, and the underwriters have not, authorized anyone to provide you with information different from that contained in this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, offering to sell or solicit any security other than the ordinary shares offered by this prospectus. In addition, we are not offering, and the underwriters are not offering, to sell or solicit any security other than the ordinary shares of from any person in any jurisdiction where it is unlawful to make this offer to or solicit an offer from a person in that jurisdiction. The information contained in this prospectus is accurate as of the date on the front of this prospectus only, regardless of the time of delivery of this prospectus or of any sale of our ordinary shares. Our business, financial condition, results of operations and prospects may have changed since that date.

We have obtained the statistical data, market data and other industry data and forecasts used throughout this prospectus from publicly available information and from reports we commissioned. We have not sought the consent of the sources to refer to the publicly available reports mentioned in this prospectus.

#### **BIOLINERX LTD.**

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Unless the context otherwise requires, all references to "BioLineRx," "we," "us," "our," the "Company," the "Group" and similar designations refer to BioLineRx Ltd. and its wholly-owned subsidiaries: BioLine Innovations Jerusalem Ltd., or BIJ Ltd.; BioLine Innovations Jerusalem Limited Partnership, or BIJ L.P.; and BioLineRx USA, Inc., or BioLineRx USA.

Through and including , 2010 (the 25<sup>th</sup> day after the date of this prospectus), federal securities laws may require all dealers that effect transactions in these securities, whether or not participating in this offering, to deliver a prospectus. This requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriter and with respect to their unsold allotments or subscriptions.

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#### SUMMARY

This summary highlights selected information contained elsewhere in this prospectus that we consider important. This summary does not contain all of the information you should consider before investing in our ordinary shares. You should read this summary together with the entire prospectus, including the risks related to our most advanced therapeutic candidates, BL-1020, BL-1040 and BL-5010, our business, our industry, investing in our ordinary shares and our location in Israel, that we describe under "Risk Factors" and our consolidated financial statements and the related notes included at the end of this prospectus before making an investment in our ordinary shares.

#### **Our Business**

We are a clinical stage biopharmaceutical development company dedicated to identifying, in-licensing and developing therapeutic candidates that have advantages over currently available therapies or that address unmet medical needs. Our current development pipeline consists of three clinical stage therapeutic candidates: BL-1020, a new chemical entity, or NCE, that we believe may be the first antipsychotic therapeutic to improve cognitive function in schizophrenia patients; BL-1040, a novel polymer solution for use in the prevention of cardiac remodeling following an acute myocardial infarction, or AMI, and BL-5010, a novel formulation for the non-surgical removal of skin lesions. In addition, we have seven therapeutic candidates in the preclinical stages of development, including a compound for the treatment of neuropathic pain that we expect will enter clinical trials in the fourth quarter of 2010. We generate our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates has been approved for marketing and, to date, there have been no commercial sales of any of our therapeutic candidates. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case by case basis, the commercialization of our therapeutic candidates independently.

#### **Our Product Pipeline**

Pre-Clinica Phase I Phase II Clinica BL-1020 Schizophrenia Out-licensed to Cypress Bioscience Inc. following completion of Phase Ilb AMI BL-1040 Out-licensed to Ikaria Holdings Inc. following Phase I/II BL-5010 Skin lesions Pre-Clinica BL-1021 Neuropathic pain BL-2030 Inflammation BL-4010 Cancer BL-4040 Acute Kidney Injury BL-5030 Deep Vein Thrombosis BL-5040 Inflammatory Bowel Disea BL-6010 Type 2 Diabetes

The table below summarizes our current pipeline of therapeutic candidates, as well as the target indication and status of each candidate.

#### **BL-1020**

Our most advanced therapeutic candidate, BL-1020, is in development for schizophrenia, a chronic, severe and disabling brain disorder that affects approximately 1% of the U.S. adult population as reported by the National Institute of Mental Health. Schizophrenia patients are typically treated with one of several commercially available antipsychotics, all of which are associated with side effects that reduce patient compliance and do not address the deterioration of cognitive function that affects the daily lives of schizophrenia patients. Despite these drawbacks, the three most commonly used antipsychotics, Risperdal, Zyprexa and Seroquel, reached aggregate sales of approximately \$7.1 billion in the United States in 2009,

based on the annual reports filed with the U.S. Securities and Exchange Commission, or SEC, by each of Johnson & Johnson, Eli Lilly and Company and AstraZeneca Pharmaceuticals LP, the companies that market those drugs.

BL-1020 is a new chemical entity that effectively reduces psychotic symptoms which we believe may also improve cognition. BL-1020 targets the imbalance of two key neurotransmitters implicated in schizophrenia, dopamine and gamma aminobutyric acid, or GABA. We believe that the reduction in psychotic symptoms is attributable to BL-1020's dopamine antagonism. BL-1020's GABAergic activity may improve cognition.

In September 2009, we announced positive topline results from our phase 2b EAGLE (Effective Anti-psychosis via GABA Level Enhancement) study, which assessed the efficacy, safety and tolerability of BL-1020 compared to placebo. Before a New Drug Application, or an NDA, can be filed with respect to BL-1020, a phase 3 clinical trial must be performed to confirm its effectiveness, monitor for potential side effects, compare it to commonly used treatments, and collect information that will allow it to be used safely. There can be no assurance that that the results of a phase 3 clinical trial will confirm the positive results obtained in the phase 2b study. In addition, the U.S. Food and Drug Administration, or the FDA, might not find BL-1020 effective or safe enough to be approved for commercial sale.

In June 2010, we entered into an exclusive, royalty-bearing out-licensing arrangement with Cypress Bioscience, Inc., or Cypress Bioscience, for BL-1020, covering the United States, Canada and Mexico. Under the arrangement, Cypress Bioscience is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize, BL-1020 for the prevention, diagnosis and treatment of all human diseases in the United States, Canada and Mexico. We have retained the rights to BL-1020 for the rest of the world. In addition, under the agreement, Cypress Bioscience has licensed to us the right to use any and all regulatory data generated by Cypress Bioscience in connection with its pursuit of regulatory approval for BL-1020 in Cypress Bioscience's territory, as described in the agreement, for use by us outside of Cypress Bioscience's territory, subject to our future reimbursement of certain pre-commercialization expenses incurred by Cypress Bioscience in generating such data. We received an upfront fee of \$30.0 million from Cypress Bioscience upon our receipt of consent from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, or the OCS, to the agreement in August 2010, and we are entitled to receive up to an additional \$250.0 million in connection with the achievement of certain performance-based milestones and an additional up to \$85.0 million upon the achievement of certain sales-based milestones. Cypress Bioscience may pay a portion of the first performance-based milestone payment by purchasing our ordinary shares, in its sole discretion. Upon execution of the licensing agreement, Cypress Bioscience deposited \$30.0 million in an escrow account pending approval of the agreement by the OCS. We are also entitled to royalties, ranging from 12% to 18%, on annual net sales of BL-1020 in Cypress Bioscience's territory under the agreement for the applicable royalty term. We are obligated to pay to Bar Ilan Research and Development Company Ltd., or Bar Ilan Research and Development, and Ramot at Tel Aviv University Ltd., or Ramot, collectively, a payment equal to 22.5% of the net consideration we receive from Cypress Bioscience in connection with our in-licensing of BL-1020. In August 2010, we paid Bar Ilan Research and Development and Ramot \$6.75 million, in the aggregate, from the \$30.0 million upfront fee. We also paid the OCS \$3.0 million as partial repayment of grants previously received for the BL-1020 development program.

#### **BL-1040**

Our second lead therapeutic candidate, BL-1040, is a novel resorbable polymer solution for use in the prevention of cardiac remodeling that may occur in patients who suffered an AMI. AMIs result from an occlusion in the coronary artery and affect the left ventricle of the heart, or the LV. Patients with severe injury to the LV may be at risk for cardiac remodeling that may lead to congestive heart failure. Cardiac remodeling refers to the changes in size, shape, and function of the heart following injury to the ventricles (typically from an AMI) that results in increased pressure or volume overload on the heart. Following an AMI, there is myocardial necrosis (cell death) and disproportionate thinning of the heart. This thin, weakened area is unable to withstand the pressure and volume load on the heart. As a result there is dilatation of the chamber arising from the infarct region. The initial remodeling phase after a myocardial infarction results in repair of the necrotic area and myocardial scarring that may, to some extent, be considered beneficial since there is an improvement in or maintenance of LV function and cardiac output. Over time, however, as cardiac remodeling

progresses, the heart becomes less elliptical and more spherical. Ventricular mass and volume increase, which together adversely affect cardiac function. Eventually, diastolic function may become impaired, further causing decline. Based on our review of data regarding the incidence of myocardial infarctions in the United States, we believe that approximately 400,000 people in the United States were at risk of significant cardiac remodeling following an AMI in 2009. Preventing cardiac remodeling following an AMI may prevent transition to congestive heart failure and/or improve patient survival over the long-term.

Following an AMI, BL-1040 is administered via intracoronary injection during standard vessel reopening procedures, such as balloon catheterization and stenting. Upon contact with damaged cardiac tissue, the liquid BL-1040 transitions into a gel within the infarcted cardiac tissue and forms a "scaffold" that supports, retains the shape of, and enhances the mechanical strength of the heart muscle during the recovery and repair phases that follow an AMI. Based on data from our pilot phase 1/2 study and preclinical testing, we believe treatment with BL-1040 preserves the normal functioning of the heart.

In July 2009, we entered into an exclusive, worldwide out-licensing arrangement with a wholly-owned subsidiary of Ikaria Holdings, Inc., or Ikaria, with regard to BL-1040. Under the arrangement, Ikaria is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or a product related thereto. We received \$7.0 million from Ikaria in September 2009. On February 24, 2010, we received the final assessment of the Independent Safety Monitoring Board, or ISMB, relating to the pilot phase 1/2 study of BL-1040, which was designed to assess the safety and feasibility of BL-1040. The ISMB's conclusions, relating to the 27 patients who participated in the study and completed a six-month follow-up period, indicated that the treatment is safe and that it would be appropriate to continue clinical development of the device. The conclusions of the ISMB constituted the successful fulfillment of a milestone under our out-licensing agreement with Ikaria, and, accordingly, Ikaria made a milestone payment of \$10.0 million to us in April 2010, which was subject to U.S. withholding tax of approximately \$1.5 million. We are entitled to receive up to an additional \$265.5 million from Ikaria upon achievement of certain developmental, regulatory, and commercial milestones under the out-licensing agreement. Further, we are entitled to receive royalties from Ikaria on net sales of any product developed under the arrangement. We are obligated to pay 28% of all net consideration received under this arrangement to B.G. Negev Technologies and Applications, Ltd., the technology transfer company of Ben Gurion University, or B.G. Negev Technologies, the third party from which we licensed BL-1040 in 2004.

#### **BL-5010**

Our third lead therapeutic candidate, BL 5010, is a novel formulation composed of two acids being developed for the removal of skin lesions in a nonsurgical manner. These two acids have already been approved for use in cosmetics. If approved, BL-5010 would be a convenient alternative to invasive, painful and expensive removal treatments for skin lesions and may allow for histological examination. Because treatment with BL-5010 is non-invasive, we believe BL-5010 poses minimal infection risk, and requires no anesthesia or bandaging. In June 2009, we announced the initiation of a phase 1/2 clinical trial in 60 patients with seborrheic keratosis in Germany and the Netherlands to assess the safety and efficacy of BL-5010. The study is also designed to assess the feasibility of preserving the cellular structure of skin lesions for subsequent histological exams. Interim results from this trial, which were announced in January 2010, indicate that all treated skin lesions were completely removed within 30 days of treatment following a single application.

#### **Our Product Development Approach**

As part of our business strategy, we continuously source, evaluate and in-license therapeutic candidates. We establish and maintain close relationships with research institutes, academic institutions and biotechnology companies in Israel and, more recently, in other countries to identify and in-license therapeutic candidates. Before in-licensing, each therapeutic candidate must pass through our thorough screening process that includes our proprietary MedMatrx scoring tool. We evaluate each compound's potential for success by looking at the candidate's efficacy, safety profile, total estimated development costs, technological novelty, patent status, market need and approvability, among other information. Our Scientific Advisory Board and disease-specific third-party advisors are active in evaluating each therapeutic candidate. Our approach is consistent with our objective of proceeding only with therapeutic candidates that we believe exhibit a relatively high probability

of therapeutic and commercial success. To date, we estimate we have evaluated over 1,000 compounds, and we have presented more than 60 candidates to our Scientific Advisory Board for consideration, initiated development of 30 therapeutic candidates and terminated 20 feasibility programs.

When possible, we make use of third-party funding to develop early-stage therapeutic candidates. In January 2005, we entered into an agreement with the OCS to operate a biotechnology incubator. We develop certain of our in-licensed candidates with financial assistance from the OCS and have received approximately \$11.4 million as of June 30, 2010 in the form of loans that are forgiven unless a project reaches commercialization. We have also received \$5.0 million in grants from the OCS outside of the incubator agreement as of June 30, 2010. We are not required to repay grants for terminated projects. Of our 10 current development projects, five have been funded through the OCS, including BL-1020, BL-1021, BL-1040, BL-2030 and BL-4040. Other than BL-1020, all of these projects were also funded through our incubator. In addition, in January 2007 we entered into an agreement with our shareholder, Pan Atlantic Bank and Trust Limited, or Pan Atlantic, pursuant to which Pan Atlantic committed to provide us with grants of up to \$5.0 million to be used in connection with the in-licensing and development of early development stage therapeutic candidates.

#### **Our Strategy**

Our objective is to be a leader in developing and commercializing innovative pharmaceutical, medical device and biopharmaceutical products.

The key elements of our strategy include the following:

- facilitate the successful development and commercialization of BL-1040 by Ikaria and BL-1020 by Cypress Bioscience.
- assess the timing and conditions for the continued development and commercialization of BL-1020 outside of the United States, Canada and Mexico.
- commercialize additional therapeutic candidates through out-licensing arrangements or, where appropriate, by ourselves.
- design development programs that reach critical decisions quickly.
- use our expertise and proprietary screening methodology to evaluate in-licensing opportunities.
- leverage and expand our relationships with research institutes, academic institutions and biotechnology companies, including the specific strategic relationships that we have developed with Israeli research and academic institutions, to identify and in-license promising therapeutic candidates.

#### **Risks Related to Our Business**

We are subject to certain risks related to our lead therapeutic candidates, BL-1020, BL-1040 and BL-5010, our other therapeutic candidates, our business, our industry and this offering. The section entitled "Risk Factors" beginning on page <u>10</u> of this prospectus describes risks and uncertainties that could materially and adversely affect our business, prospects, financial condition, operating and growth strategy. In summary, significant risks related to our business include:

- our ability to achieve and sustain profitability;
- our ability to source capital to satisfy critical funding needs;
- delays in obtaining, or a failure to obtain, regulatory approval for our therapeutic candidates, including our lead candidates, BL-1020, BL-1040 and BL-5010;
- our ability to commercialize our lead therapeutic candidates and effectively secure or develop sales, marketing and distribution capabilities or arrangements;
- the expense, time and uncertainty involved in developing our therapeutic candidates, some or all of which may never reach the regulatory or approval commercialization stage;
- our lack of experience in managing the commercial sales of an approved therapeutic candidate;

- our reliance on third parties to conduct our clinical trials and to manufacture preclinical and clinical drug supplies;
- our ability to compete in the pharmaceutical industry;
- our ability to maintain our proprietary and licensed intellectually property assets;
- our ability to defend against any third party claims of intellectual property infringement; and
- risks associated with our operations in Israel.

#### Risk of Adverse U.S. Tax Consequences Related to Ownership of Our Ordinary Shares

Although we were not a passive foreign investment company, or a PFIC, in 2009, we believe that we were a PFIC during certain prior years and, although we do not anticipate being a PFIC in 2010, or in any subsequent year, our operating results for any such years may cause us to be a PFIC. If we are a PFIC in 2010, or in any subsequent year, a U.S. shareholder would suffer adverse tax consequences. For additional information, please see "Taxation — U.S. Federal Income Tax Considerations."

#### **Reverse Stock Split**

At a special meeting of our shareholders held on August 17, 2010, our shareholders authorized our Board of Directors to adopt a reverse stock split, which we intend to effect prior to this offering and which is subject to the completion of this offering. The reverse stock split will be effected at a ratio of up to 10:1, at our Board of Director's discretion. Accordingly, except as otherwise indicated, all share prices, share numbers and per share amounts set forth in this prospectus will be retroactively adjusted for all periods presented to reflect this reverse stock split.

#### **Our Corporate Information**

We were incorporated under the laws of the State of Israel in 2003. BioLineRx was founded by leading institutions in the Israeli life sciences industry, including Teva Pharmaceutical Industries Ltd., or Teva. We completed our initial public offering in Israel in February 2007 and our ordinary shares are currently traded on the Tel Aviv Stock Exchange, or TASE, under the symbol "BLRX." Our principal executive offices are located at 19 Hartum Street, P.O. Box 45152, Jerusalem 91450, Israel, and our telephone number is +972-2-548-9100. Our address on the internet is www.biolinerx.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and is not incorporated by reference herein. We have included our website address in this prospectus solely as an inactive textual reference.

BioLine Innovations Jerusalem Ltd., or BIJ Ltd., and BioLine Innovations Jerusalem Limited Partnership, or BIJ L.P., were formed in January 2005 to operate our biotechnology incubator and share our address and telephone number with us. Our wholly-owned subsidiary, BioLineRx USA Inc., was incorporated in Delaware on January 4, 2008, and is located at 15400 Calhoun Drive, Suite 125, Rockville, Maryland 20855, and its telephone number is (240) 864-0920.

This prospectus contains trademarks and trade names owned by other companies.

Ordinary shares we are offering

Offering price

Ordinary shares to be outstanding immediately after this offering

Over-allotment option

Use of proceeds

#### THE OFFERING

#### ordinary shares

We expect that the initial public offering price for our ordinary shares being sold in this offering will be between \$ and \$ per share. The offering price will be determined by reference to the closing price of our ordinary shares on the TASE on the pricing date after taking into account prevailing market conditions and through negotiations between us and the underwriters. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant. On , 2010 the last reported sale price of our ordinary shares was NIS , or \$ , per share (based on the exchange rate reported by the Bank of Israel for such date).

ordinary shares

ordinary shares

We estimate that we will receive net proceeds, after deducting the underwriting discounts and commissions and the estimated offering expenses, of approximately \$31.0 million from our sale of ordinary shares in this offering, based on an assumed public offering price of \$ per share.

We expect to use the net proceeds of this offering as follows:

- approximately \$21.0 million of the net proceeds to fund the phase 1 and phase 2 clinical trials of, and commence commercialization efforts for, two clinical stage therapeutic candidates, and to fund preclinical studies of the next two therapeutic candidates to advance from the feasibility stage to the pre-clinical and/or initial phase 1 clinical stages;
- approximately \$5.0 million of the net proceeds to fund feasibility studies for up to 12 molecules as they are introduced to our pipeline, if any; and
- approximately \$5.0 million of the net proceeds to fund our operations, for general corporate purposes and to fund business development and marketing efforts.

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	If we elect to commercialize any of our therapeutic candidates internally, a portion of the proceeds will be used to fund the commercialization. We may find it necessary or advisable to use the net proceeds for other purposes. Accordingly, our management will have significant flexibility in applying the net proceeds of this offering. See "Use of Proceeds."
Risk factors	See "Risk Factors" beginning on page $\underline{10}$ of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our ordinary shares.
TASE symbol	BLRX
Proposed NASDAQ Global Market symbol	We have applied to have our ordinary shares listed on The NASDAQ Global Market under the symbol "BLRX."

The number of ordinary shares to be outstanding after this offering is based on ordinary shares outstanding as of the date of this prospectus. The number of outstanding ordinary shares excludes the upon the exercise of outstanding options under our 2003 Share Option Plan as of , 2010.

Unless otherwise indicated, all information in this prospectus assumes:

- an initial public offering price of \$ per ordinary share, the mid-point of the range on the cover of this prospectus;
- that the underwriters' over-allotment option to purchase up to an additional ordinary shares from us is not exercised;
- with respect to all amounts represented in dollars that were incurred in New Israeli Shekels, or NIS (other than those included in, or derived from, the financial statements, those as of a transaction date or unless otherwise stated), that the exchange rate is \$1.00 = NIS 3.875, based on the exchange rate reported by the Bank of Israel for June 30, 2010;
- with respect to all amounts represented in dollars that were incurred in euros (other than those included in, or derived from, the financial statements, those as of a transaction date or unless otherwise stated), that the exchange rate is \$1.00 = €0.811 reported by European Central Bank for June 30, 2010; and
- a : reverse split of our outstanding ordinary shares, and the recapitalization of our authorized share capital so that each share has a par value of NIS , which is expected to be effected prior to the closing of this offering.

#### SUMMARY CONSOLIDATED FINANCIAL DATA

The following table is a summary of our historical consolidated financial data, which is derived from our consolidated financial statements, which have been prepared in accordance with International Financial Reporting Standards, or IFRS. The summary consolidated statements of operations data for the years ended December 31, 2007, 2008 and 2009 are derived from our audited consolidated financial statements included elsewhere in this prospectus.

You should read this summary financial data in conjunction with, and it is qualified in its entirety by, reference to our historical financial information and other information provided in this prospectus including, "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes appearing elsewhere in this prospectus. The historical results set forth below are not necessarily indicative of the results to be expected in future periods. We derived the selected consolidated financial data as of and for the six months ended June 30, 2010 and June 30, 2009 from our unaudited consolidated financial statements included elsewhere in this prospectus. In the opinion of our management, our unaudited consolidated financial statements contain all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of our financial position, results of operations and cash flows as of and for the periods indicated therein. The results of operations for the six months ended June 30, 2010 and June 30, 2009 are not necessarily indicative of the operating results to be expected for the full fiscal years encompassing those periods.

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Consolidated Statements Of	2006	2007	2008	2009	2009	2010	2010 <sup>(2)</sup>
Operations Data: <sup>(1)</sup>		(in thousands, except share and per share data) NIS				U.S.\$	
Revenues				63,909			0.0.0
Cost of revenues	_	_		(22,622)		_	
Operating expenses:				(22,022)			
Sales and marketing expenses				(3,085)	(1,477)	(2,184)	(564)
Research and development	(42,193)	(75,863)	(106,156)	(90,302)	(49,850)	(37,032)	(9,557)
expenses, net							
General and administrative expenses	(6,357)	(13,611)	(13,083)	(11,182)	(4,307)	(6,224)	(1,606)
Gain on adjusting warrants to fair value	—	27,557	3,658	—	—	—	—
Capital loss, net	(121)						
Operating loss	(48,671)	(61,917)	(115,581)	(63,282)	(55,634)	(45,440)	(11,727)
Financial income	584	7,875	13,001	3,928	3,799	2,878	743
Financial expenses	(834)	(5,377)	(12,269)	(2,164)	(1,739)	(1,062)	(274)
Net loss	(48,921)	(59,419)	(114,849)	(61,158)	(53,574)	(43,624)	(11,258)
Net loss per ordinary share <sup>(3)</sup>	(1,772.6)	(0.88)	(1.44)	(0.63)	(0.68)	(0.35)	(0.09)
Number of ordinary shares used in	38,521	69,302,075	78,131,103	123,497,029	78,131,578	123,512,879	123,512,879
computing loss per ordinary share							
					As of June 30,           2010         2010 <sup>(2)</sup>		
Consolidated Balance Sheet Data:							2010 <sup>(2)</sup>
					(in thousands	s NIS) (in th	ousands U.S.\$)
Cash and cash equivalents					88,	489	22,836
Accounts receivable						_	
Property, plant and equipme	ent, net				4,	696	1,212
Total assets					110,	,311	28,467
Total liabilities					32,	815	8,468
Total shareholders' equity					77,	496	19,999

(1) Data on diluted loss per share was not presented in the financial statements because the effect of the exercise of the options and warrants is anti-dilutive.

(2) Calculated using the exchange rate reported by the Bank of Israel for June 30, 2010 at the rate of one U.S. dollar per NIS 3.875.

(3) The net loss per share has been adjusted to reflect the benefit component related to the issuance of rights to investors.

#### **RISK FACTORS**

You should carefully consider the risks we describe below, in addition to the other information set forth elsewhere in this prospectus, including our consolidated financial statements and the related notes beginning on page F-1, before deciding to invest in our ordinary shares. These material risks could adversely impact our results of operations, possibly causing the trading price of our ordinary shares to decline, and you could lose all or part of your investment.

#### **Risks Related to Our Financial Condition and Capital Requirements**

### We are a clinical stage biopharmaceutical development company with a history of operating losses, expect to incur additional losses in the future and may never be profitable.

We are a clinical stage biopharmaceutical development company that was incorporated in 2003. Since our incorporation, we have been focused on research and development. Our most advanced therapeutic candidates are in clinical development. We, or our licensees, as applicable, will be required to conduct significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial sales of our therapeutic candidates. We have incurred losses since inception, principally as a result of research and development and general administrative expenses in support of our operations. We experienced net losses of approximately NIS 43.6 million for the six months ended June 30, 2010, approximately NIS 61.5 million in 2009, approximately NIS 114.8 million in 2008 and approximately NIS 59.4 million in 2007. As of June 30, 2010, we had an accumulated deficit of approximately NIS 368.9 million. We anticipate that we will incur significant additional losses as we continue to focus our resources on prioritizing, selecting and advancing our most promising therapeutic candidates. We may never be profitable and we may never achieve significant sustained revenues.

#### We cannot ensure that our existing cash and investment balances will be sufficient to meet our future capital requirements.

We believe that our existing cash and investment balances and other sources of liquidity, not including potential milestone payments under our out-licensing agreements with Ikaria and Cypress Bioscience, will be sufficient to meet our requirements through the fourth quarter of 2012. We have funded our operations primarily through public (in Israel) and private offerings of our securities and grants from the OCS. We expect to fund our future operations through out-licensing arrangements with respect to our therapeutic candidates. We have entered into an out-licensing arrangement with Ikaria in connection with our BL-1040 therapeutic candidate and with Cypress Bioscience with respect to our BL-1020 therapeutic candidate in the United States, Canada and Mexico. The adequacy of our available funds to meet our operating and capital requirements will depend on many factors including: the number, breadth, progress and results of our research, product development and clinical programs; the costs and timing of obtaining regulatory approvals for any of our therapeutic candidates; the terms and conditions of in-licensing and out-licensing therapeutic candidates; and costs incurred in enforcing and defending our patent claims and other intellectual property rights.

While we will continue to explore alternative financing sources, including the possibility of future securities offerings and continued government funding, we cannot be certain that in the future these liquidity sources will be available when needed on commercially reasonable terms or at all, or that our actual cash requirements will not be greater than anticipated. We may seek to finance our operations through other sources, including out-licensing arrangements for the development and commercialization of our therapeutic candidates or other partnerships or joint ventures. If we are unable to obtain future financing through the methods we describe above or through other means, we may be unable to complete our business objectives and may be unable to continue operations, which would have a material adverse effect on our business and financial condition.

#### Our limited operating history makes it difficult to evaluate our business and prospects.

We have a limited operating history and our operations to date have been limited to organizing and staffing our company, conducting product development activities for our therapeutic candidates and performing research and development with respect to our preclinical programs. We have not yet demonstrated an ability to obtain regulatory approval for or to commercialize a therapeutic candidate. Consequently, any predictions

about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products or medical devices.

#### **Risks Related to Our Business and Regulatory Matters**

### If we or our licensees are unable to obtain U.S. and/or foreign regulatory approval for our therapeutic candidates, we will be unable to commercialize our therapeutic candidates.

To date, we have not marketed, distributed or sold an approved product. Our therapeutic candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization of drugs and devices. We may not obtain marketing approval for any of our therapeutic candidates in a timely manner or at all. In connection with the clinical trials for BL-1020, BL-1040 and BL-5010, and other therapeutic candidates that we may seek to develop in the future, either on our own or through out-licensing arrangements, we face the risk that:

- a therapeutic candidate or medical device may not prove safe or efficacious;
- the results with respect to any therapeutic candidate may not confirm the positive results from earlier preclinical studies or clinical trials;
- · the results may not meet the level of statistical significance required by the FDA or other regulatory authorities; and
- the results will justify only limited and/or restrictive uses, including the inclusion of warnings and contraindications, which could significantly limit the marketability and profitability of the therapeutic candidate.

Any delay in obtaining, or the failure to obtain, required regulatory approvals will materially and adversely affect our ability to generate future revenues from a particular therapeutic candidate. Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product or may impose restrictive conditions of use, including cautionary information, thereby limiting the size of the market for the product. We and our licensees, as applicable, also are, and will be, subject to numerous foreign regulatory requirements that govern the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all of the risks associated with the FDA approval process that we describe above, as well as risks attributable to the satisfaction of foreign requirements. Approval by the FDA does not ensure approval by regulatory authorities outside the United States. Foreign jurisdictions may have different approval processes than those required by the FDA and may impose additional testing requirements for our therapeutic candidates.

#### We have no experience selling, marketing or distributing products and no internal capability to do so.

We currently have no sales, marketing or distribution capabilities and no experience in building a sales force or distribution capabilities. To be able to commercialize any of our therapeutic candidates upon approval, if at all, we must either develop internal sales, marketing and distribution capabilities, which will be expensive and time consuming, or enter into out-licensing arrangements with third parties to perform these services. In July 2009, we entered into an exclusive, royalty-bearing worldwide out-licensing arrangement with Ikaria with respect to BL-1040. Under the arrangement, Ikaria is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or a product related thereto. In June 2010, we entered into an exclusive, royalty-bearing out-licensing arrangement with respect to BL-1020. Under the arrangement, Cypress Bioscience is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize, BL-1020 for the prevention, diagnosis and treatment of all human diseases in the United States, Canada and Mexico. We have retained the rights to develop and commercialize BL-1020 outside the United States, Canada and Mexico.

If we decide to market any of our other therapeutic candidates directly, including BL-1020, outside of the United States, Canada and Mexico, we must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. Factors that may inhibit our efforts to commercialize our products directly and without strategic partners include:



- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our therapeutic candidates;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

We may not be successful in recruiting the sales and marketing personnel necessary to sell any of our therapeutic candidates upon approval, if at all, and even if we do build a sales force, it may not be successful in marketing our therapeutic candidates, which would have a material adverse effect on our business, financial condition and results of operations.

#### We depend on out-licensing arrangements to develop, market and commercialize our therapeutic candidates.

We depend on out-licensing arrangements to develop, market and commercialize our therapeutic candidates. We have limited experience in developing, marketing and commercializing therapeutic candidates. Dependence on out-licensing arrangements will subject us to a number of risks, including the risk that:

- we may not be able to control the amount and timing of resources that our licensees devote to our therapeutic candidates;
- our licensees may experience financial difficulties;
- our licensees may fail to secure adequate commercial supplies of our therapeutic candidates upon marketing approval, if at all;
- our future revenues will depend heavily on the efforts of our licensees;
- business combinations or significant changes in a licensee's business strategy may adversely affect the licensee's willingness or ability to complete its obligations under any arrangement with us;
- a licensee could move forward with a competing therapeutic candidate developed either independently or in collaboration with others, including our competitors; and
- out-licensing arrangements are often terminated or allowed to expire, which would delay the development and may increase the development costs of our therapeutic candidates.

If we or any of our licensees, including Ikaria or Cypress Bioscience, breach or terminate their agreements with us, or if any of our licensees otherwise fail to conduct their development and commercialization activities in a timely manner or there is a dispute about their obligations, we may need to seek other licensees, or we may have to develop our own internal sales and marketing capability for our therapeutic candidates. Our dependence on our licensees' experience and the rights of our licensees will limit our flexibility in considering alternative out-licensing arrangements for our therapeutic candidates. Any failure to successfully develop these arrangements or failure by our licensees to successfully develop or commercialize any of our therapeutic candidates in a competitive and timely manner, will have a material adverse effect on the commercialization of our therapeutic candidates.

### Cypress Bioscience is the target of a tender offer by certain of its shareholders; if Cypress Bioscience undergoes a change of control, the acquirer may not honor its obligations to us under the out-licensing arrangement.

Cypress Bioscience is the target of a tender offer by certain of its shareholders. In public filings, the potential acquiror indicated that it decided to make the tender offer in part because it does not think that our out-licensing arrangement with Cypress Bioscience is in the best interest of Cypress Bioscience and its shareholders. We worked with the current management team of Cypress Bioscience in entering into our out-licensing arrangement with Cypress Bioscience. If the tender offer results in a change of control of Cypress Bioscience, the new management may elect to terminate or breach the out-licensing agreement. In addition,



even if the tender offer does not result in a change of control, the attention of Cypress Bioscience's management to the tender offer and related matters may result in delays in its development efforts with respect to BL-1020. Any termination or breach by Cypress Bioscience of the out-licensing agreement, or delay in the development efforts required thereunder, may have a material adverse effect on our business, financial condition and results of operations.

### If we are unable to enter into agreements with third parties to develop, market and commercialize our therapeutic candidates, we may not generate product revenue.

We plan to develop, market and commercialize our therapeutic candidates primarily through out-licensing arrangements or, when appropriate, by ourselves. The preclinical and clinical development of our therapeutic candidates, even if undertaken through licensing arrangements with third parties, will require that we expend significant funds and will be subject to the risks of failure inherent in the development of pharmaceutical products. In order to successfully commercialize any of our therapeutic candidates that may be approved in the future by the FDA or other regulatory authorities, we must enter into out-licensing arrangements with third parties to perform these services for us or build internal sales and marketing capabilities. Our ability to commercialize our therapeutic candidates will depend on our ability to:

- attract suitable licensees on reasonable terms;
- obtain and maintain necessary intellectual property rights to our therapeutic candidates;
- where appropriate, enter into arrangements with third parties to manufacture our products, if any, on our behalf; and
- · deploy sales and marketing resources effectively or enter into arrangements with third parties to provide these services.

If we are unable to enter into an out-licensing arrangement with respect to BL-5010 or any of our other therapeutic candidates, whether with third parties or independently, our ability to develop a commercially viable product or generate product revenue based on the therapeutic candidate will be adversely affected, and we may not become profitable. We face significant competition in seeking out-licensing arrangements with third parties. We may not be able to negotiate out-licensing arrangements on acceptable terms, if at all. In addition, these out-licensing arrangements may be unsuccessful. If we fail to negotiate and maintain suitable out-licensing arrangements, we may have to limit the size or scope of, or delay, one or more of our development or research programs. If we elect to fund development or research programs independently, we will have to increase our expenditures significantly and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms. We will also need to make significant investments in pharmaceutical product development, marketing, sales and regulatory compliance resources, and we will have to establish or contract for the manufacture of products under applicable regulatory requirements. Any failure to enter into an out-licensing arrangement with respect to the development, marketing and commercialization of any therapeutic candidate, or failure to develop, market and commercialize the therapeutic candidate independently, will have a material adverse effect on our business, financial condition and results of operations.

## Modifications to our therapeutic candidates, or to any other therapeutic candidates that we may develop in the future, may require new regulatory clearances or approvals or may require us or our licensees, as applicable, to recall or cease marketing these therapeutic candidates until clearances are obtained.

Modifications to our therapeutic candidates, after they have been approved for marketing, if at all, or to any other pharmaceutical product or medical device that we may develop in the future, may require new regulatory clearance, or approvals, and, if necessitated by a problem with a marketed product, may result in the recall or suspension of marketing of the previously approved and marketed product until clearances or approvals of the modified product are obtained. The FDA requires pharmaceutical products and device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine in conformity with applicable regulations and guidelines that a modification may be implemented without pre-clearance by the FDA; however, the FDA

can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. If the FDA requires new clearances or approvals of any pharmaceutical product or medical device for which we or our licensees receive marketing approval, if any, we or our licensees may be required to recall such product and to stop marketing the product as modified, which could require us or our licensees to redesign the product and will have a material adverse affect on our business, financial condition and results of operations. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect the safety or efficacy of the device, would constitute a major change in its intended use, or otherwise requires pre-clearance, the modification may not be implemented without the requisite clearance. We or our licensees may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. For those products sold in the European Union, or E.U., we, or our licensees, as applicable, must notify the applicable E.U. Notified Body, an organization appointed by a member State of the E.U. either for the approval and monitoring of a manufacturer's quality assurance system or for direct product inspection, if significant changes are made to the product or if there are substantial changes to the quality assurance systems affecting the product. Delays in obtaining required future clearances or approvals would materially and adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would have a material adverse effect on our business, financial condition and results of operations.

### Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including FDA approval. Clinical trials are expensive and complex, can take many years and have uncertain outcomes. We cannot predict whether we or our licensees will encounter problems with any of the completed, ongoing or planned clinical trials that will cause us, our licensees or regulatory authorities to delay or suspend clinical trials, or delay the analysis of data from completed or ongoing clinical trials. We estimate that clinical trials of our most advanced therapeutic candidates will continue for several years, but they may take significantly longer to complete. Failure can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future therapeutic candidates, including but not limited to:

- delays in securing clinical investigators or trial sites for the clinical trials;
- delays in obtaining institutional review board and other regulatory approvals to commence a clinical trial;
- slower than anticipated patient recruitment and enrollment;
- negative or inconclusive results from clinical trials;
- unforeseen safety issues;
- uncertain dosing issues;
- an inability to monitor patients adequately during or after treatment; and
- problems with investigator or patient compliance with the trial protocols.

A number of companies in the pharmaceutical, medical device and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier clinical trials. Despite the results reported in earlier clinical trials for our therapeutic candidates, we do not know whether any phase 3 or other clinical trials we or our licensees may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our therapeutic candidates. If later-stage clinical trials of any therapeutic candidate do not produce favorable results, our ability to obtain regulatory approval for the therapeutic candidate may be adversely impacted, which will have a material adverse effect on our business, financial condition and results of operations.

### We rely on third parties to conduct our clinical trials and provide other services, and those third parties may not perform satisfactorily, including by failing to meet established deadlines for the completion of such services.

We do not have the ability to conduct certain preclinical studies and clinical trials independently for our therapeutic candidates, and we rely on third parties, such as contract laboratories, contract research organizations, medical institutions and clinical investigators to conduct these studies and our clinical trials. Our reliance on these third parties limits our control over these activities. The third-party contractors may not assign as great a priority to our clinical development programs or pursue them as diligently as we would if we were undertaking such programs directly. Accordingly, these third-party contractors may not complete activities on schedule, or may not conduct the studies or our clinical trials in accordance with regulatory requirements or with our trial design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if their performance is substandard, we may be required to replace them. Although we believe that there are a number of other third-party contractors that we could engage to continue these activities, replacement of these third parties will result in delays. As a result, our efforts to obtain regulatory approvals for, and to commercialize, our therapeutic candidates may be delayed. The third-party contractors may also have relationships with other commercial entities, some of whom may compete with us. If the third-party contractors assist our competitors, our competitive position may be harmed.

In addition, our ability to bring future products to market depends on the quality and integrity of data that we present to regulatory authorities in order to obtain marketing authorizations. Although we attempt to audit and control the quality of third-party data, we cannot guarantee the authenticity or accuracy of such data, nor can we be certain that such data has not been fraudulently generated. The failure of these third parties to carry out their obligations would materially adversely affect our ability to develop and market new products and implement our strategies.

### If our competitors develop and market products that are more effective, safer or less expensive than our current or future therapeutic candidates, our future prospects will be negatively impacted.

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address the indications for which we are currently developing therapeutic candidates or for which we may develop therapeutic candidates in the future. Specifically, we are aware of several other companies who currently market and/or are in the process of developing products that address schizophrenia, AMI and skin lesions. There are a number of treatments currently marketed for schizophrenia patients, including atypical anti-psychotics from Johnson & Johnson, Eli Lilly and Company, AstraZeneca, Bristol-Myers Squibb/Otsuka Pharmaceutical Co., Ltd., Pfizer Inc. and others. In addition, there are a number of generic brands of typical and atypical antipsychotics available for commercial use. We are also aware of a number of potentially competitive compounds under development to treat schizophrenia including: Cariprazine, which is being developed by Forest Laboratories, Inc.; Bifeprunox, which is being developed by Solvay Pharmaceuticals, Inc., and Lurasidone, which is being developed by Dainippon Sumitomo Pharma Co., Ltd. There are a number of therapies currently in development that treat cardiac remodeling, including BioHeart, Inc.'s MyoCell®

implantation procedure, Paracor Medical, Inc.'s HeartNet<sup>TM</sup> and Acorn Cardiovascular, Inc.'s CorCap<sup>TM</sup> device. Skin lesions are generally removed using either cryotherapy (liquid nitrogen), electro-coagulation (electrical burning), laser treatments or through surgery. Galderma Pharma SA produces a non-destructive, non-surgical, cream-based treatment for skin lesions called Metvix<sup>®</sup> which has been approved in many countries. Any therapeutic candidates we may develop in the future are also likely to face competition from other drugs and therapies. Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing and in obtaining regulatory approvals for drugs. These companies also have significantly greater research and marketing capabilities than we do. If our competitors market products that are more effective, safer or less expensive than our future therapeutic candidates, if any, we may not achieve commercial success.

We currently depend on third-party manufacturers to produce our preclinical and clinical therapeutic supplies. We may rely upon third-party manufacturers to produce commercial supplies of any approved therapeutic candidates. If we manufacture any of our therapeutic candidates in the future, we will be required to incur significant costs and devote significant efforts to establish and maintain manufacturing capabilities.

We have relied on third parties to produce material for preclinical and clinical testing purposes and intend to continue to do so in the future. We do not own or operate manufacturing facilities for clinical or commercial production of our therapeutic candidates. We have limited personnel with experience in drug or medical device manufacturing and we lack the resources and capabilities to manufacture any of our therapeutic candidates on a clinical or commercial scale. The manufacture of pharmaceutical products and medical devices requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products and medical devices often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields and quality control, including stability of the therapeutic candidate.

We do not currently have any long-term agreements with third party manufacturers for the supply of any of our therapeutic candidates. We believe that our current supply of therapeutic candidates is sufficient to complete our current clinical trials. However, if we require additional supplies of our therapeutic candidates to complete our clinical trials or if we elect to commercialize our products independently, we may be unable to enter into agreements for clinical or commercial supply, as applicable, with third party manufacturers, or may be unable to do so on acceptable terms. Even if we enter into these agreements, the manufacturers of each therapeutic candidate will be single source suppliers to us for a significant period of time.

Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured therapeutic candidates ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- limitations on supply availability resulting from capacity and scheduling constraints of the third parties;
- impact on our reputation in the marketplace if manufacturers of our products, once commercialized, fail to meet customer demands;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and
- the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

The failure of any of our contract manufacturers to maintain high manufacturing standards could result in injury or death of clinical trial participants or patients being treated with our products. Such failure could also result in product liability claims, product recalls, product seizures or withdrawals, delays or failures in testing or delivery, cost overruns or other problems that could seriously harm our business or profitability.

#### Our contract manufacturers are, and will be, subject to FDA and other comparable agency regulations.

Our contract manufacturers are, and will be, required to adhere to FDA regulations setting forth current Good Manufacturing Practice, or cGMP, for drugs and Quality System Regulations, or QSR, for devices. These regulations cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our therapeutic candidates. Our manufacturers may not be able to comply with applicable regulations. Our manufacturers are and will be subject to unannounced inspections by the FDA, state regulators and similar regulators outside the United States. Our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in the imposition of sanctions on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our therapeutic candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of our candidates or products,



operating restrictions and criminal prosecutions, any of which could significantly and adversely affect regulatory approval and supplies of our therapeutic candidates, and materially and adversely affect our business.

#### We depend on our ability to identify and in-license technologies and therapeutic candidates.

In order to identify therapeutic candidates likely to achieve commercial success efficiently and effectively, we employ a proprietary screening system developed by us that includes evaluation through our proprietary MedMatrx scoring tool. Our Scientific Advisory Board and disease-specific third-party advisors evaluate each therapeutic candidate. However, there can be no assurance that our screening system will accurately or consistently select among various therapeutic candidates those that that have the highest likelihood to achieve, and which ultimately achieve, commercial success. As a result, we may spend substantial resources developing therapeutic candidates that will not achieve commercial success and we may not advance those therapeutic candidates with the greatest potential for commercial success.

An important element of our strategy is maintaining relationships with universities, medical institutions and biotechnology companies in order to in-license potential therapeutic candidates. We may not be able to maintain relationships with these entities and they may elect not to enter into in-licensing agreements with us or to terminate existing agreements. We may not be able to acquire licenses on commercially reasonable terms, or at all. Failure to license or otherwise acquire necessary technologies could materially and adversely affect our business, financial condition and results of operations.

### If we cannot meet requirements under our in-license agreements, we could lose the rights to our therapeutic candidates, which could have a material adverse effect on our business.

We depend on in-licensing agreements with third parties to maintain the intellectual property rights to certain of our therapeutic candidates. We have in-licensed rights from Bar Ilan Research and Development and Ramot with respect to our BL-1020 therapeutic candidate, and from B.G. Negev Technologies with respect to our BL-1040 therapeutic candidate. See "Business — Our Product Pipeline." Our in-license agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these agreements. The royalty rates and revenue sharing payments vary from case to case but generally range from 20% to 29% of the consideration we receive from sublicensing the applicable therapeutic candidate. In some instances, we are required to pay a substantially lower percentage (generally less than 5%) if we elect to commercialize the subject of the agreements, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our in-license agreements in a timely manner, we could lose the rights to our proprietary technology which could have a material adverse effect on our business, financial condition and results of operations.

## Even if we obtain regulatory approvals, our therapeutic candidates will be subject to ongoing regulatory review and if we fail to comply with continuing U.S. and applicable foreign regulations, we could lose those approvals and our business would be seriously harmed.

Even if products we or our licensees develop receive regulatory approval or clearance, we or our licensees, as applicable, will be subject to ongoing reporting obligations and the products and the manufacturing operations will be subject to continuing regulatory review, including FDA inspections. The results of this ongoing review may result in the withdrawal of a product from the market, the interruption of the manufacturing operations and/or the imposition of labeling and/or marketing limitations. Since many more patients are exposed to drugs and medical devices following their marketing approval, serious but infrequent adverse reactions that were not observed in clinical trials may be observed during the commercial marketing of the product. In addition, the manufacturer and the manufacturing facilities we or our licensees, as applicable, will use to produce any therapeutic candidate will be subject to periodic review and inspection by the FDA and other, similar foreign regulators. Later discovery of previously unknown problems with any product, manufacturer or manufacturing process, or failure to comply with regulatory requirements, may result in actions such as:



- restrictions on such product, manufacturer or manufacturing process;
- warning letters from the FDA or other regulatory authorities;
- withdrawal of the product from the market;
- suspension or withdrawal of regulatory approvals;
- · refusal to approve pending applications or supplements to approved applications that we or our licensees submit;
- voluntary or mandatory recall;
- fines;
- refusal to permit the import or export of our products;
- product seizure or detentions;
- · injunctions or the imposition of civil or criminal penalties; or
- adverse publicity.

If we, or our licensees, suppliers, third party contractors, partners or clinical investigators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or the adoption of new regulatory requirements or policies, we or our licensees may lose marketing approval for any of our products, if any of our therapeutic products are approved, resulting in decreased or lost revenue from milestones, product sales or royalties.

#### Our business could suffer if we are unable to attract and retain key employees.

Our success depends upon the continued service and performance of our senior management and other key personnel. The loss of the services of these personnel could delay or prevent the successful completion of our planned clinical trials or the commercialization of our therapeutic candidates or otherwise affect our ability to manage our company effectively and to carry out our business plan. We do not maintain key-man life insurance. Although we have entered into employment agreements with all of the members of our senior management team, members of our senior management team may resign at any time. High demand exists for senior management and other key personnel in the pharmaceutical industry. There can be no assurance that we will be able to continue to retain and attract such personnel.

Our growth and success also depend on our ability to attract and retain additional highly qualified scientific, technical, sales, managerial and finance personnel. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers. In addition, if we elect to independently commercialize any therapeutic candidate, we will need to expand our marketing and sales capabilities. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel. If we cannot attract and retain sufficiently qualified technical employees on acceptable terms, we may not be able to develop and commercialize competitive products. Further, any failure to effectively integrate new personnel could prevent us from successfully growing our company.

#### **Risks Related to Our Industry**

### Even if our therapeutic candidates receive regulatory approval or do not require regulatory approval, they may not become commercially viable products.

Even if our therapeutic candidates are approved for commercialization, they may not become commercially viable products. For example, if we or our licensees receive regulatory approval to market a product, approval may be subject to limitations on the indicated uses or subject to labeling or marketing restrictions which could materially and adversely affect the marketability and profitability of the product. In addition, a new product may appear promising at an early stage of development or after clinical trials but



never reach the market, or it may reach the market but not result in sufficient product sales, if any. A therapeutic candidate may not result in commercial success for various reasons, including:

- difficulty in large-scale manufacturing;
- low market acceptance by physicians, healthcare payors, patients and the medical community as a result of lower demonstrated clinical safety or efficacy compared to other products, prevalence and severity of adverse side effects, or other potential disadvantages relative to alternative treatment methods;
- · insufficient or unfavorable levels of reimbursement from government or third-party payors;
- infringement on proprietary rights of others for which we or our licensees have not received licenses;
- incompatibility with other therapeutic products;
- other potential advantages of alternative treatment methods;
- ineffective marketing and distribution support;
- lack of cost-effectiveness; or
- timing of market introduction of competitive products.

If we are unable to develop commercially viable products, either on our own or through licensees, our business, results of operations and financial condition will be materially and adversely affected.

### We could be adversely affected if healthcare reform measures substantially change the market for medical care or healthcare coverage in the United States.

The U.S. Congress recently adopted important legislation regarding health insurance. Under the new legislation, substantial changes are going to be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payors and government programs (Medicare, Medicaid and State Children's Health Insurance Program), creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs and biopharmaceuticals, such as those we and our licensees are currently developing. If reimbursement for our approved products, if any, is substantially reduced in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

Extending medical benefits to those who currently lack coverage will likely result in substantial cost to the U.S. federal government, which may force significant changes to the healthcare system in the United States. Much of the funding for expanded healthcare coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of care. Cost of care could be reduced by decreasing the level of reimbursement for medical services or products (including those biopharmaceuticals currently being developed by us or our licensees), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for, any product for which we receive marketing approval in the future could have a materially adverse effect on our financial performance.

### If third-party payors do not adequately reimburse customers for any of our therapeutic candidates that are approved for marketing, they might not be purchased or used, and our revenues and profits will not develop or increase.

Our revenues and profits will depend heavily upon the availability of adequate reimbursement for the use of our approved candidates, if any, from governmental or other third-party payors, both in the United States



and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that the use of an approved product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a product from each government or other third-party payor is a time-consuming and costly process that could require us or our licensees to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. Even when a payor determines that a product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or comparable foreign regulatory authorities. Reimbursement rates may vary according to the use of the product and the clinical setting in which it used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare, Medicaid or other data used to calculate these rates.

In the United States, there have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for our products in the United States. We believe that legislation that reduces reimbursement for our therapeutic candidates could adversely impact how much or under what circumstances healthcare providers will prescribe or administer our products, if approved. This could materially and adversely impact our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our products, if approved.

Further, the Centers for Medicare and Medicaid Services, or CMS, frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both CMS and other third-party payors may have sufficient market power to demand significant price reductions.

### Our business has a substantial risk of clinical trial and product liability claims. If we are unable to obtain and maintain appropriate levels of insurance, a claim could adversely affect our business.

Our business exposes us to significant potential clinical trial and product liability risks that are inherent in the development, manufacturing and sales and marketing of human therapeutic products. Although we do not currently commercialize any products, claims could be made against us based on the use of our therapeutic candidates in clinical trials. We currently carry life science liability insurance covering bodily and personal injury, general liability and products liability with an annual coverage amount of \$5.0 million in the aggregate, and clinical trial insurance with a coverage amount of \$10.0 million in the aggregate. In addition to these policies, we carry an excess liability insurance with a coverage amount of \$5.0 million which increases the coverage limit provided by our life science insurance package. However, our insurance may not provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage or obtain additional or sufficient insurance at a reasonable cost to protect against losses that could have a material adverse effect on us. If a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as damages awards beyond the coverage of our insurance policies resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any claims, we might be required to direct significant financial and managerial resources to such defense, and adverse publicity is likely to result.

### We deal with hazardous materials and must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do business.

Our activities and those of our third-party manufacturers on our behalf involve the controlled storage, use and disposal of hazardous materials, including microbial agents, corrosive, explosive and flammable chemicals and other hazardous compounds. We and our manufacturers are subject to U.S. federal, state, local, Israeli and other foreign laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In addition, if we develop a manufacturing capacity, we may incur substantial costs to comply with environmental regulations and would be subject to the risk of accidental contamination or injury from the use of hazardous materials in our manufacturing process.

In the event of an accident, government authorities may curtail our use of these materials and interrupt our business operations. In addition, we could be liable for any civil damages that result, which may exceed our financial resources and may seriously harm our business. Although our Israeli insurance program covers certain unforeseen sudden pollutions, we do not maintain a separate insurance policy for any of the foregoing types of risks. In addition, although the general liability section of our life sciences policy covers certain environmental issues, pollution in the United States and Canada is excluded from the policy. In the event of environmental discharge or contamination or an accident, we may be held liable for any resulting damages, and any liability could exceed our resources. In addition, we may be subject to liability and may be required to comply with new or existing environmental laws regulating pharmaceuticals or other medical products in the environment.

#### **Risks Related to Intellectual Property**

## Our access to most of the intellectual property associated with our therapeutic candidates results from in-license agreements with universities, research institutions and biotechnology companies, the termination of which would prevent us from commercializing the associated therapeutic candidates.

We do not conduct our own initial research with respect to the identification of our therapeutic candidates. Instead, we rely upon research and development work conducted by third parties as the primary source of our therapeutic candidates. As such, we have obtained our rights to the majority of our therapeutic candidates through in-license agreements entered into with universities, research institutions and biotechnology companies that invent and own the intellectual property underlying our candidates. There is no assurance that such in-licenses or rights will not be terminated or expire due to a material breach of the agreements, such as a failure on our part to achieve certain progress milestones set forth in the terms of the in-licenses or due to the loss of the rights to the underlying intellectual property by any of our licensors. There is no assurance that we will be able to renew or renegotiate an inlicensing agreement on acceptable terms if and when the agreement terminates. We cannot guarantee that any in-license is enforceable or will not be terminated or converted into a non-exclusive license in the future. The termination of any in-license or our inability to enforce our rights under any in-license would materially and adversely affect our ability to commercialize certain of our therapeutic candidates.

We currently have in-licensing agreements relating to our lead therapeutic candidates under clinical development. In April 2004, we in-licensed the rights to BL-1020 under a research and license agreement with Bar Ilan Research and Development and Ramot. Under the BL-1020 research and license agreement, we are obligated to use commercially reasonable efforts to develop, commercialize and market the licensed technology, including meeting certain specified diligence goals. In January 2005, we inlicensed the rights to BL-1040 under a license agreement with B.G. Negev Technologies. Under the BL-1040 license agreement, we are obligated to use commercially reasonable efforts to develop the licensed technology in accordance with a specified development plan, including meeting certain specified diligence goals. In November 2007, we in-licensed the rights to develop and commercialize BL-5010 under a license agreement with Innovative Pharmaceutical Concepts, Inc., or IPC. Under the IPC license agreement, we are obligated to use commercially reasonable efforts to develop the licensed technology in accordance with a specified development plan, including meeting certain specified diligence goals.

Each of the three in-licensing agreements will remain in effect until the expiration, under the applicable agreement, of all of the licensing, royalty and sublicense revenue obligations to the applicable licensors, determined on a product-by-product and country-by-country basis. We may terminate any in-licensing agreement by providing 60 days' prior written notice to Ramot, in the case of the BL-1020 in-licensing agreement or to B.G. Negev Technologies, in the case of the BL-1040 in-licensing agreement. We may terminate the BL-5010 in-licensing agreement by providing 30 days' prior written notice to IPC. However, if we elect to terminate the BL-5010 in-licensing agreement without cause, we may be required to fund the completion of certain clinical trials of the licensed technology in an amount not to exceed \$600,000. We may also elect to terminate the BL-5010 in-licensing agreement upon 60 days' prior written notice to IPC for scientific, regulatory or medical reasons which, as determined by our Scientific Advisory Board, would prevent us from continuing the development of the licensed technology pursuant to the agreed upon development plan.

Any party to any of the three in-licensing agreements may terminate the respective agreement for material breach by the other party if the breaching party is unable to cure the breach within 30 days after receiving written notice of the breach from the nonbreaching party. Notwithstanding the foregoing, in the case of the BL-1020 in-licensing agreement, Ramot, but not Bar Ilan Research and Development, has the right to provide us with notice of material breach and to terminate the agreement. In addition, with respect to the BL-1040 in-licensing agreement, the breaching party is entitled to 60 days' prior written notice of the material breach prior to termination instead of 30 days. Each of the three in-licensing agreements provide that with respect to any termination for material breach, if the breach is not susceptible to cure within the stated period and the breaching party uses diligent, good faith efforts to cure such breach, the stated period will be extended by an additional 30 days. In addition, either party to one of the three in-licensing agreements (except Bar Ilan Research and Development, in the case of the BL-1020 in-licensing agreement) may terminate the agreement upon notice to the other upon the occurrence of certain bankruptcy events.

#### Patent protection for our products is important and uncertain.

Our success depends, in part, on our ability, and the ability of our licensees and licensors to obtain patent protection for our therapeutic candidates, maintain the confidentiality of our trade secrets and know how, operate without infringing on the proprietary rights of others and prevent others from infringing our proprietary rights.

We try to protect our proprietary position by, among other things, filing U.S., European, Israeli and other patent applications related to our proprietary products, technologies, inventions and improvements that may be important to the continuing development of our therapeutic candidates. As of September 1, 2010, our portfolio of owned and licensed patents consists of 13 patent families that, collectively, contain over 12 issued patents and over 60 patent applications relating to our clinical candidates. We are also pursuing patent protection for other drug candidates in our pipeline.

Because the patent position of biopharmaceutical companies involves complex legal and factual questions, we cannot predict the validity and enforceability of patents with certainty. Our issued patents and the issued patents of our licensees or licensors may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in patents being issued. If these patents are issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology. The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage.

Patent rights are territorial; thus, the patent protection we do have will only extend to those countries in which we have issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the United States and Israel. For example, the patent laws of China and India are relatively new and are not as developed as are older, more established patent laws of other countries. Competitors may successfully challenge our patents, produce similar drugs or products that do not infringe our patents, or produce drugs in countries where we have not applied for patent protection or that

do not respect our patents. Furthermore, it is not possible to know the scope of claims that will be allowed in published applications and it is also not possible to know which claims of granted patents, if any, will be deemed enforceable in a court of law.

Our technology may infringe the rights of third parties. The nature of claims contained in unpublished patent filings around the world is unknown to us and it is not possible to know which countries patent holders may choose for the extension of their filings under the Patent Cooperation Treaty, or other mechanisms. Any infringement by us of the proprietary rights of third parties may have a material adverse effect on our business, financial condition and results of operations.

#### If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.

We rely on a combination of patents, trade secrets, know-how, technology, trademarks and regulatory exclusivity to maintain our competitive position. We generally try to protect trade secrets, know-how and technology by entering into confidentiality or non-disclosure agreements with parties that have access to it, such as our licensees, employees, contractors and consultants. We also enter into agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees, advisors, research collaborators, contractors and consultants while we employ or engage them. However, these agreements can be difficult and costly to enforce or may not provide adequate remedies. Any of these parties may breach the confidentiality agreements and willfully or unintentionally disclose our confidential information, or our competitors might learn of the information in some other way. The disclosure to, or independent development by, a competitor of any trade secret, know-how or other technology not protected by a patent could materially adversely affect any competitive advantage we may have over any such competitor.

To the extent that any of our employees, advisors, research collaborators, contractors or consultants independently develop, or use independently developed, intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises with respect to any proprietary right, enforcement of our rights can be costly and unpredictable and a court may determine that the right belongs to a third party.

### Legal proceedings or third-party claims of intellectual property infringement may require us to spend substantial time and money and could prevent us from developing or commercializing products.

The development, manufacture, use, offer for sale, sale or importation of our therapeutic candidates may infringe on the claims of third-party patents. A party might file an infringement action against us. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation or defense of a patent litigation or other proceedings may also absorb significant management time. Consequently, we are unable to guarantee that we will be able to manufacture, use, offer for sale, sell or import our therapeutic candidates in the event of an infringement action. At present, we are not aware of pending or threatened patent infringement actions against us.

In the event of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could potentially limit our competitive advantage. Ultimately, we could be prevented from commercializing a therapeutic candidate or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This inability to enter into licenses could harm our business significantly. At present, we have not received any written demands from third parties that we take a license under their patents nor have we received any notice form a third party accusing us of patent infringement.

Our license agreement with Ikaria contains, and any contract that we enter into with licensees in the future will likely contain, indemnity provisions that obligate us to indemnify the licensees against any losses

that arise from third-party claims that are brought alleging that our therapeutic candidates infringe third party intellectual property rights. In addition, our in-license agreements contain provisions that obligate us to indemnify the licensors against any damages arising from the development, manufacture and use of products developed on the basis of the in-licensed intellectual property.

### We may be subject to other patent-related litigation or proceedings that could be costly to defend and uncertain in their outcome.

In addition to infringement claims against us, we may in the future become a party to other patent litigation or proceedings, including interference or re-examination proceedings filed with the U.S. Patent and Trademark Office or opposition proceedings in other foreign patent offices regarding intellectual property rights with respect to our products and technology, as well as other disputes regarding intellectual property rights with licensees, licensors or others with whom we have contractual or other business relationships. Post-issuance oppositions are not uncommon and we, our licensee or our licensor will be required to defend these opposition procedures as a matter of course. Opposition procedures may be costly, and there is a risk that we may not prevail.

### We may be subject to damages resulting from claims that we or our employees or contractors have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees and contractors were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or any employ or contractor has inadvertently or otherwise used or disclosed trade secrets or other proprietary information of his or her former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain therapeutic candidates, which could severely harm our business, financial condition and results of operations. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

## The intellectual property associated with certain of our therapeutic candidates, including BL-1040, is pledged as security for our obligations associated with the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor's biotechnology incubator program.

In May 2004, the OCS invited companies to bid to establish and operate OCS-funded biotechnological incubators to provide a physical, organized and professional platform for commercializing biotechnological research and development projects. We submitted a proposal to operate a biotechnological incubator, and our proposal was selected by the OCS. Accordingly, we entered into an incubator agreement with the OCS in January 2005. The funding provided to us under the incubator agreement is in the form of separate loans for each approved project initiated by our incubator. Each loan is subject to repayment solely out of the revenues generated by that project. If revenues are not achieved with respect to a project, the loan for the project will be forgiven, subject to certain terms and conditions. If revenues are prescribed by the OCS at the commencement of each loan, and range from 3.11% to 5.34%, but are doubled if the loan is not repaid within five years of our achievement of certain development milestones, or within two years following the completion of the applicable incubator program. All intellectual property held by our incubator for development through the incubator program is pledged as security for our obligations under the incubator agreement. If we are unable to meet our obligations under the incubator agreement, the intellectual property held by the incubator would be subject to seizure and would not be available for sale for the benefit of or distribution to our creditors or shareholders in the event of a reorganization or insolvency. Any loss of the rights to the intellectual property held by our incubator would have a material adverse effect on our business and prospects.



#### **Risks Related to an Investment in our Ordinary Shares**

### We may be a passive foreign investment company, or PFIC, for U.S. federal income tax purposes in 2010 or in any subsequent year. There may be negative tax consequences for U.S. taxpayers that are holders of our ordinary shares.

We will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (i) at least 75% of our gross income is "passive income" or (ii) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account. Although we were not a PFIC in 2009, we believe that we were a PFIC during certain prior years and, although we do not anticipate being a PFIC in 2010, or in any subsequent year, our operating results for any such years may cause us to be a PFIC. If we are a PFIC in 2010, or any subsequent year, and a U.S. shareholder does not make an election to treat us as a "qualified electing fund," or OEF, or make a "mark-to-market" election, then "excess distributions" to a U.S. shareholder, and any gain realized on the sale or other disposition of our ordinary shares will be subject to special rules. Under these rules: (i) the excess distribution or gain would be allocated ratably over the U.S. shareholder's holding period for the ordinary shares; (ii) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (iii) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, if the U.S. Internal Revenue Service determines that we are a PFIC for a year with respect to which we have determined that we were not a PFIC, it may be too late for a U.S. shareholder to make a timely QEF or mark-to-market election. U.S. shareholders who hold our ordinary shares during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to exceptions for U.S. shareholders who made a timely QEF or mark-to-market election. A U.S. shareholder can make a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. Upon request, we will annually furnish U.S. shareholders with information needed in order to complete IRS Form 8621 (which form would be required to be filed with the IRS on an annual basis by the U.S. shareholder) and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC.

#### The market price of our ordinary shares is subject to fluctuation, which could result in substantial losses by our investors.

The stock market in general and the market price of our ordinary shares on the TASE in particular, is subject to fluctuation, and changes in our share price may be unrelated to our operating performance. The market price of our ordinary shares on the TASE has fluctuated in the past, and we expect it will continue to do so, as a result of a number of factors, including:

- announcements of technological innovations or new products by us or others;
- public concern as to the safety of drugs we, our licensees or others develop;
- general market conditions;
- that the market prices for shares of biotechnology companies tends to be volatile;
- success of research and development projects;
- developments concerning intellectual property rights or regulatory approvals;
- variations in our and our competitors' results of operations;

- changes in earnings estimates or recommendations by securities analysts, if our ordinary shares are covered by analysts;
- changes in government regulations or patent decisions;
- · developments by our licensees; and
- general market conditions and other factors, including factors unrelated to our operating performance.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our ordinary shares and result in substantial losses by our investors.

Additionally, market prices for securities of biotechnology and pharmaceutical companies historically have been very volatile. The market for these securities has from time to time experienced significant price and volume fluctuations for reasons unrelated to the operating performance of any one company. In the past, following periods of market volatility, shareholders have often instituted securities class action litigation. If we were involved in securities litigation, it could have a substantial cost and divert resources and attention of management from our business.

#### Future sales of our ordinary shares could reduce the market price of our ordinary shares.

If we or our shareholders sell substantial amounts of our ordinary shares, either on the TASE or on The NASDAQ Global Market, the market price of our ordinary shares may decline. We and the beneficial owners of % of our ordinary shares (such shares representing holdings immediately prior to the consummation of this offering) have agreed with the underwriters of this offering not to sell any ordinary shares, other than the shares offered by this prospectus, for a period of at least 180 days following the date of this prospectus. The ordinary shares we are offering for sale in this offering will be freely tradable immediately following this offering. In addition, all of our outstanding ordinary shares are registered and available for sale in Israel. Except for the holders of % of our ordinary shares that are the subject of lock-up agreements entered into by the holders thereof in connection with this offering, all of our outstanding shares are available for sale without restriction. Sales by us or our shareholders of substantial amounts of our ordinary shares, or the perception that these sales may occur in the future, could cause a reduction in the market price of our ordinary shares.

On May 3, 2009, we filed a shelf prospectus with the TASE and Israeli Securities Authority. The shelf prospectus allows us, for a period of two years, to issue the securities described in the prospectus to the public in Israel by means of shelf offering reports, without being required to publish a full prospectus. Following the issuance of our ordinary shares under the shelf registration statement, such ordinary shares will be registered for trade on the TASE with no lock-up period. As permitted under applicable Israeli law, our shelf prospectus did not contain a NIS or dollar limitation on the aggregate amount of the securities to be offered thereunder. The shelf prospectus registered different classes of securities, including ordinary shares, up to three series of ordinary debentures convertible into ordinary shares, up to three series of warrants exercisable into shares and up to three series of warrants exercisable into debentures. On December 29, 2009, we issued 11,293,419 ordinary shares, and Series 2 Warrants to purchase 7,528,946 ordinary shares, under the shelf prospectus for aggregate gross proceeds of approximately NIS 47.1 million, or \$12.4 million (based on the exchange rate reported by the Bank of Israel for that date). The issuance of any additional ordinary shares under the shelf prospectus, or any securities that are exercisable for or convertible into our ordinary shares, may have an adverse effect on the market price of our ordinary shares and will have a dilutive effect on our shareholders.

#### Raising additional capital by issuing securities may cause dilution to existing shareholders.

We may need to raise substantial future capital to continue to complete clinical development and commercialize our products and therapeutic candidates and to conduct the research and development and clinical and regulatory activities necessary to bring our therapeutic candidates to market. Our future capital requirements will depend on many factors, including:

- the failure to obtain regulatory approval or achieve commercial success of our therapeutic candidates, including BL-1020, BL-1040 and BL-5010;
- our success in effecting out-licensing arrangements with third-parties;
- our success in establishing other out-licensing arrangements;
- the success of our licensees in selling products that utilize our technologies;
- the results of our preclinical studies and clinical trials for our earlier stage therapeutic candidates, and any decisions to initiate clinical trials if supported by the preclinical results;
- · the costs, timing and outcome of regulatory review of our therapeutic candidates that progress to clinical trials;
- the costs of establishing or acquiring specialty sales, marketing and distribution capabilities, if any of our therapeutic candidates are approved, and we decide to commercialize them ourselves;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our issued patents and defending intellectual property-related claims;
- the extent to which we acquire or invest in businesses, products or technologies and other strategic relationships; and
- the costs of financing unanticipated working capital requirements and responding to competitive pressures.

If we raise additional funds through licensing arrangements with third parties, we may have to relinquish valuable rights to our therapeutic candidates, or grant licenses on terms that are not favorable to us. If we raise additional funds by issuing equity or convertible debt securities, we will reduce the percentage ownership of our then-existing shareholders, and these securities may have rights, preferences or privileges senior to those of our existing shareholders. See also "— Future sales of our ordinary shares could reduce the market price of our ordinary shares."

#### Investors in this offering will immediately experience substantial dilution in net tangible book value.

The initial public offering price of our ordinary shares in this offering is considerably greater than the pro forma net tangible book value per share of our outstanding ordinary shares. Accordingly, investors purchasing ordinary shares in this offering will incur immediate dilution of \$ per share, based on an assumed initial public offering price of \$ per share, the mid-point of the range shown on the cover of this prospectus. See "Dilution." In addition, as of June 30, 2010, there were outstanding and exercisable options to purchase 7,084,160 of our ordinary shares, at a weighted average exercise price equal to NIS 3.54 (or approximately \$0.91 based on the exchange rate reported by the Bank of Israel for June 30, 2010) per share. Moreover, we expect to issue additional options to purchase our ordinary shares to compensate employees, consultants and directors and may issue additional shares to raise capital, to pay for services, or for other corporate purposes. To the extent these outstanding options are exercised at a price below net tangible book value per share, there will be additional dilution to investors.

#### We have broad discretion as to the use of the net proceeds from this offering and may not use them effectively.

We cannot specify with certainty the particular uses of the net proceeds that we will receive from this offering. Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the "Use of Proceeds" section of this prospectus on page <u>37</u>. Our shareholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds from this offering. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results of operation. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

#### **Risks Associated with Potential NASDAQ Listing of our Ordinary Shares**

#### Our ordinary shares will be traded on more than one market and this may result in price variations.

Our ordinary shares have been traded on the TASE since February 2007 and we have applied to have our ordinary shares listed on The NASDAQ Global Market. Trading in our ordinary shares on these markets will take place in different currencies (dollars on The NASDAQ Global Market and NIS on the TASE), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Israel). The trading prices of our ordinary shares on these two markets may differ due to these and other factors. Any decrease in the price of our ordinary shares on one of these markets could cause a decrease in the trading price of our ordinary shares on the other market.

### Our ordinary shares have no prior trading history in the United States, and an active market may not develop, which may limit the ability of our shareholders to sell our ordinary shares in the United States following this offering.

There is no public market for our ordinary shares in the United States. Although we have applied to have our ordinary shares listed on The NASDAQ Global Market, an active trading market for our ordinary shares may never develop or may not be sustained following this offering. If an active market for our ordinary shares does not develop, it may be difficult to sell your shares. The price of our ordinary shares in the initial public offering in the United States will be determined through our negotiations with the underwriters and may be higher than the market price of our ordinary shares after the closing of this offering. Consequently, you may not be able to sell our ordinary shares that you purchase in this offering at prices equal to or greater than the purchase price.

## We will incur significant additional increased costs as a result of the listing of our ordinary shares for trading on The NASDAQ Global Market, and our management will be required to devote substantial time to new compliance initiatives as well as to compliance with ongoing U.S. and Israeli reporting requirements.

As a public company in the United States, we will incur additional significant accounting, legal and other expenses that we did not incur before the offering. We also anticipate that we will incur costs associated with corporate governance requirements of the SEC and the Marketplace Rules of The NASDAQ Stock Market, as well as requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. We expect these rules and regulations to increase our legal and financial compliance costs, introduce new costs such as investor relations, stock exchange listing fees and shareholder reporting, and to make some activities more time consuming and costly. The implementation and testing of such processes and systems may require us to hire outside consultants and incur other significant costs. Any future changes in the laws and regulations affecting public companies in the U.S. and Israel, including Section 404 and other provisions of the Sarbanes-Oxley Act, the rules and regulations adopted by the SEC and the Marketplace Rules of The NASDAQ Stock Market, as well as applicable Israeli reporting requirements, for so long as they apply to us, will result in increased costs to us as we respond to such changes. These laws, rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our board committees or as executive officers. Furthermore, until such time as our shareholders may vote to approve our transition from Israeli securities law reporting requirements to U.S. requirements, we will also be required to comply fully with both Israeli and U.S. requirements. The need to comply with both U.S. and Israeli reporting and other securities law requirements will also add to our legal and financial compliance costs and require devotion of additional management resources to reporting and compliance efforts.



## As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of applicable SEC and NASDAQ requirements, which may result in less protection than is accorded to investors under rules applicable to domestic issuers.

As a foreign private issuer, we will be permitted to follow certain home country corporate governance practices instead of those otherwise required under the Marketplace Rules of The NASDAQ Stock Market for domestic issuers. For instance, we may follow home country practice in Israel with regard to, among other things, composition of the Board of Directors, director nomination procedure, approval of compensation of officers, and quorum at shareholders' meetings. In addition, we will follow our home country law, instead of the Marketplace Rules of The NASDAQ Stock Market, which require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the company and certain acquisitions of the stock or assets of another company. We will evaluate the extent to which we will avail ourselves of the exemptions available to foreign private issuers in connection with the actual listing of our ordinary shares for trading on The NASDAQ Global Market. Following our home country governance practices as opposed to the requirements that would otherwise apply to a United States company listed on the NASDAQ Global Market may provide less protection than is accorded to investors under the Marketplace Rules of The NASDAQ Stock Market applicable to domestic issuers.

In addition, as a foreign private issuer, we will be exempt from the rules and regulations under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as domestic companies whose securities are registered under the Exchange Act.

## If, after this offering, we are unable to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 as they apply to a foreign private issuer that is listing on a U.S. exchange for the first time, or our internal controls over financial reporting are not effective, the reliability of our financial statements may be questioned and our stock price may suffer.

After the completion of this offering, we will become subject to the requirements of the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires companies subject to the reporting requirements of the U.S. securities laws to do a comprehensive evaluation of its and its subsidiaries' internal controls over financial reporting. To comply with this statute, we will be required to document and test our internal control procedures; our management will be required to assess and issue a report concerning our internal controls over financial reporting. In addition, our independent registered public accounting firm will be required to issue an opinion on management's assessment of those matters, which will first be tested in connection with the filing of our second annual report on Form 20-F after this offering.

We will need to prepare for compliance with Section 404 by strengthening, assessing and testing our system of internal controls to provide the basis for our report. However, the continuous process of strengthening our internal controls and complying with Section 404 is complicated and time-consuming. Furthermore, as our business continues to grow both domestically and internationally, our internal controls will become more complex and will require significantly more resources and attention to ensure our internal controls remain effective overall. During the course of its testing, our management may identify material weaknesses or significant deficiencies, which may not be remedied in a timely manner to meet the deadline imposed by the Sarbanes-Oxley Act. If our management cannot favorably assess the effectiveness of our internal controls over financial reporting, or our independent registered public accounting firm identifies material weaknesses in our internal controls, investor confidence in our financial results may weaken, and our share price may suffer.

#### **Risks Related to Our Operations in Israel**

### We conduct our operations in Israel and therefore our results may be adversely affected by political, economic and military instability in Israel.

Our headquarters, all of our operations and some of our suppliers and third party contractors are located in central Israel and our key employees, officers and most of our directors are residents of Israel. Accordingly, political, economic and military conditions in Israel may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could adversely affect our operations and results of operations and could make it more difficult for us to raise capital. During the winter of 2008, Israel was engaged in an armed conflict with Hamas, a militia group and political party operating in the Gaza Strip, and during the summer of 2006, Israel was engaged in an armed conflict, with Hezbollah, a Lebanese Islamist Shiite militia group and political party. These conflicts involved missile strikes against civilian targets in various parts of Israel, and negatively affected business conditions in Israel. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations. For example, any major escalation in hostilities in the region could result in a portion of our employees being called up to perform military duty for an extended period of time. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in the agreements.

Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

#### Our operations may be disrupted as a result of the obligation of management or key personnel to perform military service.

Many of our male employees in Israel, including members of our senior management, are obligated to perform one month, and in some cases more, of annual military reserve duty until they reach the age of 45 (or older, for reservists with certain occupations) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists, and recently some of our employees have been called up in connection with armed conflicts. It is possible that there will be military reserve duty call-ups in the future. Our operations could be disrupted by the absence of a significant number of our employees or of one or more of our key employees. Such disruption could materially adversely affect our business and operations.

### Because a certain portion of our expenses is incurred in currencies other than the NIS, our results of operations may be harmed by currency fluctuations and inflation.

Our reporting and functional currency is the NIS, and we pay a substantial portion of our expenses in NIS. The revenues from our licensing agreements with Ikaria and Cypress Bioscience are payable in U.S. dollars and we expect our revenues from future licensing arrangements to be denominated in U.S. dollars or in Euros. As a result, we are exposed to the currency fluctuation risks relating to the recording of our revenues in NIS. For example, if the NIS strengthens against either the U.S. dollar or the Euro, our reported revenues in NIS may be lower than anticipated. The Israeli rate of inflation has not offset or compounded the effects caused by fluctuations between the NIS and the U.S. dollar or the Euro. To date, we have not engaged in

hedging transactions. Although the Israeli rate of inflation has not had a material adverse effect on our financial condition during 2007, 2008, 2009, or 2010 to date, we may, in the future, decide to enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of the currencies mentioned above in relation to the NIS. These measures, however, may not adequately protect us from material adverse effects.

# We have received Israeli government grants and loans for the operation of a biotechnology incubator and for certain research and development expenditures. The terms of these grants and loans may require us to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. We may be required to pay penalties in addition to repayment of the grants and loans. Such grants and loans may be terminated or reduced in the future, which would increase our costs.

Our research and development efforts, including the operation of our biotechnology incubator, have been financed, in part, through grants and loans that we have received from the OCS. Of our 10 current development projects, five have been funded by the OCS, either directly or through our incubator, including BL-1020, BL-1021, BL-1040, BL-2030 and BL-4040. Of the five projects funded by the OCS, four have been funded through our incubator. We therefore must comply with the requirements of the Israeli Law for the Encouragement of Industrial Research and Development, 1984, and related regulations, or the Research Law. As of June 30, 2010, we have received approximately \$16.4 million in grants and loans from the OCS, including accrued interest, of which approximately \$11.4 million was granted in the form of loans to our biotechnology incubator. Such amounts include loans equal to approximately \$5.0 million for projects that have been terminated, which we do not expect that we will be required to repay. When know-how, technology or products are developed using OCS grants, the terms of these grants and the Research Law restrict the transfer of that know-how (as well has know-how that is derived from funded know-how) and the development or manufacture of those products out of Israel without the prior approval of the OCS. Therefore, the discretionary approval of an OCS committee will be required for any transfer to third parties of our therapeutic candidates developed with OCS funding, including through out-licensing arrangements pursuant to which we commercialize our product candidates. There is no assurance that we will receive the required approvals should we wish to transfer this technology or development out of Israel in the future. Furthermore, the OCS committee may impose certain conditions on any arrangement under which we transfer technology or development out of Israel. Transfers of know-how from OCS funded programs, including our biotechnology incubator, even if approved by the OCS, may be subject to restrictions set forth in the Research Law, and may include payments to the OCS, as described more fully under "Government Regulation and Funding — Israeli Government Programs — Office of the Chief Scientist."

The incubator agreement has a six-year term and we are entitled to apply for a three-year extension to the term. The incubator agreement is currently scheduled to terminate on December 31, 2010. We applied for an extension to the agreement in June 2010 and are waiting for notification from the OCS of its approval of the extension. If the incubator agreement terminates, we will no longer be eligible for funding from the OCS through the incubator for new projects in the incubator, but existing projects and the terms of any outstanding loans will not be affected by the termination. There can be no assurance that the OCS will extend the term of the agreement. In addition, if the OCS elects to extend the term of the agreement, there can be no assurance that it will extend the term for the full three-year extension period or require additional terms as a condition for the extension. If the OCS does not extend the term of the agreement for the three-year period, in whole or in part, or if the OCS requires terms and conditions that are not favorable to our company, our business, financial condition and results of operations may be materially and adversely affected.

The transfer abroad of the manufacturing of any OCS-supported product or technology is also subject to various conditions, including the payment of increased royalties equal to, in the aggregate, up to 300% of the total grant amounts received in connection with the product or technology, plus interest, depending on the portion of total manufacturing that is performed outside of Israel. Payment of the increased royalties would constitute the total repayment amount required with respect to the OCS grants received for the development of the products or technology for which the manufacturing is performed outside of Israel. In addition, any decrease in the percentage of manufacture performed in Israel of any product or technology, as originally declared in the application to the OCS with respect to the product or technology, may require us to notify, or to obtain the approval of, the OCS, and may result in increased royalty payments to the OCS of up to 300%

of the total grant amounts received in connection with the product or technology, plus interest, depending on the portion of total manufacturing that is performed outside of Israel. These restrictions may impair our ability to sell our technology assets or to outsource or transfer development or manufacturing activities with respect to any product or technology. These restrictions continue to apply even after we have repaid any grants, in whole or in part.

We cannot be certain that any approval of the OCS will be obtained on terms that are acceptable to us, or at all. Furthermore, if we undertake a transaction involving the transfer to a non-Israeli entity of technology developed with OCS funding pursuant to a merger or similar transaction, the consideration available to our shareholders may be reduced by the amounts we are required to pay to the OCS. If we fail to comply with the conditions imposed by the OCS, including the payment of royalties with respect to grants received, we may be required to refund any payments previously received, together with interest and penalties, and may be subject to criminal penalties. See "Government Regulation and Funding — Israeli Government Programs."

# Provisions of Israeli law may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, a majority of each class of securities of the target company must approve a merger. Moreover, a full tender offer can only be completed if the acquirer receives at least 95% of the issued share capital, and the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within three months following the completion of the tender offer, petition the court to alter the consideration for the acquisition.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of numerous conditions, including a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are restricted. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no actual disposition of the shares has occurred.

These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders. See "— Description of Share Capital — Acquisitions Under Israeli Law."

We have received Israeli government grants and loans for the operation of a biotechnology incubator and for certain research and development expenditures. The terms of these grants and loans may require us to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. We may be required to pay penalties in addition to repayment of the grants and loans. Such grants and loans may be terminated or reduced in the future, which would increase our costs. See "— Government Regulation and Funding — Israeli Government Programs."

# It may be difficult to enforce a U.S. judgment against us and our officers and directors named in this prospectus in Israel or the United States, or to serve process on our officers and directors.

We are incorporated in Israel. Most of our executive officers and all of our directors listed in this prospectus reside outside of the United States, and all of our assets and most of the assets of our executive officers and directors are located outside of the United States. Therefore, a judgment obtained against us or most of our executive officers and all of our directors in the United States, including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not

be enforced by an Israeli court. It also may be difficult for you to effect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel. See "Enforceability of Civil Liabilities" for additional information on your ability to enforce a civil claim against us and our executive officers or directors named in this prospectus.

# Your rights and responsibilities as a shareholder will be governed by Israeli law which may differ in some respects from the rights and responsibilities of shareholders of U.S. companies.

We are incorporated under Israeli law. The rights and responsibilities of the holders of our ordinary shares are governed by our Articles of Association and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders in typical U.S.-based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith toward the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at the general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and interested party transactions requiring shareholder approval. In addition, a shareholder who knows that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. There is limited case law available to assist us in understanding the implications of these provisions that govern shareholders' actions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. corporations.

## FORWARD-LOOKING STATEMENTS

Some of the statements under the sections entitled "Prospectus Summary," "Risk Factors," "Use of Proceeds," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" and elsewhere in this prospectus constitute forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. In addition, the sections of this prospectus entitled "Summary" and "Business" contain information obtained from independent industry sources that we have not independently verified. You should not put undue reliance on any forward-looking statements. Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements.

Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to:

- the initiation, timing, progress and results of our preclinical studies, clinical trials, and other therapeutic candidate development efforts;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials;
- our receipt of regulatory approvals for our therapeutic candidates, and the timing of other regulatory filings and approvals;
- the clinical development, commercialization, and market acceptance of our therapeutic candidates;
- our ability to establish and maintain corporate collaborations;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;
- the implementation of our business model, strategic plans for our business and therapeutic candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- competitive companies, technologies and our industry;
- · statements as to the impact of the political and security situation in Israel on our business; and
- our use of the net proceeds from this offering.

## **EXCHANGE RATE INFORMATION**

We prepare our financial statements in NIS. No representation is made that the NIS amounts referred to in this prospectus could have been or could be converted into U.S. dollars at any particular rate or at all.

Fluctuations in the exchange rates between the NIS and the U.S. dollar will affect the dollar amounts received by owners of our ordinary shares on payment of dividends, if any, paid in NIS.

The following table sets forth information regarding the exchange rates of U.S. dollars per NIS for the periods indicated. Average rates are calculated by using the daily representative rates as reported by the Bank of Israel on the last day of each month during the periods presented.

	NIS per U.S.\$			
Year Ended December 31,	High	Low	Average	Period End
2009	4.256	3.690	3.923	3.775
2008	4.022	3.230	3.586	3.802
2007	4.342	3.830	4.110	3.846
2006	4.725	4.176	4.453	4.225
2005	4.741	4.299	4.486	4.603

The following table sets forth the high and low daily representative rates for the NIS as reported by the Bank of Israel for each of the prior six months.

	NIS per U.S.\$				
Month	High	Low	Average	Period End	
September 2010 (up to September 14)	3.798	3.770	3.780	3.772	
August 2010	3.829	3.753	3.791	3.817	
July 2010	3.894	3.779	3.854	3.779	
June 2010	3.888	3.814	3.852	3.875	
May 2010	3.870	3.730	3.785	3.829	
April 2010	3.749	3.682	3.713	3.716	
March 2010	3.787	3.714	3.744	3.750	

On June 30, 2010, the closing representative rate was \$1.00 to NIS 3.875, as reported by the Bank of Israel.

## PRICE RANGE OF OUR ORDINARY SHARES

Our ordinary shares have been trading on the TASE under the symbol "BLRX" since February 2007. No trading market currently exists for our ordinary shares in the United States. We have applied to have our ordinary shares listed on The NASDAQ Global Market under the symbol "BLRX."

The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our ordinary shares on the TASE in NIS and U.S. dollars. U.S. dollar per ordinary share amounts are calculated using the U.S. dollar representative rate of exchange on the date to which the high or low market price is applicable, as reported by the Bank of Israel. The prices set forth in this section do not give effect to the reverse stock split which we expect to complete immediately prior to the date of this prospectus.

	NIS	NIS		U.S.\$		
	Price Distance Distan		Price Ordinary			
	High	Low	High	Low		
Annual:						
2009	5.68	0.86	1.53	0.23		
2008	4.25	0.69	1.10	0.17		
2007 (from February 8, 2007)	6.65	3.80	1.57	0.89		
Quarterly:						
Second Quarter 2010	4.69	3.00	1.27	0.78		
First Quarter 2010	4.75	3.80	1.26	1.03		
Fourth Quarter 2009	5.68	3.50	1.53	0.93		
Third Quarter 2009	4.60	1.74	1.22	0.44		
Second Quarter 2009	2.79	1.33	0.72	0.32		
First Quarter 2009	1.86	0.86	0.47	0.23		
Fourth Quarter 2008	1.81	0.69	0.52	0.17		
Third Quarter 2008	3.00	1.79	0.86	0.52		
Second Quarter 2008	3.50	2.37	1.02	0.71		
First Quarter 2008	4.25	2.38	1.10	0.70		
Most Recent Six Months:						
September 2010 (up to September 14)	3.51	3.26	0.93	0.86		
August 2010	3.82	3.26	1.01	0.85		
July 2010	3.63	3.22	0.44	0.83		
June 2010	4.45	3.15	1.17	0.81		
May 2010	4.23	3.00	1.13	0.78		
April 2010	4.69	4.30	1.27	1.15		
March 2010	4.75	4.18	1.26	1.10		

On June 30, 2010, the last reported sales price of our ordinary shares on the TASE was NIS 3.34 per share, or \$0.86 per share (based on the exchange rate reported by the Bank of Israel for such date). On June 30, 2010, the exchange rate of the NIS to the dollar was \$1.00 = NIS 3.875, as reported by the Bank of Israel. As of June 30, 2010 there were three shareholders of record of our ordinary shares. The number of record holders is not representative of the number of beneficial holders of our ordinary shares.

Our Series 2 Warrants are also traded on the TASE. Currently there are 7,528,946 Series 2 Warrants outstanding, all of which are exercisable for one ordinary share at a per share exercise price of NIS 6.08, or \$1.57 (based on the exchange rate on June 30, 2010). The Series 2 Warrants expire on December 29, 2011. As of June 30, 2010, there was one shareholder of record of our Series 2 Warrants. The number of record holders of our Series 2 Warrants is not representative of the number of beneficial holders of our Series 2 Warrants. On June 30, 2010, the last reported sales price of our Series 2 Warrants on the TASE was NIS 0.74, or \$0.19 per share (based on the exchange rate reported by the Bank of Israel for such date).

## **USE OF PROCEEDS**

We estimate that we will receive net proceeds from this offering of approximately \$31.0 million, based on an assumed initial public offering price per ordinary share of \$ , the midpoint of the estimated initial public offering price range, after deducting the underwriting discounts and the estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we will receive additional proceeds of approximately \$4.5 million, after deducting underwriting discounts and commissions and the estimated expenses payable by us.

We expect to use the net proceeds of this offering as follows:

- approximately \$21.0 million of the net proceeds to fund the phase 1 and phase 2 clinical trials of, and commence
  commercialization efforts for our next two therapeutic candidates and to fund pre-clinical studies of the next two
  therapeutic candidates to advance from the feasibility stage to the pre-clinical and initial phase 1 clinical stages;
- approximately \$5.0 million of the net proceeds to fund feasibility studies for up to 12 molecules as they are introduced to our pipeline, if any; and
- approximately \$5.0 million of the net proceeds to fund our operations and for general corporate purposes and business development and marketing efforts.

We do not expect to use any of the proceeds of this offering to develop BL-1020 and BL-1040 further, in light of the fact that they have been out-licensed to Cypress Bioscience and Ikaria, respectively, and we are not responsible for further development costs under the out-licensing agreements. We do not expect to perform further studies on BL-5010, other than the study currently in progress; however, we may elect to do so if we believe there will be a significant advantage in our commercialization efforts in respect of the compound. Any additional study, the cost of which is not expected to exceed \$5.0 million, would be funded from our current cash resources.

If we elect to commercialize any of our therapeutic candidates internally, we may use a portion of the net proceeds to fund the commercialization. We may also use a portion of the net proceeds for the potential acquisition of, or investment in, technologies, products or companies that complement our business, although we have no current understandings, commitments or agreements to do so.

The amounts and timing of our actual expenditures will depend upon numerous factors, including the progress of our research, development and commercialization efforts, the progress of our preclinical and clinical trials, our ability to enter into our licensing arrangements and strategic collaborations and our operating costs and expenditures. We may find it necessary or advisable to use the net proceeds for other purposes. Accordingly, our management will have significant flexibility in applying the net proceeds of this offering. Pending the uses described above, we intend to invest the net proceeds in short term, interest-bearing investment-grade securities.

We will require substantial additional funds to complete the research and development and clinical and regulatory activities necessary to bring our therapeutic candidates to market. We believe that the net proceeds from this offering, our existing cash and cash equivalents, and funding we expect to receive under our current license agreements will be sufficient to fund our operations for at least the next 24 months. However, our funding requirements may change and will depend upon numerous factors, many of which are currently unknown to us, and we may need additional funds sooner than planned. Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through payments received under our collaborations, debt or equity financings, or by out-licensing other product candidates. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We cannot assure you that additional funds will be available when we need them on terms that are acceptable to us, or at all.

## **DIVIDEND POLICY**

We have never declared or paid cash dividends to our shareholders. Currently we do not intend to pay cash dividends. We intend to reinvest any earnings in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our Board of Directors and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, applicable Israeli law and other factors our Board of Directors may deem relevant.

# CAPITALIZATION

The following table sets forth our consolidated capitalization as determined in accordance with IFRS as of June 30, 2010:

- on an actual basis;
- as adjusted to reflect the sale of ordinary shares at an assumed initial public offering price of \$ , the midpoint of the estimated initial public offering price range and the receipt by us of net proceeds equal to \$ million, after deducting the underwriting discounts and commissions and the estimated offering expenses payable by us.

This table should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this prospectus.

•	As of Ju	ine 30, 2010
	Actual	Pro forma as adjusted
	(una (NIS in	audited) thousands)
Liabilities and shareholders' equity		
Current Liabilities:		
Accounts payable and accruals:		
Trade		
Other		
Total current liabilities		
Long-Term Liabilities:		
Long-term loan, less current maturities		
Total liabilities		
Shareholders' equity:		
Ordinary shares		
Warrants		
Share premium		
Capital reserve		
Accumulated loss		
Total stockholder's equity		
* · ·		

## DILUTION

Our net tangible book value on June 30, 2010 was approximately \$19.4 million, equivalent to \$0.16 per ordinary share. We have calculated our net tangible book value per share by:

- subtracting our liabilities from our total assets and deducting goodwill, intangible assets and debt issuance costs; and
- dividing the difference by the number of ordinary shares outstanding.

After giving effect to adjustments relating to the offering, our pro forma net tangible book value on June 30, 2010 would have been approximately \$ million, equivalent to \$ per ordinary share. The adjustments made to determine our pro forma book value are as follows:

- an increase in total assets to reflect the net proceeds of the offering received by us as described under "Use of Proceeds;" and
- the addition of the ordinary shares offered in this prospectus to the number of ordinary shares outstanding.

The following table illustrates the immediate increase in our pro forma net tangible book value of \$ per ordinary share and the immediate pro forma dilution to new investors:

Assumed public offering price per ordinary share		\$
Net tangible book value per share as of June 30, 2010	\$ 0.16	
Increase in net tangible book value per share attributable to the offering		
Pro forma net tangible book value per share as of June 30, 2010 after		
giving effect to the offering		
Dilution per ordinary share to new investors		\$

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share (the midpoint of the range on the cover of this prospectus) would increase (decrease) the net tangible book value by \$ , the net tangible book value per ordinary share after this offering by \$ per ordinary share and the dilution in net tangible book value per ordinary share to investors in this offering by \$ per ordinary share, assuming that the number of ordinary shares offered by us remains the same and after deducting the estimated underwriting discount and offering expenses payable by us.

The table below summarizes, as of June 30, 2010, the differences for our existing shareholders and new shareholders in this offering, with respect to the number of ordinary shares purchased from us, the total consideration paid and the average per ordinary share price paid before deducting fees and offering expenses.

	Shares issued		Total con	sideration	Average price	
	Number	%	Amount	%	per share	
		(in thousands of U.S. dollars, except per share data)				
Our existing shareholders		%	\$	%	\$	
New shareholders in this offering						
Total		%	\$	%		

The discussion and table above assume no exercise of the underwriters' over-allotment option. If the underwriters exercise their over-allotment option, the pro forma number of our ordinary shares held by new shareholders will increase to , or approximately

%, of the total pro forma number of our ordinary shares outstanding after this offering. The discussion and table above also do not include (i) an aggregate of 7,084,166 ordinary shares we have reserved for issuance upon the exercise of outstanding options as of June 30, 2010 or (ii) an aggregate of 7,528,946 ordinary shares issuable upon exercise of our outstanding Series 2 Warrants, which amounts do not give effect to the proposed reverse stock split. If all of the outstanding options and warrants were exercised, pro forma net tangible book value per ordinary share would be \$ and dilution to new investors would be \$ .

## SELECTED CONSOLIDATED FINANCIAL DATA

The following table sets forth our selected consolidated financial data for the periods ended and as of the dates indicated. The following selected historical consolidated financial data for our company should be read in conjunction with the historical financial information, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other information provided elsewhere in this prospectus and our consolidated financial statements and related notes. The selected consolidated financial data in this section is not intended to replace the consolidated financial statements and is qualified in its entirety thereby. We derived the selected consolidated financial data as of and for the six months ended June 30, 2010 and June 30, 2009 from our unaudited consolidated financial statements contain all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of our financial position, results of operations and cash flows as of and for the periods indicated therein. The results of operations for the six months ended June 30, 2009 are not necessarily indicative of the operating results to be expected for the full fiscal years encompassing those periods.

We have derived the selected consolidated financial statements as of and for the periods ended December 31, 2007, 2008, and 2009 from our audited consolidated financial statements included elsewhere in this prospectus.

Our consolidated financial statements included in this prospectus were prepared in NIS in accordance with IFRS. Year Ended December 31, Six Months Ended June 30,

		rear Enueu	December 51	L,	SIX IV	ionuis Endeu J	June 50,
Consolidated Statements Of Operations	2006	2007	2008	2009	2009	2010	2010 <sup>(2)</sup>
Data: <sup>(1)</sup>							
Dutu			(in thousands	, except share a	nd per share d	ata)	-
				NIS	na per snare a	ata)	U.S.\$
Revenues				63,909	_	_	-
Cost of revenues			_	(22,622)	—	_	-
Operating expenses:							
Sales and marketing expenses			—	(3,085)	(1,477)	(2,184)	(56
Research and development expenses, net	(42,193)	(75,863)	(106, 156)	(90,302)	(49,850)	(37,032)	(9,55
General and administrative expenses	(6,357)	(13,611)	(13,083)	(11,182)	(4,307)	(6,224)	(1,60
Gain on adjusting warrants to fair value	—	27,557	3,658	—	—	_	-
Capital loss, net	(121)						-
Operating loss	(48,671)	(61,917)	(115,581)	(63,282)	(55,634)	(45,440)	(11,7)
Financial income	584	7,875	13,001	3,928	3,799	2,878	7
Financial expenses	(834)	(5,377)	(12,269)	(2,164)	(1,739)	(1,062)	(2
Net loss	(48,921)	(59,419)	(114,849)	(61,158)	(53,574)	(43,624)	(11,2
Net loss per ordinary share <sup>(3)</sup>	(1,772.6)	(0.88)	(1.44)	(0.63)	(0.68)	(0.35)	(0.
Number of ordinary shares used in	38,521	69,302,075	78,131,103	123,497,029	78,131,578	123,512,879	123,512,8
computing loss per ordinary share				. <u> </u>			
						As of June 3	30,
Consolidated Balance Sheet Data:					20	)10	2010 <sup>(2)</sup>
					(in the		thousands
						IS)	U.S.\$)
Cash and cash equivalents						8,489	22,836
Accounts receivable							
Property, plant and equipment, n	et					4,696	1,212
Total assets						0,311	28,467
Total liabilities						2,815	8,468
Total shareholders' equity						7,496	19,999
						,	_ ,000

(1) Data on diluted loss per share was not presented in the financial statements because the effect of the exercise of the options and warrants is anti-dilutive.

(2) Calculated using the exchange rate reported by the Bank of Israel for June 30, 2010 at the rate of one U.S. dollar per NIS 3,875.

(3) The net loss per share has been adjusted to reflect the benefit component related to the issuance of rights to investors.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this prospectus. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this prospectus, particularly those in the "Risk Factors."

We are a clinical stage biopharmaceutical development company dedicated to identifying, in-licensing and developing therapeutic candidates that have advantages over currently available therapies or address unmet medical needs. Our current development pipeline consists of three clinical therapeutic candidates, BL-1020, BL-1040 and BL-5010. In addition, we have seven therapeutic candidates in the advanced preclinical, early preclinical and discovery stages, including a compound for the treatment of neuropathic pain that we expect will enter clinical trials in 2010. We generate our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. We also operate, with the financial participation of the OCS, a biotechnology incubator to evaluate therapeutic candidates. As of June 30, 2010, we have received approximately \$11.4 million in grants in the form of loans from the OCS to operate the incubator, which does not include \$5.0 million we have received from the OCS outside of the incubator agreement, as of that date. Such amounts include loans equal to approximately \$5.0 million for terminated programs. We do not expect to be required to repay loans for terminated programs. Our strategy includes commercializing our therapeutic candidates through outlicensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case by case basis, the commercialization of our therapeutic candidates independently.

The following is a description of our three clinical therapeutic candidates:

- BL-1020 is a new chemical entity in development for the treatment of schizophrenia. In September 2009, we announced positive topline results from a phase 2b clinical trial of BL-1020. We have entered into an exclusive, royalty-bearing outlicensing arrangement with Cypress Bioscience with respect to the development of, obtaining regulatory approval for, and the commercialization of BL-1020 in the United States, Canada and Mexico.
- BL-1040 is a novel resorbable polymer solution for use in the prevention of cardiac remodeling that may occur in patients
  who have suffered an AMI. BL-1040, which is being developed as a medical device. In March 2010, we announced positive
  results from a phase 1/2 clinical trial. We have entered into an exclusive, worldwide, royalty-bearing out-licensing
  arrangement with Ikaria with respect to the development, manufacture and commercialization of BL-1040.
- BL-5010 is a novel therapeutic candidate for the non-surgical removal of skin lesions. BL-5010 is currently the subject of a phase 1/2 clinical trial. We anticipate that the phase 1/2 clinical trial will be completed in the fourth quarter of 2010.

In July 2009, we entered into an exclusive, worldwide, royalty-bearing licensing arrangement with Ikaria which was amended and restated in August 2009. Under the agreement, we granted Ikaria an exclusive, worldwide license to develop, manufacture and commercialize BL-1040 for use in the prevention, mitigation and treatment of injuries to the myocardial tissue of the heart. Under the arrangement, Ikaria is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or products related thereto. We received an upfront payment equal to \$7.0 million upon the execution of the license agreement. Upon successful completion of the phase 1/2 clinical trial, Ikaria paid us a milestone payment equal to \$10.0 million and we are entitled to receive additional milestone and royalty payments upon the occurrence of certain events.

In June 2010, we entered into an exclusive, royalty-bearing out-licensing arrangement with Cypress Bioscience with regard to BL-1020, covering the United States, Canada and Mexico, which became effective in August 2010. Under the arrangement, Cypress Bioscience is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize, BL-1020 for the prevention, diagnosis

and treatment of all human diseases in the United States, Canada and Mexico. We have retained the rights to BL-1020 for the rest of the world. In addition, under the agreement Cypress Bioscience has licensed to us the right to use any and all regulatory data generated by Cypress Bioscience in connection with its pursuit of regulatory approval for BL-1020 in Cypress Bioscience's territory for use by us outside of Cypress Bioscience's territory, subject to our future reimbursement of certain precommercialization expenses incurred by Cypress Bioscience in generating such data. We received an upfront fee of \$30.0 million from Cypress Bioscience upon the consent of the OCS to the agreement, and we are entitled to receive up to an additional \$250.0 million in connection with the achievement of certain performance-based milestones and up to an additional \$85.0 million upon the achievement of certain sales-based milestones. Cypress Bioscience may pay a portion of the first performance-based milestone payment by purchasing our ordinary shares, in its sole discretion.

Since inception in 2003, we have generated significant losses in connection with our research and development, including the clinical development and phase 2b clinical trial of BL-1020. At June 30, 2010, we had an accumulated deficit of NIS 368.9 million. Although we have begun to recognize revenues in connection with our licensing arrangement with Ikaria for BL-1040, and will recognize revenues in the third quarter of 2010 in connection with our licensing arrangement with Cypress Bioscience for BL-1020, we may continue to generate losses in connection with the research and development activities relating to our pipeline of therapeutic candidates. Such research and development activities are budgeted to expand over time and will require further resources if we are to be successful. As a result, we may continue to incur operating losses, which may be substantial over the next several years, and we may need to obtain additional funds to further develop our research and development programs.

We have funded our operations primarily through the sale of equity securities (both in private placements and in three public offerings on the TASE), funding received from the OCS, payments received under the licensing arrangements with Ikaria and Cypress Bioscience, and interest earned on investments. We expect to continue to fund our operations over the next several years through our existing cash resources, the net proceeds of this offering, potential future milestone payments that we expect to receive from Ikaria and Cypress Bioscience, interest earned on our investments and additional capital to be raised through public or private equity offerings or debt financings. As of June 30, 2010, we had approximately \$22.8 million of cash and cash equivalents based on the exchange rate reported by the Bank of Israel as of that date. In addition, as of August 31, 2010, we had approximately \$41.6 million of cash and cash equivalents, which reflects our receipt of the \$30.0 million upfront payment from Cypress Bioscience less payments of \$9.75 million, in the aggregate, that we made to the OCS, Bar Ilan Research and Development and Ramot.

#### Revenues

Our revenues to date have been generated primarily from milestone payments under our licensing arrangement with Ikaria. We entered into a license and collaboration agreement with Ikaria in July 2009, which was amended and restated in August 2009. Ikaria subsequently paid us an up-front payment of \$7.0 million. In addition, upon successful completion of the phase 1/2 clinical trial, Ikaria paid us a milestone payment of \$10.0 million. In June 2010, we entered into a license agreement with Cypress Bioscience, which closed upon receipt of consent by the OCS in August 2010.

Under the terms of our agreement with Ikaria, in addition to the payments mentioned above, the maximum future developmentrelated payments to which we are entitled is \$115.5 million. We are also entitled to maximum commercialization milestone payments of \$150.0 million, subject to the terms and conditions of the license agreement. Certain payments we have received from Ikaria have been subject to a 15% withholding tax in the United States, and certain payments we may receive in the future, if at all, may also be subject to a 15% withholding tax in the United States. We received an upfront fee of \$30.0 million from Cypress Bioscience upon the consent of the OCS to the agreement in August 2010. In addition, we are entitled to up to an additional \$250.0 million in connection with the achievement of certain performance-based milestones and an additional up to \$85.0 million upon the achievement of certain sales-based milestones. We believe that the sales-based milestone and royalty payments will be subject to a 15% withholding tax. Receipt of any milestone payment under either of the agreements depends on many factors, some of which are beyond our control. We cannot assure you that we will receive any of these future payments. We may be able to use U.S. taxes withheld from payments to us as credits against Israeli corporate income tax when we have

income, if at all, but there can be no assurance that we will be able to realize the credits. In addition, we believe that we may be able to get a refund of such withholding taxes from the U.S. government but there can be no assurance that we will be able to get such a refund. Our payments to our in-licensors are to be made from the net consideration received from our out-licensees.

We expect our revenues for the next several years to be derived primarily from payments under our current agreements with Ikaria and Cypress Bioscience, as well as additional collaborations that we may enter into in the future, including with regard to BL-5010 or other therapeutic candidates. Furthermore, we may receive future royalties on product sales, if any, under our agreements with Ikaria and Cypress Bioscience, as well as under any future agreement on BL-5010 or other compounds.

Our remaining therapeutic candidates are currently in development and, therefore, we do not expect to generate any revenues from these products for at least the next several years, if at all.

#### **Research and Development**

Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to external service providers, up-front and milestone payments under our license agreements, patent-related legal fees, costs of preclinical studies and clinical trials, drug and laboratory supplies and costs for facilities and equipment. We primarily use external service providers to manufacture our product candidates for clinical trials and for the majority of our preclinical and clinical development work. We charge all research and development expenses to operations as they are incurred. We expect our research and development expense in the near future as we continue to develop our therapeutic candidates.

The following table identifies our current major research and development projects:

Status	Expected Near Term Milestone
Completed phase 2b	A clinical trial assessing BL-1020's effect on cognition
	and psychosis is expected to commence in 2011
Completed phase 1/2	Ikaria reports that a phase 2 and a pivotal phase 3 are
	expected to commence in 2011
Phase 1/2	Completion of phase 1/2 study in the fourth quarter of
	2010
Preclinical	Phase 1 trial by the end of the fourth quarter of 2010
	Completed phase 2b Completed phase 1/2 Phase 1/2

In addition to the projects set forth above, we have a number of projects that are in the research and discovery phase with relatively immaterial costs.

We record costs for each development project on a "direct cost" basis only. Direct costs, which include contract research organization expenses, consulting expenses, patent expenses, materials, and other, similar expenses, are recorded to the project for which such expenses are incurred. However, salary and overhead costs, including, but not limited to salary expenses (including salaries for research and development personnel), facilities, depreciation, and stock-based compensation, are considered overhead, and are shared among all of our projects and are not recorded on a project-by-project basis. We do not allocate direct salaries to projects due to the fact that our project managers are generally involved in several projects at different stages of development, and the related salary expense is not significant to the overall cost of the applicable projects. In addition, indirect labor costs relating to our departments that support the research and development process, such as chemistry, manufacturing and controls (CMC), preclinical analysis, laboratory testing and initial drug sample production, as well as rent and other administrative overhead costs, are shared by many different projects and have never been considered by management to be of significance in its decision-making process with respect to any specific project. Accordingly, such costs have not been specifically allocated to individual projects. Certain of such costs are covered by OCS funding.

Set forth below is a summary of the gross direct costs allocated to our main projects on an individual basis, as well as the gross direct costs allocated to our less significant projects on an aggregate basis, for the six months ended June 30, 2010 and the years ended December 31, 2007, 2008 and 2009, and on an aggregate basis since project inception:

	Year Ended December 31,			Six Months Ended June 30,	Total Costs Since Project Inception
	2007	2008	2009	2010	
			(U.S. \$ in the	ousands)	
BL-1020	8,410	14,090	11,820	285	41,175
BL-1040	2,940	3,340	2,050	114	10,185
BL-5010		670	860	208	1,738
BL-1021	830	3,580	1,010	404	6,064
Other projects	2,960	7,220	1,240	1,244	18,004
Total gross direct project costs	15,140	28,900	16,980	2,255	77,166

A significant portion of our research and development costs have been incurred in connection with our phase 2b clinical trial of BL-1020.

The costs and expenses of our projects are partially funded by grants we have received from the OCS. Each grant is deducted from the related research and development expenses as the costs are incurred. For additional information regarding the grant process, see "Government Regulation and Funding — Israeli Government Programs." There can be no assurance that we will continue to receive grants from the OCS in amounts sufficient to fund our operations, if at all. In addition, under our licensing agreement with Ikaria, Ikaria is responsible for the costs associated with conducting all development activities for BL-1040, other than the costs associated with the phase 1/2 studies, and under our out-licensing agreement with Cypress Bioscience, Cypress Bioscience is responsible for substantially all of the costs associated with development activities for BL-1020 in the United States, Canada and Mexico. See "Business — Out-Licensing Agreement with Ikaria Holdings" and "Business — Out-Licensing Agreement with Cypress Bioscience."

From our inception through June 30, 2010, we have incurred research and development expense of \$100.4 million. We expect that a large percentage of our research and development expense in the future will be incurred in support of our current and future preclinical and clinical development projects. Due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage of our preclinical product development projects, we are unable to estimate with any certainty the costs we will incur in the continued development of the therapeutic candidates in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test our product candidates in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for each product candidate. If we are not able to enter into an out-licensing arrangement with respect to any therapeutic candidate prior to the commencement of later stage clinical trials, we may fund the trials for the therapeutic candidate ourselves.

While we are currently focused on advancing each of our product development projects, our future research and development expenses will depend on the clinical success of each therapeutic candidate, as well as ongoing assessments of each therapeutic candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which therapeutic candidates may be subject to future out-licensing arrangements, when such out-licensing arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. See "Risk Factors — If we or our licensees are unable to obtain U.S. and/or foreign regulatory approval for our therapeutic candidates, we will be unable to commercialize our therapeutic candidates."

As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for certain therapeutic candidates or projects in order to focus our resources on more promising therapeutic candidates or projects. Completion of clinical trials by us or our licensees may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a therapeutic candidate.

The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- the number of sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the number of patients that participate in the clinical trials;
- the duration of patient follow-up;
- the development stage of the therapeutic candidate; and
- the efficacy and safety profile of the therapeutic candidate.

We expect our research and development expenses to increase in the future from current levels as we continue the advancement of our clinical trials and preclinical product development projects and place significant emphasis on in-licensing new product candidates. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Because of the factors set forth above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects.

## **General and Administrative Expenses**

General and administrative expenses consist primarily of compensation for employees in executive and operational functions, including accounting, finance, legal, business development, investor relations, information technology and human resources. Other significant general and administration costs include facilities costs, professional fees for outside accounting and legal services, travel costs, insurance premiums and depreciation.

## **Financial Expense and Income**

Financial expense and income consists of interest earned on our cash and cash equivalents; bank fees and other transactional costs; and expense or income resulting from fluctuations of the dollar and other currencies, in which a portion of our assets and liabilities are denominated, against the NIS (our functional currency).

## **Critical Accounting Policies and Estimates**

We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the year ended December 31, 2009. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepare in accordance with IFRS. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

## **Functional Currency**

The currency of the primary economic environment in which our operations are conducted is the NIS. As we have not recorded significant recurring revenues since our inception, we consider the currency of the primary economic environment to be the currency in which we expend cash. A significant portion of our expenses and capital expenditures are incurred in NIS, and almost all of our financing has been provided in NIS.



#### **Revenue recognition**

We recognize revenues in accordance with International Accounting Standard No. 18, or IAS 18. Under IAS 18, revenues incurred in connection with the out-licensing of our patents and other intellectual property are recognized when all of the following criteria have been met as of the applicable balance sheet date:

- we have transferred to the licensee the significant risks and rewards of the rights to the patents and intellectual property;
- we do not retain either the continuing managerial involvement to the degree usually associated with ownership or the effective control over the patents and intellectual property;
- we can reliably measure the amount of revenue to be recognized;
- · it is probable that the economic benefits associated with the transaction will flow to us; and
- we can reliably measure the costs incurred or to be incurred in respect of the out-licensing.

We recognize revenues incurred in connection with the rendering of services by reference to the stage of completion of the transaction at the balance sheet date, if and when the outcome of the transaction can be estimated reliably.

We recognize revenues from royalties on an accrual basis when they become probable in accordance with the substance of the relevant agreement.

#### Accrued Expenses

We are required to estimate accrued expenses as part of our process of preparing financial statements. This process involves estimating the level of service performed on our behalf and the associated cost incurred in instances where we have not been invoiced or otherwise notified of actual costs. Examples of areas in which subjective judgments may be required include costs associated with services provided by contract organizations for preclinical development, clinical trials and manufacturing of clinical materials. We account for expenses associated with these external services by determining the total cost of a given study based on the terms of the related contract. We accrue for costs incurred as the services are being provided by monitoring the status of the trials and the invoices received from our external service providers. In the case of clinical trials, the estimated cost normally relates to the projected costs of treating the patients in our trials, which we recognize over the estimated term of the trial according to the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. As actual costs become known to us, we adjust our accruals.

## Investments in Financial Assets

The primary objective of our investment activities is to preserve principal while maximizing the income that we receive from our investments without significantly increasing risk and loss. Our investments are exposed to market risk due to fluctuations in interest rates, which may affect our interest income and the fair market value of our investments. We manage this exposure by performing ongoing evaluations of our investments. Due to the short-term maturities of our investments to date, their carrying value has always approximated their fair value.

A financial asset is classified in this category if our management has designated it as a financial asset upon initial recognition, because it is managed and its performance is evaluated on a fair-value basis in accordance with a documented risk management or investment strategy. Our investment policy with regard to excess cash, as adopted by our Board of Directors, is composed of the following objectives: (i) preserving investment principal; (ii) providing liquidity; and (iii) providing optimum yields pursuant to the policy guidelines and market conditions. The policy provides detailed guidelines as to the securities and other financial instruments in which we are allowed to invest. In addition, in order to maintain liquidity, investments are structured to provide flexibility to liquidate at least 50% of all investments within 15 business days. Information about these assets, including details of the portfolio and income earned, is provided internally on a quarterly basis to our key management personnel. Any divergence from this investment policy requires approval from our Board of Directors.

#### Government participation in research and development expenses

We receive research and development funding from the State of Israel through the OCS, both in the form of loans extended to our biotechnology incubator, as well as in the form of grants. In accordance with the OCS programs, we are entitled to a specific grant or loan with respect to a development project only after we incur development costs related to the project. Such loans and grants qualify as "forgivable loans" in accordance with IAS 20, "Accounting for Government Grants and Disclosure of Government Assistance," since they are repayable only if we generate revenues related to the underlying project.

In accordance with IAS 20, we account for each forgivable loan as a liability unless it is more likely than not that we will meet the terms of forgiveness of the loan, in which case the forgivable loan is accounted for as a government grant and carried to income as a reduction of the research and development expenses. Upon the initiation of any project for which we have received a loan, we consider it more likely than not that the project will not reach the revenue-generating stage during the entire development phase of the project when determining the accounting treatment of the related loan. Our determination is based on the high risk nature of pharmaceutical development generally and specifically on our strategy of initializing projects in the earliest stages of development. Therefore, we record a liability in respect of forgivable loans on a project only when it becomes probable that we will repay the loan.

Liabilities to the OCS in respect of out-licensing transactions are generally discussed and negotiated with the OCS, due to the fact that such licensing transactions do not fit into the standard development funding model contemplated by the Israeli Research and Development Law. In June 2010, we received a notification regarding the payment due in connection with the BL-1040 project, which we have paid in full. Accordingly, we have no further liabilities to the OCS with respect to BL-1040. We have accrued a liability of \$4.5 million to the OCS in connection with the BL-1020 out-licensing transaction (of which \$3.0 million was paid in August 2010), representing the full amount of the grants received from the OCS in respect of the BL-1020 project. This represents our best estimate of the liability to the OCS related to BL-1020. We may incur additional liabilities to the OCS, depending on the portion of total manufacturing that is performed outside of Israel in respect of BL-1020. Such liabilities will only accrue, if at all, with respect to any payment received in connection with BL-1020, when we determine that it is more likely than not that the payment will become payable.

## Stock-based Compensation

We account for stock-based compensation arrangements in accordance with the provisions of IFRS 2. IFRS 2 requires companies to recognize stock compensation expense for awards of equity instruments based on grant-date fair value of those awards (with limited exceptions). The cost is recognized as compensation expense over the life of the instruments, based upon the grant-date fair value of the equity or liability instruments issued. The fair value of our option grants is computed as of the grant date based on the Black-Scholes model, using the standard parameters established in that model including estimates relating to volatility of our stock, risk-free interest rates, estimated life of the equity instruments issued and the market price of our stock. As our stock is publicly traded on the TASE, we do not need to estimate the fair market value of our shares. Rather, we use the actual closing market price of our shares on the date of grant, as reported by the TASE.

#### Warrants

We issued Series 1 Warrants in connection with our Israeli initial public offering in February 2007. In accordance with IFRS, we allocated a portion of the consideration received to the warrants based on their fair value at the time. The consideration allocated to warrants is generally reflected in shareholders' equity, except in cases in which the exercise price of the warrants is not fixed. Due to the fact that the exercise price of the warrants we issued was linked to the Israeli consumer price index, the warrants were reflected as a financial liability and changes in the market value of the warrants were recorded in our statement of operations. Effective July 2008, the linkage to the Israeli consumer price index was no longer applicable, and such warrants were reclassified to shareholders' equity at their then current fair value. Subsequent changes in the market value of those warrants have no longer been reflected in our financial statements effective as of such date. In December 2009, we issued Series 2 Warrants exercisable for 7,528,946 ordinary shares. The Series 2 Warrants have a fixed exercise price and are classified as shareholders' equity.

## **Recent Accounting Pronouncements**

The recent accounting pronouncements set forth below became effective in 2009. None of the accounting pronouncements had a material adverse effect on our financial statements.

IFRS 7 "Financial instruments — Disclosures" (amendment) (effective January 1, 2009) requires enhanced disclosures about fair value measurement and liquidity risk. In particular, the amendment requires disclosure of fair value measurements in accordance with a fair value measurement hierarchy.

IAS 1 (revised) "Presentation of financial statements" (effective January 1, 2009) is a revised standard that establishes overall requirements for presentation of the financial statements, as well as guidelines for their structure and minimal requirements for their content. Among other things, the revised standard prohibits the presentation of items of income and expense (i.e., "non-owner changes in equity") in the statement of changes in equity, requiring non-owner changes in equity to be presented separately from owner changes in equity in a statement of comprehensive income. As a result of the revised standard, we present all owner changes in equity in our consolidated statement of changes in equity, and we present all non-owner changes in equity in the consolidated statement of comprehensive information to conform with the revised standard.

IFRS 2 (amendment), "Share-based payment" (effective January 1, 2009) covers vesting conditions and cancellations. It clarifies that vesting conditions are service conditions and performance conditions only. Other features of a share-based payment are not vesting conditions. Such features would need to be included in the grant date fair value for transactions with employees and others providing similar services; they would not impact the number of awards expected to vest or valuation thereof subsequent to grant date. All cancellations, whether by the entity or by other parties, should receive the same accounting treatment in the financial statements. We adopted IFRS 2 (amendment) effective January 1, 2009. The amendment did not have a material impact on our financial statements for the periods reported herein.

IAS 38 (amendment), "Intangible Assets" (effective January 1, 2009) is part of the IASB's annual improvements project published in May 2008. The amendment stipulates that a prepayment may only be recognized if that payment has been made in advance of obtaining the right of access to goods or receipt of services.

IAS 20 (amendment), "Accounting for Government Grants and Disclosure of Government Assistance" (effective January 1, 2009) requires that the benefit of a below-market-rate government loan be measured as the difference between the carrying amount of the loan upon initial recognition in accordance with IAS 39, "Financial Instruments: Recognition and Measurement," and the proceeds received with the benefit accounted for in accordance with IAS 20.

The standards and amendments to existing standards set forth below have been published and are mandatory for accounting periods beginning on or after January 1, 2010 or later periods, and may be adopted early. We have not elected to adopt the standards and amendments to existing standards early.

IFRS 3 (revised), "Business combinations" (effective July 1, 2009) is a revised standard that continues to apply the acquisition method to business combinations, with some significant changes. For example, all payments to purchase a business are to be recorded at fair value at the acquisition date, with contingent payments classified as debt subsequently remeasured through the income statement. There is a choice on an acquisition-by-acquisition basis to measure the non-controlling interest in the acquiree at fair value or at the non-controlling interest's proportionate share of the acquiree's net assets. All acquisition-related costs are to be expensed. We intend to apply IFRS 3 (revised) prospectively to all business combinations commencing on January 1, 2010, and we are currently assessing the possible effects of applying the revised standard on our financial statements in future periods.

IAS 27 (revised), "Consolidated and separate financial statements" (effective July 1, 2009) is a revised standard that requires the effects of all transactions with non-controlling interests to be recorded in equity if there is no change in control and these transactions will no longer result in goodwill or gains and losses. The standard also specifies the accounting treatment when control is lost. Any remaining interest in the entity is remeasured to fair value, and a gain or loss is recognized in profit or loss. We intend to apply IAS 27 (revised) prospectively to transactions with non-controlling interests commencing on January 1, 2010.

IAS 32 (amendment), "Classification of rights issues" (effective October 2009) modifies the accounting treatment of rights issues. The current practice with respect to rights issues offered for a fixed amount of foreign currency requires that the issues be accounted for as derivative liabilities. IAS 32 (amendment) provides that if such rights are issued pro rata to all existing shareholders of an entity in the same class for a fixed amount of currency, they should be classified as equity regardless of the currency in which the exercise price is denominated. The amendment is effective for annual periods beginning on or after February 1, 2010, with early application permissible. We intend to apply this amendment in our financial statements commencing on January 1, 2011.

International Financial Reporting Interpretations Committee interpretation (IFRIC) 17 (amendment), "Distribution of non-cash assets to owners," effective July 1, 2009 provides guidance on accounting for arrangements in which an entity distributes non-cash assets to its shareholders either as a distribution of reserves or as dividends. IFRS 5 has also been amended to require that assets are classified as held for distribution only when they are available for distribution in their present condition and the distribution is highly probable. We intend to apply IFRIC 17 commencing on January 1, 2010.

IFRS 5 (amendment), "Disclosures required in respect of non-current assets (or disposal groups) classified as held for sale or discontinued operations" (effective January 1, 2010) clarifies that IFRS 5 specifies the disclosures required in respect of noncurrent assets (or disposal groups) classified as held for sale or discontinued operations. It also clarifies that the general requirements of IAS 1 still apply, particularly paragraph 15 (to achieve a fair presentation) and paragraph 125 (sources of estimation uncertainty). We intend to apply IFRS 5 (amendment) commencing on January 1, 2010.

## **Results of Operations**

#### Revenues

In accordance with the out-licensing arrangement we entered into with Ikaria in July 2009, we were entitled to an upfront payment of NIS 26.1 million (\$7.0 million based on the exchange rate reported by the Bank of Israel for the date of payment), which we received in October 2009. In addition, upon notification in February 2010 of the successful completion of our phase 1/2 clinical trial (which was substantially complete as of July 2009), we were entitled to a milestone payment of NIS 37.8 million (\$10.0 million). This payment was received in April 2010. See "Business — Out-Licensing Agreement with Ikaria Holdings." These payments were recognized as revenue for the year ended December 31, 2009. We did not record any revenue during the year ended December 31, 2008.

In August 2010, we received a payment of \$30.0 million in connection with our out-licensing arrangement with Cypress Bioscience. See "Business — Out-Licensing Agreement with Cypress Bioscience."

#### Cost of revenues

Cost of revenues for the year ended December 31, 2009 consists primarily of royalty payments due to the licensor under the inlicensing agreement related to BL-1040 as well as NIS 4.4 million paid to the OCS, which represents a portion of the payments we made to the OCS in connection with the payments we received from Ikaria under our out-licensing agreement covering BL-1040. We did not record any cost of revenues during the year ended December 31, 2008.

## **Research and development expenses**

At December 31, 2009, our drug development pipeline consisted of 12 therapeutic candidates. We discontinued the development of three compounds during the year ended December 31, 2009. Subsequently, we discontinued the development of one compound during the quarter ended March 31, 2010 and one compound in April 2010. We did not add any new compounds to our pipeline during such periods and our pipeline now consists of 10 therapeutic compounds. Our research and development expenses for the year ended December 31, 2009 were NIS 90.3 million, a decrease of NIS 15.9 million, or 15.0%, compared to NIS 106.2 million for the year ended December 31, 2008. Research and development expenses for the year ended December 31, 2008. Research and development expenses for the year ended December 31, 2009, which had been previously reflected in prior periods as a reduction in research and development expenses.

## Comparison of the Six Months Ended June 30, 2010 to the Six Months Ended June 30, 2009

#### Sales and marketing expenses

Sales and marketing expenses for the six months ended June 30, 2010 were NIS 2.2 million, an increase of NIS 0.7 million, or 47%, compared to NIS 1.5 million for the six months ended June 30, 2009. The increase resulted primarily from the strategic partnering efforts in connection with BL-1020 that commenced during the fourth quarter of 2009.

#### **Research and development expenses**

Research and development expenses for the six months ended June 30, 2010 were NIS 37.0 million, a decrease of NIS 12.9 million, or 26%, compared to NIS 49.9 million for the six months ended June 30, 2009. The decrease resulted primarily from significantly decreased costs relating to the BL-1020 and BL-1040 clinical trials, reduced spending on other projects and the cessation of new project introductions during 2009. The decrease was partly offset by our accrual of a liability to the OCS of NIS 17.0 million during the second quarter of 2010 in connection with our out-licensing of BL-1020.

## General and administrative expenses

General and administrative expenses were NIS 6.2 million for the six months ended June 30, 2010, an increase of NIS 1.9 million, or 44%, compared to NIS 4.3 million for the six months ended June 30, 2009. The increase in general and administrative expenses resulted primarily from options granted at the end of the first quarter of 2010 and from certain legal and other professional fees.

#### Financial income, net

We recognized net financial income of NIS 1.8 million for the six months ended June 30, 2010, a decrease of NIS 0.3 million, or 14%, compared to net financial income of NIS 2.1 million for the six months ended June 30, 2009. The decrease in net financial income resulted primarily from the decrease in the average exchange rate of foreign currencies in relation to the NIS during 2010, which had a negative effect on our net assets denominated in such foreign currencies during the six months ended June 30, 2010.

## Comparison of the Year Ended December 31, 2009 to the Year Ended December 31, 2008

## **Research and development expenses**

Research and development expenses for the year ended December 31, 2009 were NIS 90.3 million, a decrease of NIS 15.9 million, or 15.0%, compared to NIS 106.2 million for the year ended December 31, 2008. The decrease resulted primarily from decreased costs relating to the BL-1020 and BL-1040 clinical trials, reduced spending on other projects and the cessation of new project introductions during 2009 in connection with the spending reduction plan we instituted at the beginning of 2009 to conserve our cash resources and focus on the completion of our BL-1020 and BL-1040 clinical trials. In addition, our research and development costs were reduced in connection with the reduction of research and personnel from 45 employees as of December 31, 2008. to 33 employees as of December 31, 2009.

## General and administrative expenses

General and administrative expenses were NIS 11.2 million for the year ended December 31, 2009, a decrease of NIS 1.9 million, or 14.5%, compared to NIS 13.1 million for the year ended December 31, 2008. The decrease in general and administrative expenses resulted primarily from cost reductions instituted at the beginning of 2009, as well as a decrease in share-based compensation expense compared with the year ended December 31, 2008.

## Gain on adjusting warrants to fair value

In accordance with IFRS, we recognized a gain of NIS 3.7 million for the year ended December 31, 2008 on the fair value adjustment of outstanding warrants which were reflected as a liability on our balance sheet from the date of their issuance in February 2007 through June 2008. The remaining liability in connection with the warrants was reclassified to shareholders' equity effective July 1, 2008, and the warrants expired in February 2009. Accordingly, the warrants had no effect on our results of operations for the year ended December 31, 2009.



#### Financial income, net

We recognized net financial income of NIS 1.8 million for the year ended December 31, 2009, an increase of NIS 1.1 million, or 157.0%, compared to net financial income of NIS 0.7 million for the year ended December 31, 2008. The increase in net financial income resulted primarily from the increase in the average exchange rate of foreign currencies in relation to the NIS during 2009, which had a positive effect on our net assets denominated in such foreign currencies during the year ended December 31, 2009.

## Comparison of the Year Ended December 31, 2008 to the Year Ended December 31, 2007

## **Research and development expenses**

Research and development expenses for the year ended December 31, 2008 were NIS 106.2 million, an increase of NIS 30.3 million, or 39.9%, compared to NIS 75.9 million for the year ended December 31, 2007. The increase resulted primarily from the costs incurred in connection with the progress in our phase 2b clinical trial for BL-1020 and increased spending on certain of our other projects in the preclinical stage. In addition, our research and development costs increased in connection as the number of research and personnel increased to 45 employees as of December 31, 2008, from 32 employees as of December 31, 2007. During the year ended December 31, 2008, we added three compounds to our pipeline, discontinued the development of five compounds and suspended the development of one compound.

#### General and administrative expenses

General and administrative expenses were NIS 13.1 million for the year ended December 31, 2008, a decrease of NIS 500,000, or 3.7%, compared to NIS 13.6 million for the year ended December 31, 2007. The decrease resulted primarily from a decrease in share-based compensation expense, as well as a reduction in professional fees, compared to the same expenses for the year ended December 31, 2007. The decreases were partially offset by an increase in general and administrative employees and related payroll costs for the year ended December 31, 2008.

#### Gain on adjusting warrants to fair value

In accordance with IFRS, we recognized a gain of NIS 3.7 million on the fair value adjustment of outstanding stock warrants reflected as a liability on our balance sheet from the date of their issuance in February 2007 through June 2008. We recognized a gain of NIS 27.6 million on the fair value adjustment of outstanding stock warrants reflected as a liability on our balance sheet for the year ended December 31, 2007.

#### Financial income, net

We recognized net financial income of NIS 732,000 for the year ended December 31, 2008, a decrease of NIS 1.8 million, or 71.0%, compared to net financial income of NIS 2.5 million for the year ended December 31, 2007. The decrease in net financial income resulted primarily from a decrease in cash balances and in global interest rates during the year ended December 31, 2008. The decrease was partially offset by expenses related to the issuance of warrants in 2007. Exchange rate changes on our net assets denominated in foreign currencies were not materially different between 2008 and 2007.

### **Quarterly Results of Operations**

The following tables show our unaudited quarterly statements of operations for the periods indicated. We have prepared this quarterly information on a basis consistent with our audited consolidated financial statements and we believe it includes all adjustments, consisting of normal recurring adjustments necessary for a fair presentation of the information shown. Operating results for any quarter are not necessarily indicative of results for a full fiscal year.

# Three Months

Ended										
	March 31	June 30	Sept. 30	Dec. 31	March 31	June 30	Sept. 30	Dec. 31	March 31	June 30
		20	08			20	09		20	10
(in thousands NIS) Consolidated										
statements of										
Operations										
Revenues							26,138	37,771		
Cost of revenues							(7,340)	(15,282)		
Sales and					(423)	(1,054)	(329)	(3,085)	(959)	(1,225)
marketing										
expenses										
Research and	(28,271)	(18,910)	(28,359)	(30,616)	(26,486)	(23,364)	(32,636)	(7,816)	(10,736)	(26,296)
development										
expenses, net										
General and	(3,705)	(3,333)	(2,840)	(3,205)	(2,545)	(1,762)	(2,932)	(2,137)	(2,935)	(3,289)
administrative										
expenses										
Gain on adjusting	3,242	416						_	_	_
options to fair										
value										
Operating profit	(28,734)	(21,827)	(31,199)	(33,821)	(29,454)	(26,180)	(17,099)	9,451	(14,630)	(30,810)
(loss)										
Financial income,	1,602	2,456	1,707	7,236	3,790	9	63	66	193	2,685
net				·						,
Financial	(4,094)	(6,942)	(54)	(1,179)	(29)	(1,710)	(181)	(244)	(1,038)	(24)
expenses, net							. ,			
Net profit (loss)	(31,226)	(26,313)	(29,546)	(27,764)	(25,693)	(27,881)	(17,217)	9,273	(15,475)	(28,149)
(1000)	(==,==0)	(==;,010)	(==;,0.10)	(=:,, 01)	(=2,000)	()	(=:,=17)		(==;, ;; ;; ;)	(==;,= !;;)

Our quarterly revenues and operating results of operations have varied in the past and can be expected to vary in the future due to numerous factors. We believe that period-to-period comparisons of our operating results are not necessarily meaningful and should not be relied upon as indications of future performance.

#### Liquidity and Capital Resources

Since inception, we have funded our operations primarily through public (in Israel) and private offerings of our equity securities, grants and loans from the OCS, and payments received under our strategic licensing arrangements. Since inception, we have raised approximately NIS 381.7 million in net proceeds from sales of our equity securities, including NIS 198.0 million from our initial public offering of ordinary shares and warrants on the TASE in February 2007, after deduction of offering expenses, NIS 51.8 million, after deduction of offering expenses, from our rights offering of ordinary shares completed in July 2009 and NIS 45.7 million, after deduction of offering expenses, from our follow-on offering in December 2009. At June 30, 2010, we held approximately NIS 88.5 million in cash and cash equivalents, and at December 31, 2009, we held approximately NIS 105.9 million in cash and cash equivalents, and at December 31, 2009, we held approximately NIS 105.9 million in cash and cash equivalents, and at December 31, 2009, we held approximately NIS 105.9 million in cash and cash equivalents, and the uncertain of \$7.0 million in connection with our licensing arrangement with Ikaria. In April 2010, we received a milestone payment of \$10.0 million from Ikaria which was subject to U.S. withholding tax of approximately \$1.5 million. In August 2010, we received a payment of \$30.0 million from Cypress Bioscience and, subsequently, we paid the OCS \$3.0 million, and paid Bar Ilan Research and Development and Ramot, the institutions from which we in-licensed the rights to BL-1020, \$6.75 million, in the aggregate. We may be able to use U.S. taxes withheld as credits against Israeli corporate income tax when we have income, if at all, but there can be no



assurance that we will be able to realize the credits. In addition, we believe that we may be able to get a refund of such withholding tax from the U.S. government but there can be no assurance that we will be able to get such a refund.

Net cash used in operating activities was NIS 18.7 million and NIS 67.2 million for the six months ended June 30, 2010 and 2009, respectively, and NIS 84.5 million, NIS 93.8 million and NIS 58.3 million for the years ended December 31, 2009, 2008 and 2007, respectively. The NIS 48.5 million decrease in net cash used in operating activities during the six months ended June 30, 2010, compared to the same period in 2009, was primarily the result of a decrease in the loss for the period and a decrease in trade accounts receivable and other receivables. The NIS 9.3 million decrease in net cash used in operating activities during 2009, compared to 2008, was primarily the result of reduced spending on other projects and the cessation of new project introductions during 2009 in connection with the spending reduction plan we instituted at the beginning of 2009 to conserve our cash resources. The NIS 35.5 million increase in net cash used in operating activities during the result of clinical trial expenses.

Net cash flows related to investing activities was minimal for the six months ended June 30, 2010. Net cash provided from investing activities for the six months ended June 30, 2009 was NIS 31.1 million, relating primarily to proceeds from the sale of financial assets at fair value through profit or loss.

Net cash provided by investing activities for the year ended December 31, 2009 was NIS 30.8 million and net cash used in investing activities was NIS 33.3 million and NIS 0.4 million for the years ended December 31, 2008 and 2007, respectively. The cash provided by investing activities during the year December 31, 2009 primarily resulted from the maturity of all our short-term investments during the year and their reinvestment into cash and cash equivalents.

Net cash flows related to financing activities was minimal for the six months ended June 30, 2010. Net cash provided from financing activities for the six months ended June 30, 2009 was NIS 15.8 million relating primarily to our public offering in Israel in June 2009.

Net cash provided by financing activities amounted to NIS 97.7 million for the year ended December 31, 2009, primarily relating to our two public offerings in Israel completed in July and December 2009. Net cash provided by financing activities for the year ended December 31, 2007 was NIS 246.2. The cash provided in 2007 relates primarily to our initial public offering of ordinary shares and warrants in February 2007.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Although we believe our existing cash resources will be sufficient to fund our projected cash requirements through the fourth quarter of 2012, we will require significant additional financing in the future to fund our operations. Additional financing may not be available on acceptable terms, if at all. Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues we receive under our collaboration or licensing arrangements;
- the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval of our therapeutic candidates;
- the ability of our collaborators to achieve development milestones, marketing approval and other events or developments under our collaboration agreements;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;

- the costs of establishing sales and marketing capabilities or contracting with third parties to provide these capabilities for us;
- the costs of acquiring or undertaking development and commercialization efforts for any future product candidates;
- the magnitude of our general and administrative expenses;
- any cost that we may incur under current and future licensing arrangements relating to our therapeutic candidates; and
- payments to the OCS.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through payments received under our collaborations, debt or equity financings, or by out-licensing other product candidates. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts.

## **Contractual Obligations**

The following table summarizes our significant contractual obligations at June 30, 2010:

	Total	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
			(in NIS)		
Car leasing obligations	1,569,804	998,631	376,048	195,125	—
Premises leasing obligations	2,153,719	846,464	873,120	434,135	
Purchase commitments	6,147,000	6,147,000		-	_
Total	9,870,523	7,992,095	1,249,168	629,260	<u> </u>

The foregoing table does not include our in-licensing agreements. Under our in-licensing agreements, we are obligated to make certain payments to our licensors upon the achievement of agreed upon milestones. We are unable at this time to estimate the actual amount or timing of the costs we will incur in the future under these agreements; however, we do not expect any of the milestones to be achieved within the next 12 months. If all of the milestones are achieved over the life of each in-licensing agreement, we will be required to pay approximately \$16.3 million, in the aggregate, to the applicable licensors. Some of the in-licensing agreements are accompanied by consulting, support and cooperation agreements, pursuant to which we are required to pay the licensors a fixed monthly amount, over a period stipulated in the applicable agreement, for their assistance in the continued research and development under the applicable license. All of our in-licensing agreements are terminable at-will by us upon prior written notice of 30 to 60 days. We are unable at this time to estimate the actual amount or timing of the costs we will incur in the future under these agreements. See "— In-Licensing Agreements."

#### Quantitative and Qualitative Disclosure About Market Risk

Market risk is the risk of loss related to changes in market prices, including interest rates and foreign exchange rates, of financial instruments that may adversely impact our consolidated financial position, results of operations or cash flows.

## Risk of Interest Rate Fluctuation

Following this offering, we do not anticipate undertaking any significant long-term borrowings. At present, our investments consist primarily of cash and cash equivalents. Following this offering, we may also invest in investment-grade marketable securities with maturities of up to three years, including commercial paper, money market funds, and government/non-government debt securities. The primary objective of our investment activities is to preserve principal while maximizing the income that we receive from our investments without significantly increasing risk and loss. Our investments are exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments. We manage this exposure by performing ongoing evaluations of our investments. Due to the short-term

maturities of our investments to date, their carrying value has always approximated their fair value. It will be our policy to hold investments to maturity in order to limit our exposure to interest rate fluctuations.

## Foreign Currency Exchange Risk

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the NIS, our functional and reporting currency, mainly against the dollar and the euro. Although the NIS is our functional currency, a significant portion of our expenses are denominated in both dollars and euros and currently all of our revenues are denominated in dollars. Our dollar and euro expenses consist principally of payments made to sub-contractors and consultants for preclinical studies, clinical trials and other research and development activities. We anticipate that a sizable portion of our expenses will continue to be denominated in currencies other than the NIS. If the NIS fluctuates significantly against either the dollar or the euro, it may have a negative impact on our results of operations. To date, fluctuations in the exchange rates have not materially affected our results of operations or financial condition for the periods under review.

To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

## **Off-Balance Sheet Arrangements**

Since inception, except for standard operating leases, we have not engaged in any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K, such as the use of unconsolidated subsidiaries, structured finance, special purpose entities or variable interest entities.

## BUSINESS

## Overview

We are a clinical stage biopharmaceutical development company dedicated to identifying, in-licensing and developing therapeutic candidates that have advantages over currently available therapies or that address unmet medical needs. Our current development pipeline consists of three clinical stage therapeutic candidates: BL-1020, a new chemical entity, or NCE, that we believe may be the first antipsychotic therapeutic to improve cognitive function in schizophrenia patients; BL-1040, a novel polymer solution for use in the prevention of cardiac remodeling following an acute myocardial infarction, or AMI, and BL-5010, a novel formulation for the non-surgical removal of skin lesions. In addition, we have seven therapeutic candidates in the preclinical stages of development. We generate our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. None of our therapeutic candidates have been approved for marketing and, to date, there have been no commercial sales of any of our therapeutic candidates. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case by case basis, the commercialization of our therapeutic candidates independently.

Our most advanced therapeutic candidate, BL-1020, is in development for schizophrenia, a chronic, severe and disabling brain disorder that affects approximately 1.0% of the U.S. adult population as reported by the National Institute of Mental Health. Schizophrenia patients are typically treated with one of several commercially available antipsychotics, all of which are associated with side effects that reduce patient compliance and do not address the deterioration of cognitive function that affects the daily lives of schizophrenia patients. Despite these drawbacks, the three most commonly used antipsychotics, Risperdal, Zyprexa and Seroquel, reached aggregate sales of approximately \$7.1 billion in the United States in 2009, based on the annual reports filed with the SEC by each of Johnson & Johnson, Eli Lilly and Company and AstraZeneca Pharmaceuticals LP, the companies that market those drugs.

BL-1020 is a new chemical entity that effectively reduces psychotic symptoms which we believe may also improve cognition. BL-1020 targets the imbalance of two key neurotransmitters implicated in schizophrenia, dopamine and gamma aminobutyric acid, or GABA. We believe that the reduction in psychotic symptoms is attributed to BL-1020's dopamine antagonism and that BL-1020 may also improve cognition.

In our recently completed, 363-patient phase 2b EAGLE (Effective Anti-psychosis via GABA Level Enhancement) study, BL-1020 matched the antipsychotic efficacy of Risperdal, one of the leading approved antipsychotics, without evidence of the metabolic side effects associated with the use of atypical antipsychotics. Most significantly, BL-1020 demonstrated a clinically relevant and statistically significant improvement in cognition. Currently, there is no commercially available antipsychotic that improves cognitive function and this remains an important unmet medical need in the treatment of schizophrenia and other psychiatric and neurological diseases.

In June 2010, we entered into an exclusive, royalty-bearing out-licensing arrangement with Cypress Bioscience with regard to BL-1020, covering the United States, Canada and Mexico. The license became effective in August 2010, following receipt of consent by the OCS. Under the arrangement, Cypress Bioscience is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize, BL-1020 for the prevention, diagnosis and treatment of all human diseases in the United States, Canada and Mexico. We have retained the rights to BL-1020 for the rest of the world. In addition, under the agreement, Cypress Bioscience licensed to us the right to use any and all regulatory data generated by Cypress Bioscience in connection with its pursuit of regulatory approval for BL-1020 in Cypress Bioscience's territory for use by us outside of Cypress Bioscience in generating such data. We received an upfront fee of \$30.0 million from Cypress Bioscience upon the consent of the OCS to the agreement in August 2010, and we are entitled to receive up to an additional \$250.0 million in connection with the achievement of certain performance-based milestones and up to an additional \$85.0 million upon the achievement of certain sales-based milestones. We are also entitled to royalties, ranging from 12% to 18%, on annual net sales of BL-1020 in Cypress Bioscience's territory under the agreement for the applicable royalty

term. We are obligated to pay to Bar Ilan Research and Development and Ramot, collectively, a royalty payment equal to 22.5% of the net consideration we receive from Cypress Bioscience in connection with our in-licensing of BL-1020. We paid Bar Ilan Research and Development and Ramot \$6.75 million, in the aggregate, from the \$30.0 million upfront fee. We also paid the OCS \$3.0 million as partial repayment of grants previously received for the BL-1020 development program. See "— In-Licensing Agreements — BL-1020."

Our second lead therapeutic candidate, BL-1040, is a novel resorbable polymer solution for use in the prevention of cardiac remodeling in patients who suffered an AMI. Preventing cardiac remodeling following an AMI may prevent transition to congestive heart failure and/or improve patient survival over the long term. Following an AMI, BL-1040 is administered via intracoronary injection during standard vessel reopening procedures, such as balloon catheterization and stenting. Upon contact with damaged cardiac tissue, the liquid BL-1040 transitions into a gel within the infarcted cardiac tissue and forms a "scaffold" that supports, retains the shape of, and enhances the mechanical strength of the heart muscle during the recovery and repair phases following an AMI. The data from our preclinical trials indicate that, by supporting the damaged heart tissue, BL-1040 preserves the normal functioning of the heart and the data from our clinical trials indicate that BL-1040 should be safe. After consultation with the FDA and other comparable regulatory agencies, BL-1040 is being developed as a class III medical device under the FDA's premarketing approval, or PMA, regulatory pathway.

In July 2009, we entered into an out-licensing arrangement with Ikaria Holdings, Inc., or Ikaria, with regard to BL-1040. The July 2009 agreement was amended and restated in August 2009, and, under the arrangement, Ikaria is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or a product related thereto. To date, we have received \$17.0 million from Ikaria, which was subject to U.S. withholding tax of approximately \$1.5 million, and we are entitled to receive up to an additional \$265.5 million from Ikaria royalties from net sales of any product development, regulatory, and commercial milestones. In addition, we are entitled to receive from Ikaria royalties from net sales of any product developed under the arrangement. We are obligated to pay 28% of all net consideration received under this arrangement to B.G. Negev Technologies, the party from which we in-licensed BL-1020 in 2004. See "— In-Licensing Agreements — BL-1040." We have agreed to pay Ramot a portion of the payments we make to B.G. Negev Technologies in connection with the in-license arrangement to satisfy contractual obligations between B.G. Negev Technologies and Ramot with respect to certain intellectual property rights to the licensed technology. We have also agreed to indemnify Ramot and certain of its related parties in connection with our use of the technology we in-licensed from B.G. Negev Technologies.

Our third lead therapeutic candidate, BL 5010, is a novel formulation composed of two acids being developed for the removal of skin lesions in a nonsurgical manner. These two acids have already been approved for use in cosmetics. If approved, BL-5010 would be a convenient alternative to invasive, painful and expensive removal treatments for skin lesions and may allow for histological examination. Because treatment with BL-5010 is non-invasive, we believe BL-5010 poses minimal infection risk, and requires no anesthesia or bandaging. In June 2009, we announced the initiation of a phase 1/2 clinical trial in 60 patients with seborrheic keratosis in Germany and the Netherlands to assess the safety and efficacy of BL-5010. In addition, the study is designed to assess the feasibility of preserving the cellular structure of skin lesions for subsequent histological exams. Interim results from this trial, which were announced in January 2010, indicate that all treated skin lesions were completely removed within 30 days of treatment following a single application. The results also indicate that BL-5010 is safe and is not associated with any adverse events, including irritation and inflammation. In addition, preliminary histological examination of treated lesions indicate BL-5010's efficacy in preserving the cellular structure of treated lesions.

As part of our business strategy, we continue to actively source, rigorously evaluate and in-license selected therapeutic candidates. We establish and maintain close relationships with research institutes, academic institutions and biotechnology companies in Israel and, more recently, in other countries to identify and in-license therapeutic candidates. Before in-licensing, each therapeutic candidate must pass through our thorough screening process that includes our proprietary MedMatrx scoring tool. Our Scientific Advisory Board and disease-specific third-party advisors are active in evaluating each therapeutic candidate. Our approach is consistent with our objective of proceeding only with therapeutic candidates that we believe

exhibit a relatively high probability of therapeutic and commercial success. To date, we have screened over 1,000 compounds, presented more than 60 candidates to our Scientific Advisory Board for consideration, initiated development of 30 therapeutic candidates and terminated 20 feasibility programs.

BioLineRx was founded in 2003 by leading institutions in the Israeli life sciences industry, including Teva. We completed our initial public offering in Israel in February 2007 and our ordinary shares are traded on the TASE under the symbol "BLRX."

## **Our Strategy**

Our objective is to be a leader in developing innovative pharmaceutical and biopharmaceutical products. We continuously identify and in-license therapeutic candidates in order to maximize our potential for commercial success. We repeatedly assess compounds by evaluating their efficacy, safety, technological novelty, patent status, market potential, and development and regulatory pathways. Our approach to evaluating, in-licensing and developing therapeutic candidates allows us to:

- continually build our pipeline of therapeutic candidates;
- advance those therapeutic candidates with the greatest potential;
- quickly identify, and terminate the development of, unattractive therapeutic candidates; and
- avoid dependency on a small number of therapeutic candidates.

Using this approach, we have successfully advanced three therapeutic candidates, BL-1020, BL-1040 and BL-5010, into clinical development. Specific elements of our current strategy include the following:

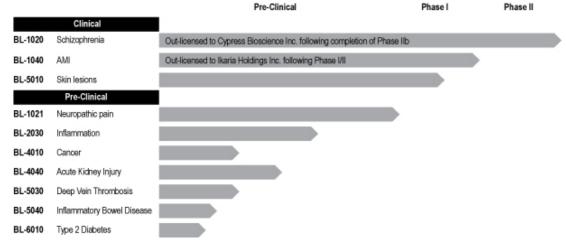
- Facilitate the successful development and commercialization of BL-1040 by Ikaria. We intend to assist our licensee, Ikaria, to develop and commercialize BL-1040. We are currently meeting with Ikaria on a quarterly basis to facilitate the transition of our BL-1040 assets to its organization and intend to lend our assistance and provide our expertise in their development and commercialization efforts as necessary.
- Assess the timing and conditions for the development and commercialization of BL-1020 outside of the United States, Canada and Mexico. We have retained the rights to commercialize BL-1020 worldwide, except for the United States, Canada and Mexico. We intend to monitor Cypress Bioscience's clinical and regulatory development of BL-1020 and to pursue development and commercialization activities outside the United States, Canada and Mexico when and if we find the timing and conditions to be optimal.
- **Facilitate the successful development and commercialization of BL-1020 by Cypress Bioscience.** We intend to assist our licensee, Cypress Bioscience, to develop and commercialize BL-1020. We plan to meet with Cypress Bioscience regularly to consider how our experience and expertise may be a resource for Cypress Bioscience's efforts under the outlicensing arrangement.
- Commercialize additional therapeutic candidates through out-licensing arrangements or, where appropriate, by ourselves. We intend to commercialize many of our products through out-licensing arrangements with third parties who may perform any or all of the following tasks: completing development, securing regulatory approvals, manufacturing and/or marketing. If appropriate, we may commercialize certain therapeutic candidates ourselves.
- **Design development programs that reach critical decisions quickly.** At each step of our screening process for therapeutic candidates, a candidate is subjected to rigorous feasibility testing and potential advancement or termination. We believe our feasibility approach reduces costs and increases the probability of commercial success by eliminate less promising candidates quickly before advancing them into more costly preclinical and clinical programs.
- Use our expertise and proprietary screening methodology to evaluate in-licensing opportunities. In order to review and select among various candidates efficiently and effectively, we employ a proprietary screening system we developed that includes our proprietary MedMatrx

scoring tool. Our Scientific Advisory Board and disease-specific third-party advisors evaluate each candidate. We intend to in-license a sufficient number of therapeutic candidates to allow us to move a new therapeutic candidate into clinical development every 12 to 18 months.

• Leverage and expand our relationships with research institutes, academic institutions and biotechnology companies, including the specific strategic relationships that we have developed with Israeli research and academic institutions, to identify and in-license promising therapeutic candidates. To date, we have successfully in-licensed compounds from many major Israeli universities, as well as from many Israeli hospitals, technology transfer offices, research and development authorities, university faculty, and many biotechnology companies to actively seek out early stage compounds. In addition, we actively source and evaluate non-Israeli compounds although we currently do not have any compound in our pipeline that was sourced outside of Israel.

## **Our Product Pipeline**

The table below summarizes our current pipeline of therapeutic candidates, as well as the target indication and status of each candidate.



## Lead Therapeutic Candidates

#### BL-1020

BL-1020 is an orally administered antipsychotic for the treatment of schizophrenia. We believe that BL-1020 will deliver antipsychotic effectiveness equal to, or exceeding, currently available treatments. Furthermore, we believe BL-1020 may be the first antipsychotic drug that improves cognitive function in schizophrenia patients. Based on our preclinical and clinical trials, we believe that BL-1020 works by blocking the dopamine receptors in the brain and activating the gamma aminobutyric acid, or GABA receptors. We believe that the dopamine antagonism in BL-1020 is responsible for reducing psychotic symptoms. The activation of GABA, or GABAergic activity, of the BL-1020 molecule may also be involved in improving patient cognition. In July 2009, we successfully completed our 363-patient phase 2b EAGLE (Effective Anti-psychosis via GABA Level Enhancement) study. We in-licensed the worldwide, exclusive rights to research, develop and commercialize BL-1020 from Bar Ilan Research and Development and Ramot.

*Schizophrenia*. Schizophrenia is a chronic, severe, and disabling brain disorder that affects approximately 1% of the U.S. adult population as reported by the National Institute of Mental Health. IMS Health, a leading provider of market intelligence, reports that the market for antipsychotic drugs was less than \$500 million in 1991 and increased to \$5.0 billion in 2000. According to Datamonitor, a provider of business information to the pharmaceutical and other industries, the market for antipsychotic drugs in 2008 in the United States alone was \$13.6 billion, with an additional \$4.2 billion in aggregate sales in Japan, France, Germany, Italy, Spain and the United Kingdom. Sales in these seven countries are projected by Datamonitor to stay stable, when aggregated, through 2018.

Schizophrenia is characterized by impairments in the perception or expression of reality, most commonly manifesting as auditory hallucinations, paranoid or bizarre delusions or disorganized speech and thinking. Schizophrenia patients also suffer from significant cognitive dysfunction. This is reflected in difficulty of daily functioning, decreased ability to maintain normal social relationships and impaired job performance. Schizophrenia is a multi-factorial disease that involves an imbalance in two key chemicals that transmit signals between neurons and other cells, known as neurotransmitters: dopamine and GABA.

Currently available treatments for schizophrenia include two broad classes of antipsychotics: "typical" and "atypical." Both classes of medications are similarly effective at treating schizophrenia but have varying and severe side effects that limit patient compliance. Atypical antipsychotics are the current standard of care for schizophrenia patients. Typical antipsychotics generally cause debilitating movement disorders known as Extra-Pyramidal Side (EPS) effects. Atypical antipsychotics have fewer motor side effects but may cause increased risks of obesity, diabetes and high blood cholesterol. Both classes of antipsychotics do not adequately address cognitive function, and improvement in cognition represents an unmet medical need for patients of schizophrenia and other psychiatric and neurological diseases.

There are a number of different medications available to treat schizophrenia. The most commonly used atypical antipsychotics available on the market are Risperdal, Zyprexa and Seroquel. Risperdal is marketed by Janssen, a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., a Johnson & Johnson company. Johnson & Johnson reported annuals sales of Risperdal of \$1.4 billion for 2009 in its annual report for the year ended December 31, 2009. Zyprexa is marketed by Lilly USA, LLC, a company of Eli Lilly and Company. Eli Lilly reported annual sales of Zyprexa of \$2.3 billion for 2009 in its annual report for the year ended December 31, 2009. Approximately 10% to 30% of schizophrenia patients do not respond to, or do not tolerate, a particular medication and, accordingly, will often be rotated through a series of medications until medical practitioners identify the best treatment for them, as described in an article by Daniel E. Casey et. al. published in 2003 in the journal *Pharmacology*.

## Development and Commercialization Arrangement.

In June 2010, we entered into an exclusive, royalty-bearing out-licensing arrangement with Cypress Bioscience with regard to BL-1020, covering the United States, Canada and Mexico. Under the arrangement, Cypress Bioscience is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize, BL-1020 for the prevention, diagnosis and treatment of all human diseases in the United States, Canada and Mexico. We received an upfront fee of \$30.0 million from Cypress Bioscience upon the consent of the OCS to the agreement in August 2010, and we are entitled to receive up to an additional \$250.0 million in connection with the achievement of certain performance-based milestones and up to an additional \$85.0 million upon the achievement of certain sales-based milestones. We are also entitled to royalties, ranging from 12% to 18%, on annual net sales of BL-1020 under the agreement. See "— In-Licensing Agreements — BL-1020."

Under our agreement with Cypress Bioscience, we have retained the rights to develop and commercialize BL-1020 outside of the United States, Canada and Mexico. In addition, under the agreement, Cypress Bioscience has licensed to us the right to use any and all regulatory data generated by Cypress Bioscience in connection with its pursuit of regulatory approval for BL-1020 in Cypress Bioscience's territory for use by us outside of Cypress Bioscience's territory. We are required to reimburse Cypress Bioscience for certain pre-commercialization expenses incurred by Cypress Bioscience in connection with the generation of such data

when and if we elect to use the data. We intend to monitor Cypress Bioscience's progress in the development and commercialization of BL-1020 and, when we believe the timing and conditions are optimal, may pursue development and commercialization efforts relating to BL-1020 outside the United States, Canada and Mexico. Our obligation to reimburse Cypress Bioscience for the pre-commercialization expenses is based on certain conditions relating to our use of the information and we are allowed to sublicense the rights to the data. We do not have a present intention to out-license BL-1020 outside of the United States, Canada and Mexico, but we intend to continue to consider potential out-licensing opportunities, as well as the potential to develop and commercialize BL-1020 internally.

*Clinical and Preclinical Results.* We conducted a phase 2b clinical trial, which we refer to as the EAGLE trial, in order to assess the efficacy, safety and tolerability of BL-1020 compared to placebo. Risperdal, a commonly prescribed antipsychotic, was used in the trial, at a dose of 2 – 8 mg, as a positive control to validate the study's results. The EAGLE trial was conducted under an FDA Investigational New Drug (IND) application process at 40 sites in the United States, Europe and India and included patients suffering from acute exacerbation of schizophrenia. In this six-week study, 363 patients were randomized for treatment with a low (10 mg/day) or high (20 – 30mg/day) dose of BL-1020, Risperdal (2 – 8mg/day) or placebo. The study was designed to demonstrate statistically significant superiority of BL-1020 to placebo on the Positive and Negative Symptom Scale (PANSS), the primary efficacy measure. The key secondary efficacy measures included the Clinical Global Impression of Severity (CGI-S) and the Clinical Global Impression of Change (CGI-C), which are recognized measures of severity and improvement in schizophrenia. The secondary efficacy measures also included a Readiness to Discharge Questionnaire (RDQ) and a Strauss Carpenter Level of Functioning Scale. A pre-specified exploratory end point of the study was cognition as measured by the "Brief Assessment of Cognition in Schizophrenia" (BACS) test. The study was completed in July 2009 and we announced the results of the study in September 2009.

The results show that the BL-1020 high dose group (20 - 30 mg/day) experienced a significant improvement in primary and secondary efficacy measures. For the primary efficacy measure, the high dose group (20 - 30 mg/day) showed a reduction in PANSS versus placebo (LS mean -23.6 vs. -14.4; p=0.002). The superiority of BL-1020 (20 - 30 mg/day) over placebo was also supported by secondary efficacy measures including CGI-S and CGI-C. Furthermore, statistically significant increases in the number of patients rated as "responders" in the BL-1020 (20 - 30 mg/day) group compared to placebo on the PANSS, CGI-S, and CGI-C was in line with all other efficacy measures.

The following table presents a summary of the EAGLE trial results for efficacy:

Endpoint	Placebo	BL-1020 (20 – 30mg)	Risperdal
PANSS	-14.4	-23.6	-26.2
		P=0.002 (vs. placebo)	P<0.001 (vs. placebo)
		P=0.39 (vs. Risperdal)	
CGI-S	-0.68	-1.27	-1.35
		P<0.001 (vs. placebo)	P<0.001 (vs. placebo)
		P=0.607 (vs. Risperdal)	
Strauss Carpenter Level of	0.20	1.93	2.35
Functioning Scale		P=0.017 (vs. placebo)	P=0.003 (vs. placebo)
		P=0.563 vs. Risperdal	
Clinical Responders	47.3%	70.8%	72.5%
-		P=0.01 (vs. placebo)	P<0.001 (vs. placebo)
		P= 0.796 vs. Risperdal	

Cognitive function in the EAGLE trial was assessed by the BACS test. The BACS test comprises the following six components: verbal memory, digit sequencing, token motor task, verbal fluency, symbol coding and the "Tower of London" puzzle. The EAGLE trial results indicate that patients treated for six weeks with the 20 – 30mg dose of BL-1020 exhibited a clinically relevant and statistically significant improvement of 9.27 points in the BACS score as opposed to the placebo control group (6.01 points). In addition, the high

dose group of BL-1020 was superior to the Risperdal control group (with 6.2 points improvement). BL-1020 exhibited statistical significance to both the placebo and Risperdal control groups (p=0.027 for both).

The following table presents a summary of the EAGLE trial results for cognition:

Parameter	Placebo	BL-1020 (20 – 30mg)	Risperdal
BACS (LS mean, LOCF)	6.01	9.27	6.2
P value vs. placebo		P=0.027	P=0.893
P value vs. Risperdal		P=0.027	

Analysis of safety did not indicate any increased toxicity associated with BL-1020 treatment in comparison with the placebo. There was no incidence of SAEs (Severe Adverse Events) in the BL-1020 (20 – 30mg/day) group but the Risperdal and placebo groups experienced SAE rates of 3.3% and 6.5%, respectively. Discontinuations due to Adverse Events (AEs) were similar in the BL-1020 (20 – 30mg/day) group (4.5%) and in the placebo group (4.3%) but higher in the Risperdal group (8.8%). There were no statistically significant or clinically relevant AEs of body weight gain, glucose increases, and changes in lipids, all indicating that BL-1020 has no metabolic AE propensity. BL-1020 at its high dose level induced a slight increase in the Extra-Pyramidal Symptoms Rating Scale (ESRS) that did not differ significantly from Risperdal. The incidence of cardiovascular, sexual, psychiatric, autonomic and gastrointestinal AEs was low and was not increased compared to placebo. There were no statistically significant or clinically relevant changes in the measurements of the ECG, laboratory or vital signs.

The following table presents a summary of the EAGLE trial results for safety:

Parameter	Placebo	BL-1020 (20 – 30mg)	Risperdal
Severe Adverse Events (SAE, % patients)	6.5	0	3.3
Discontinuation due to Adverse Events (AE, %)	4.3	4.5	8.8
ESRS	1.6	10.8	10.8
Metabolic – weight gain (% notable gain)	3.6	4.9	7.3
Metabolic – cholesterol	No change	No change	No change

In January 2010, we announced the results of a six-week extension trial of BL-1020. In the extension trial, 75 patients that completed the phase 2b EAGLE clinical trial were randomized as follows: patients that were treated with either BL-1020 or Risperdal in the phase 2b EAGLE clinical trial continued their treatment and patients that were treated with placebo in the phase 2b EAGLE clinical trial were re-randomized to one of the BL-1020 groups. Patients in the extension trial maintained the levels of improvement in PANSS and CGI identified in the phase 2b EAGLE clinical trial. In addition, patients showed additional improvement in cognition with the extension trial and there were no clinically relevant changes in the measurements of ECG, laboratory or vital signs (BP, HR, Temp.).

In February 2009, we announced the results of our open label, six-week phase 2a trial of BL-1020 in Romania. The study was designed to determine the safety and maximum tolerated dose of BL-1020 in schizophrenia patients and was conducted on 36 chronically ill hospitalized patients. Only four patients dropped out of the trial, which we believe is a relatively low dropout rate. Patients were initially treated with 20mg of BL-1020 and received increasing dosages over the first seven days in order to meet the maximum dose of 40mg. Patients that were treated with BL-1020 experienced a statistically significant improvement from baseline in the PANSS and Clinical Global Impression of Severity and Improvement (CGI-S; CGI-I). This improvement was seen as early as seven days after the onset of treatment. There was a statistically significant (p<0.001) improvement on the PANSS total (baseline+84.9; day 42=63.8), and the positive (baseline+22.3; day 42=15.1), negative (baseline=20.9; day 42=16.6) and general psychopathology subscales (baseline=42.4; day 42=32.1). More than 80% of the patients showed a statistically significant improvement as reflected by the CGI-S and CGI-I. No severe or unexpected adverse effects occurred in the trial. There was no

significant increase in extra-pyramidal symptoms at the end of the trial, and no clinically relevant change in weight. There were no notable findings on ECG, laboratory values or vital signs. All adverse events were characterized as minimal and not treatment limiting.

In July 2007, we completed a phase 1b clinical trial which examined the ability of BL-1020 to bind dopamine receptors in the brain. The level of dopamine receptors binding in the brain is directly related to antipsychotic efficacy. This study was conducted pursuant to an FDA IND application process and an application to conduct clinical trials in Sweden that was submitted to the Swedish Ministry of Health. The study investigated the ability of BL-1020 to bind dopamine receptors in the human brain and provided additional safety and tolerability data. The study was a single-center, randomized, open label study performed on three dosage groups, each with four healthy volunteers who received a single dose of either 10mg, 15mg or 20mg of BL-1020. We assessed receptor occupancy using positron emission tomography, or a PET scan, that is able to register the activity of various parts of the brain following the administration of a labeled dopamine binder. The data derived from the study demonstrated a dose dependent increase in dopamine binding with computer modeling showing receptor occupancy of between 80% and 90% at the 20mg dose upon repeated administrations. The antipsychotic efficacy of dopamine blockers is presumed to occur at dopamine binding levels of 65% or more. BL-1020 did not produce any significant changes in the subjects' electrocardiogram test results, vital signs, clinical chemistry levels or hematology levels.

In October 2006, we completed a phase 1 clinical trial conducted under the supervision of the Israel Ministry of Health. The study was a single dose escalating, double blind, placebo controlled trial. Six dosage groups of BL-1020 were tested, 2.5mg, 5mg, 10mg, 15mg, 20mg and 25mg. Each group consisted of eight volunteers with two receiving a placebo and six receiving BL-1020. The study subjects exhibited no cardiac, neurological or psychological side effects. We believe that the findings are indicative of the safety and tolerability of BL-1020.

Extensive preclinical testing indicated that BL-1020 successfully demonstrated antipsychotic efficacy in animal models of schizophrenia and did not cause Extra-Pyramidal Side Effects at the therapeutic levels. Preclinical studies also demonstrated the potential for BL-1020 to improve cognition and provided support for our belief that the GABAergic effects of the compound resulted in cognitive improvement.

#### BL-1040

BL-1040 is a novel resorbable polymer solution being developed to prevent the cardiac remodeling that may occur in patients that suffered an AMI. AMIs result from an occlusion in the coronary artery and affects the left ventricle of the heart, or the LV. Patients with severe injury to the LV may be at risk for developing harmful changes in the size, shape and function of the LV, or cardiac remodeling, that may lead to congestive heart failure (CHF). In the clinical trial, BL-1040 is administered via the coronary artery and flows into the damaged heart muscle. The liquid BL-1040 transforms into a gel within the infarcted cardiac tissue and forms a "scaffold" that supports, retains the shape of, and enhances the mechanical strength of the heart muscle during recovery and repair, which we believe prevents the pathological enlargement of the ventricle following an AMI. By supporting the damaged heart tissue during the natural healing process, we expect that BL-1040 will prevent the progressive ventricle enlargement that often follows AMIs. After discussions with the FDA and European regulatory agencies, it has been determined that BL-1040 should be developed as a medical device, specifically under the PMA pathway in the United States. There can be no assurances, however, that the FDA or comparable foreign agencies will not determine that BL-1040 needs to be assessed as a drug instead of a medical device.

BL-1040 is being developed to treat patients that suffered an AMI and are at a high risk to develop significant cardiac remodeling. Based on our review of data regarding the incidence of myocardial infarctions in the United States, we believe that in 2009, approximately 400,000 people in the United States will have been at risk of significant cardiac remodeling after an AMI. Prevention of cardiac remodeling may prevent transition to congestive heart failure and/or improve patient survival over the long term.

We believe that BL-1040 is a novel, safe and non-surgical treatment for patients who suffered heart attacks and are at risk for cardiac remodeling and CHF. We believe that the transformation of BL-1040 into a gel is a result of the polymer chains' interaction with elevated levels of calcium ions present at the injury site. We believe that as the heart heals, there is a natural decrease in the calcium concentration causing the

BL-1040 to transform back to liquid form and then be excreted naturally from the body within six weeks of injection. The data from our preclinical trials indicate that treatment with BL-1040 preserves the normal functioning of the heart.

We obtained a worldwide, exclusive license for BL-1040 from B.G. Negev Technologies to research, develop, market and sell BL-1040 and are required to pay B.G. Negev Technologies 28% of the revenues we receive as consideration in connection with any sublicensing, co-marketing or co-promotion, or a permitted assignment, of BL-1040, which includes the revenues we have received, and expect to receive, under our out-licensing agreement with Ikaria. See "— In-Licensing Agreements — BL-1040." We have agreed to pay Ramot a portion of the payments we make to B.G. Negev Technologies in connection with the in-license arrangement to satisfy contractual obligations between B.G. Negev Technologies and Ramot with respect to certain intellectual property rights to the licensed technology. We have also agreed to indemnify Ramot and certain of its related parties in connection with our use of the technology we in-licensed from B.G. Negev Technologies.

Acute Myocardial Infarction. AMI is a leading cause of mortality and morbidity among both men and women. Statistical estimates from the American Heart Association indicate that approximately 1.0 million cases of nonfatal myocardial infarction are reported each year in the United States alone. AMI is caused by a severe narrowing of coronary arteries, known as atherosclerotic occlusion, often exacerbated by the formation of clots. The narrowing and/or blockage in the coronary artery disrupts the blood supply to cardiac tissue, resulting in extensive cell death that constitutes the AMI. As a result, the affected region of the heart muscle is generally replaced by scar tissue over a six-to eight-week period. The scarred region often dilates progressively in the days and months following an AMI, leading to abnormalities in heart chamber shape, size and functional capacity as described in an article by Paul W.M. Fedak published in 2005 in the journal *Cardiovascular Pathology*. Those surviving the acute phase of an AMI (i.e., the first 30 days) are at greater risk for sudden death due to arrhythmias and progressive congestive heart failure. There are a number of different approaches to prevent cardiac remodeling that have been, or currently are, the subject of preclinical and clinical trials. Certain medications, including ACE inhibitors and |gb-Blockers have been shown to reduce cardiac remodeling. Despite the wide use of these medications, based on our review of data regarding patients with large anterior infarcts, at least 20% of those patients may progress to heart failure due to cardiac remodeling and a subsequent reduction in ejection fraction, or the fraction of blood pumped out of a ventricle with each heart beat.

*Development and Commercialization Arrangement.* In July 2009, we entered into a licensing arrangement with Ikaria which was amended and restated in August 2009. Under the amended and restated license and commercialization agreement, we granted Ikaria an exclusive, worldwide license to develop, manufacture and commercialize BL-1040 for use in the prevention, mitigation and treatment of injury to the myocardial tissue of the heart. Ikaria is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or a product related thereto. We were responsible for the costs of the completed phase 1/2 trial. Ikaria is responsible for the costs associated with conducting all other development and regulatory activities of BL-1040, including those costs relating to the completion of its clinical development, the conduct and funding of its commercialization and the prosecution and maintenance of patents. We have received \$17.0 million from Ikaria, subject to U.S. withholding tax of approximately \$1.5 million, and we are entitled to receive up to an additional \$265.5 million from Ikaria upon achievement of certain development, regulatory, and commercial milestones. In addition, we are entitled to receive from Ikaria royalties from net sales of any product developed under the agreement ranging from 11% to 15%, depending on net sales levels achieved by Ikaria, and its affiliates and sublicensees. However, if Ikaria is required to obtain a license from a third party in order to exercise its rights under the agreement with Ikaria, the royalty we receive on net sales may be less than 11%.

*Clinical and Preclinical Results.* We commenced a pilot phase 1/2 multi-center open label study of BL-1040 in March 2009. The phase 1/2 study was designed to assess the safety and feasability of BL-1040 in up to 30 patients. The trial was conducted in nine sites in Germany and Belgium. The trial was completed in January 2010. In the trial, 27 patients were successfully treated with BL-1040 with no device-related clinically significant complications, arrhythmia, elevations in cardiac enzymes or occlusions. On February 24, 2010, we received the final assessment of the Independent Safety Monitoring Board, or ISMB. The ISMB's conclusions,

relating to the 27 patients who participated in the study and completed a six-month follow-up period, indicated that the treatment is safe and that it would be appropriate to continue clinical development of the device. The FDA must approve an investigational drug exemption (IDE) for BL-1040 before human clinical trials of BL-1040 can be conducted in the United States. Ikaria reports that it plans to conduct two overlapping clinical trials, which it expects to commence in 2011. The clinical trials are expected to include a 270-patient, phase 2 trial outside of the United States commencing in the first quarter of 2011, with primary assessments at six months and, subject to the approval by the FDA of an IDE and a statistical plan, a phase 3 trial commencing in the second half of 2011 with approximately 1,200 patients, largely in the United States, with primary assessments at 12 months.

Prior to initiating the phase 1/2 study, we evaluated BL-1040 in preclinical safety, biocompatibility, and efficacy studies conducted in accordance with FDA recommendations. The safety and biocompatibility studies demonstrated that the anticipated human dosages are not expected to produce significant local or systemic toxicity. Preclinical efficacy studies in rat, dog and pig models of AMI showed that BL-1040 administered immediately following an AMI and up to seven days after the AMI provides long-term protection to the heart tissue by preventing progressive LV dilation. Our preclinical dog studies have also indicated that BL-1040 may improve survival rates following a significant AMI.

## BL-5010

BL-5010 is a novel formulation composed of two organic acids being developed for the removal of skin lesions in a nonsurgical manner. Other formulations of the components of BL-5010 have already been approved for use in cosmetics. If approved, BL-5010 would be a convenient alternative to invasive, painful and expensive removal treatments for skin lesions and may allow for histological examination. Because treatment with BL-5010 is non-invasive, we believe BL-5010 poses minimal infection risk, and requires no anesthesia or bandaging. BL-5010 is applied topically on a skin lesion with a wood applicator for a few minutes and causes the lesion to dry out gradually and shed from the skin within a few weeks. We in-licensed the exclusive, worldwide rights to develop, market and sell BL-5010 from Innovative Pharmaceutical Concepts, Inc., or IPC, in November 2007. We intend to enter into an out-licensing arrangement with respect to the development, manufacture and commercialization of BL-5010.

*Skin Lesions*. Clinically diagnosed benign skin lesions, or a growth or patch of skin that does not resemble the area surrounding it, are very common and often constitute a cosmetic and functional annoyance. Moles and warts are examples of skin lesions. Currently, skin lesions are removed using either cryotherapy (liquid nitrogen), electro-coagulation (electrical burning), laser treatments or through surgery. Cryotherapy, electro-coagulation and laser treatments do not preserve the lesions' cellular structure and are used for removing benign superficial lesions. These methods are often associated with pain and inflammation that can last for several months. Surgery is used when histological examination of skin lesions is required. Surgery has to be conducted under sterile conditions and requires anesthesia. Furthermore, the cosmetic outcome of surgical removal is generally undesirable.

*Clinical Trial.* In June 2009, we announced the initiation of a phase 1/2 clinical trial aimed at assessing the safety and efficacy of BL-5010. The open-label, single arm trial is being conducted in 60 patients in Germany and the Netherlands with seborrheic keratosis, noncancerous (benign) skin growths that many people develop as they age. The objectives of the study are to determine the safety and tolerability of the BL-5010 formulation and to assess its efficacy in completely removing skin lesions. In addition, the study is designed to assess the feasibility of preserving the cellular structure of skin lesions for subsequent histological exams. Interim results from this trial, which were announced in January 2010, indicate that all treated skin lesions were completely removed within 30 days of treatment following a single application. The results also indicate that BL-5010 is safe and is not associated with any adverse events, including irritation and inflammation. In addition, preliminary histological examination of treated lesions indicate BL-5010's efficacy in preserving the cellular structure of treated lesions.

## Other Therapeutic Candidates in Development and Feasibility Testing

#### BL-1021

BL-1021 is a new chemical entity in development for the treatment of neuropathic pain, or pain that results from damage to nerve fibers. Multiple preclinical *in vitro* and *in vivo* animal studies have demonstrated

the safety and efficacy of BL-1021. We licensed exclusive, worldwide rights to research, develop and commercialize BL-1021 from Bar Ilan Research and Development and Ramot.

*Neuropathic Pain.* Neuropathic pain is a complex, chronic state of pain that results from dysfunctional or injured nerve fibers. Over time, the body establishes recurring "pain signaling cycles" that persist for a long time after the healing of the nerve injury that first caused the pain. Neuropathic pain is associated with various conditions, including shingles and diabetes, and, according to a 2008 DataMonitor report, neuropathic pain affects 1% to 3% of the population. Neuropathic pain may cause extreme discomfort for extended periods of time. Patients describe the symptoms as burning, stabbing, electric shock or itching sensations. Medical professionals treat neuropathic pain with a variety of medications, including the antidepressants amitriptyline and duloxetine and the anti-seizure medicine gabapentin. However, these medications have significant side effects and are not always effective.

*Preclinical Results*. The efficacy of BL-1021 has been demonstrated in preclinical studies. BL-1021 showed significant reduction in symptoms of neuropathic pain with reduced side effects in animal models. The BL-1021 molecule was administered orally in such animal studies and was found to be superior to available treatments in efficacy and/or side effect measures.

We have submitted BL-1021 to the institutional review board, or Helsinki Committee, of a medical institution in Israel, and made filings with the Israeli Ministry of Health, with respect to initiating clinical trials of BL-1021 in Israel. We anticipate initiating a phase 1 clinical trial of BL-1021 in Israel in the fourth quarter of 2010.

Therapeutic Candidates in Preclinical Development

The table below sets forth the development status of our preclinical stage therapeutic candidates and the indications for which they are being developed.

Therapeutic Candidate	Description	Indication	Status	In-Licensing Source
BL-1021	Small molecule	Neuropathic pain	Preclinical studies	Bar Ilan Research and Development
BL-2030	Protein	Inflammation	Preclinical studies	BioRap Technologies Ltd., the technology arm of the Rappaport Research Institute
BL-4010	Injectable polymer for the local & sustained release of chemotherapy	Glioblastoma	Preclinical studies	PolyGene Ltd.
BL-4040	Protein	Acute kidney injury	Preclinical studies	Gene Vector Technologies Ltd.
BL-5030	Peptide	Deep Vein Thrombosis	Preclinical studies	Matrix Pharma Inc.
BL-5040	Protein	Inflammatory diseases, like colitis and Chrohn's disease	Preclinical studies	Yissum Ltd.
BL-6010	Small molecule	Type 2 diabetes	Preclinical studies	Bar Ilan Research and Development

# **Product Development Approach**

We seek to develop a pipeline of promising therapeutic candidates that exhibit distinct advantages over currently available therapies or address unmet medical needs. Our resources are focused on advancing our therapeutic candidates through development and toward commercialization. Our current drug development pipeline consists of 10 therapeutic candidates with an additional nine therapeutic candidates in our EDP pipeline, a program primarily funded by one of our shareholders to support a portion of our early feasibility work on therapeutic candidates. See "— Early Development Program Agreement."

We have established relationships with various universities, academic and research institutions and biotechnology companies that permit us to identify and select compounds at a very early stage of development. Initially, we focused on Israeli institutions as the primary source of our therapeutic candidates. In Israel, we established close relationships with the Technion — the Israel Institute of Technology, Ben Gurion University of the Negev, Hebrew University of Jerusalem, Tel Aviv University, Bar Ilan University and the Weizmann Institute. More recently, we have begun to source therapeutic candidate opportunities worldwide.

Once we identify a candidate, it enters our evaluation system and undergoes our rigorous selection process. For this process, we developed and actively use our proprietary scorecard system, MedMatrx. MedMatrx consists of a set of questions and metrics that enable us to ensure that we conduct a thorough and consistent analysis of the scientific and commercial issues that we believe must be evaluated in order for a candidate to be considered for in-licensing. We evaluate each compound's potential for success by looking at the candidate's efficacy, safety, total estimated development costs, technological novelty, patent status, market need and approvability. Following evaluation and diligence, each therapeutic candidate is evaluated by our Scientific Advisory Board and by disease-specific advisors for external scientific review. Following a Scientific Advisory Board meeting, the compound is referred to either the EDP or more advanced feasibility testing. Candidates that have successfully progressed through our EDP will generally be subject to a shorter feasibility period once the compound is introduced to our pipeline as fewer studies will be required. At each step of the process, a therapeutic candidate is subjected to critical evaluation and potential termination. Our approach is consistent with our objective of proceeding only with therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. To date, we estimate we have screened over 1,000 compounds, and we have introduced more than 60 candidates to our Scientific Advisory Board for consideration, initiated development of 30 therapeutic candidates and terminated 20 feasibility programs.

Once we approve a compound, we in-license the candidate and any related technology and our drug development team and project managers identify, define and oversee the necessary steps to development and commercialization. The initial feasibility phase of development is critical to our approach. We design experiments that challenge the identified weaknesses of a compound, verify initial data by utilizing third-party contract research organizations and test the compound in models that more accurately mimic human disease.

Our development approach focuses on identifying and following what we believe will be successful pathways to commercialization. Our team has the expertise to move our candidates through all phases of preclinical and clinical development. Our staff includes professionals with extensive experience in drug development, chemistry, manufacturing and controls, or CMC, preclinical experimentation, clinical development, regulatory affairs and business development. We perform all of our development activities in our good laboratory practices, or GLP, grade chemistry laboratory or outsource these activities to contract research organizations, or CROs, that meet applicable regulatory standards. Following the generation of sufficient preclinical data, applications to regulatory authorities for the initiation of clinical trials are submitted. Phase 1 and 2 clinical trials are then conducted to demonstrate clinical proof of safety and efficacy. Following this stage of development we seek either to sub-license the therapeutic candidate to a pharmaceutical partner or, in certain circumstances, we may elect to complete development by ourselves.

# **Out-Licensing Agreement with Ikaria Holdings**

In July 2009, we entered into a licensing arrangement with Ikaria which was amended and restated in August 2009. Under the amended and restated license and commercialization agreement, we granted Ikaria an exclusive, worldwide license to develop, manufacture and commercialize BL-1040 for use in the prevention, mitigation and treatment of injury to the myocardial tissue of the heart. Ikaria is obligated to use

commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or a product related thereto. We were responsible for the costs of the completed phase 1/2 studies. Ikaria is responsible for the costs associated with conducting all other development and regulatory activities of BL-1040, including those costs relating to the completion of its clinical development, the conduct and funding of its commercialization and the prosecution and maintenance of patents.

Pursuant to the agreement, Ikaria paid us an initial up-front payment equal to \$7.0 million on the effective date of the agreement and in April 2010 paid us a milestone payment of \$10.0 million, subject to U.S. withholding tax of \$1.5 million. We are entitled to receive up to an additional \$265.5 million from Ikaria upon achievement of certain development, regulatory, and commercial milestones. In addition, we are entitled to receive from Ikaria royalties from net sales of any product developed under the agreement ranging from 11% to 15%, depending on net sales levels achieved by Ikaria or its sublicensees, as applicable. However, if Ikaria is required to obtain a license from a third party in order to exercise its rights under the agreement with Ikaria, the royalty we receive on net sales may be less than 11%. We must pay 28% of all net consideration we receive from Ikaria to B.G. Negev Technologies, the institution from whom we initially in-licensed the development rights to BL-1040. See "- In-Licensing Agreements — BL-1040." Certain payments we have received from Ikaria have been subject to a 15% withholding tax in the United States, and certain payments we may receive in the future, if at all, may also be subject to a 15% withholding tax in the United States. We may be able to use U.S. taxes withheld as credits against Israeli corporate income tax when we have income, if at all, but there can be no assurance that we will be able to realize the credits. In addition, we believe that we may be able to get a refund of such withholding tax from the U.S. government but there can be no assurance that we will be able to get such a refund. Royalty payments to B.G. Negev Technologies are made net of the withholding taxes. We have agreed to pay Ramot a portion of the payments we make to B.G. Negev Technologies in connection with the in-license arrangement to satisfy contractual obligations between B.G. Negev Technologies and Ramot with respect to certain intellectual property rights to the licensed technology.

Ikaria has the right to sub-license BL-1040 in arms'-length transactions consistent with the terms and conditions of the license and commercialization agreement. If Ikaria receives an upfront payment under a sublicense, Ikaria is required to pay us 10% of such payment. We have the option to manufacture at least 20% of BL-1040 products pursuant to the terms of a supply agreement to be negotiated in good faith, provided this option is exercised six months prior to the date Ikaria intends to file for regulatory approval for BL-1040 in the United States.

Ikaria bears the costs of the worldwide prosecution and maintenance of the patents for BL-1040. We have the right to intervene and maintain our patents in any country where Ikaria declines to file or prosecute those patents, or if it does not take actions necessary to avoid abandonment of those patents.

Our agreement with Ikaria expires on a product-by-product basis and a country-by-country basis on the date royalties are no longer payable in connection with the product in a given country. Either party may terminate the agreement by providing 90 days' written notice of a material breach of the agreement by the other party if the breaching party does not cure the breach during that time. In addition, Ikaria may terminate the agreement upon 60 days' prior written notice if Ikaria determines, in its sole judgment, that the results of the development program under the agreement do not warrant further development of products under the agreement.

### **Out-Licensing Agreement with Cypress Bioscience**

In June 2010, we entered into an exclusive, royalty-bearing out-licensing arrangement with Cypress Bioscience with regard to BL-1020, covering the United States, Canada and Mexico. Under the arrangement, Cypress Bioscience is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize, BL-1020 for the prevention, diagnosis and treatment of all human diseases in the United States, Canada and Mexico. Cypress Bioscience is responsible for the costs associated with conducting, in the United States, Canada and Mexico, all other development and regulatory activities of BL-1020, including those costs relating to the completion of its clinical development and the conduct and funding of its commercialization.

Under our agreement with Cypress Bioscience, we have retained the rights to develop and commercialize BL-1020 outside of the United States, Canada and Mexico, in which case we would be responsible for the costs of such development and regulatory activities. In addition, under the agreement, Cypress Bioscience has licensed to us the right to use any and all regulatory data generated by Cypress Bioscience in connection with its pursuit of regulatory approval for BL-1020 in Cypress Bioscience's territory for use by us outside of Cypress Bioscience's territory. We are allowed to sublicense the rights to the data. We are required to reimburse Cypress Bioscience for certain pre-commercialization expenses incurred by Cypress Bioscience in connection with the generation of such data when and if we elect to use the data and information. Our obligation to reimburse Cypress Bioscience's progress in the development and commercialization of BL-1020 and, when we believe the timing and conditions are optimal, may pursue development and commercialization efforts relating to BL-1020 outside the United States, Canada and Mexico, but we intend to continue to consider potential out-licensing opportunities, as well as the potential to develop and commercialize BL-1020 internally.

We received an upfront payment of \$30.0 million from Cypress Bioscience upon receipt of the OCS's consent to the agreement in August 2010, and we are entitled to receive up to an additional \$250.0 million in connection with the achievement of certain performance-based milestones and up to an additional \$85.0 million upon the achievement of certain sales-based milestones. Cypress Bioscience may pay a portion of the first performance-based milestone payment by purchasing a number of our ordinary shares, in its sole discretion. We are also entitled to royalties, ranging from 12% to 18%, on annual net sales of BL-1020 in Cypress Bioscience's territory under the agreement for the applicable royalty term. We are obligated to pay to Bar Ilan Research and Development and Ramot, collectively, a royalty payment equal to 22.5% of the net consideration we receive from Cypress Bioscience in connection with our in-licensing of BL-1020. We paid Bar Ilan Research and Development and Ramot \$6.75 million, in the aggregate, from the \$30.0 million upfront fee. We also paid the OCS \$3.0 million as partial repayment of grants previously received for the BL-1020 development program. See "— In-Licensing Agreements — BL-1020." We believe that the sales-based milestone payments and royalties will be subject to a 15% U.S. withholding tax. Royalty payments to Bar Ilan Research and Development and Ramot will be made from net consideration received, if any.

Cypress Bioscience's obligation to pay us royalties under the agreement generally expires on a country by country basis upon the expiration of the later of (i) the expiration of the last-to-expire valid claim of a licensed patent covering the use, import, manufacture or commercialization of BL-1020 in the country, (ii) the expiration of regulatory exclusivity covering BL-1020 in the country and (iii) the date on which sales of generic forms of BL-1020 in the country reach a specified percentage of the aggregate sales of both BL-1020 and such generic forms in such country. However, during such time that royalties are still payable under the license agreement for net sales of any product under the agreement in a given country, the royalty amounts payable by Cypress Bioscience for such product in such country will based upon specified percentages that depend on the amount of sales of such generic product in the country. Upon the expiration of Cypress Bioscience's obligation to pay us royalties under the agreement in a given country, (i) the license granted to Cypress Bioscience under the license agreement in such country shall become fully-paid, royalty-free and non-exclusive and (ii) we and each of Bar Ilan Research and Development and Ramot shall be free to use the licensed patents to make and have made, use, offer to sell, sell, have sold, import, export, otherwise transfer physical possession of or otherwise transfer title to products developed under the agreement and to grant the other parties licenses under the licensed patents to do the same in such country.

Cypress Bioscience has the right to sub-license BL-1020 in arms'-length transactions consistent with the terms and conditions of the license and commercialization agreement. In connection with any sublicense, Cypress Bioscience will remain primarily responsible for the performance of the obligations under the license and commercialization agreement by each of its sublicencees.

We and Cypress Bioscience intend for Cypress Bioscience to prosecute and maintain the patents for BL-1020 in a manner that will provide the maximum economic advantage for both parties. We have the right to intervene and maintain our patents in any country where Cypress Bioscience declines to file or prosecute those patents, or if it does not take actions necessary to avoid abandonment of those patents.

Cypress Bioscience may terminate the agreement for any reason upon 180 days' written notice. In addition, Cypress Bioscience may terminate the agreement upon 30 days' written notice in the event of any significant adverse clinical events or other adverse toxicity, safety or efficacy data relating to the licensed product or if Cypress Bioscience determines that there is no basis for filing an NDA for the licensed product. We may terminate the agreement upon 30 days' written notice if Cypress Bioscience or any of its affiliates or sublicensees file or support a lawsuit or bring any other legal or administrative proceeding, challenging any of our licensed patents, and Cypress Bioscience or its affiliates or sublicensees fail to cease such lawsuit, proceeding, action, request, attack, contest or dispute within 30 days following Cypress' receipt of notice from us. The agreement will terminate upon expiration of the 30-day notice period.

# **In-Licensing Agreements**

We have in-licensed and intend to continue to in-license development, production and marketing rights from selected research and academic institutions in order to capitalize on the capabilities and technology developed by these entities. We also seek to obtain technologies that complement and expand our existing technology base by entering into license agreements with pharmaceutical and biotechnology companies. When entering into in-license agreements, we generally seek to obtain unrestricted sublicense rights consistent with our primarily partner-driven strategy. We are generally obligated under these agreements to diligently pursue product development, make development milestone payments, pay royalties on any product sales and make payments upon the grant of sublicense rights. We generally insist on the right to terminate any in-license for convenience upon prior written notice to the licensor.

The scope of payments we are required to make under our in-licensing agreements is comprised of various components that are paid commensurate with the progressive development and commercialization of our drug products. In general, we do not agree to make any upfront payments as part of our in-licensing arrangements.

Our in-licensing agreements generally provide for the following types of payments:

- **Revenue sharing payments.** These are payments to be made to licensors with respect to revenue we receive from sublicensing to third parties for further development and commercialization of our drug products. These payments are generally fixed at a percentage of the total revenues we earn from these sub-licenses.
- **Phase 2 payments**. These payments are generally linked to the successful achievement of milestones at the phase 2 clinical trials stage with respect to a licensed therapeutic candidate.
- Advanced phase payments. Certain of our in-licensing agreements provide for additional payments for the achievement of milestones that enable the commencement of phase 3 clinical trials and the successful completion of phase 3 clinical trials.
- **NDA payments**. Certain of our in-licensing agreements provide for additional payments upon obtaining approvals to new drug applications, or NDAs, for drug development.
- **Royalty payments**. To the extent we elect to complete the development, licensing and marketing of a therapeutic candidate, we are generally required to pay our licensors royalties on the sales of the end drug product. These royalty payments are generally based on the net revenue from these sales. In certain instances, the rate of the royalty payments decrease upon the expiration of the drug's underlying patent and its transition into a generic drug. Certain of our agreements provide that if a licensed drug product is developed and sold through a different corporate entity, the licensors may elect to receive shares in such company instead of a portion of the royalties.
- Additional payments. In addition to the above payments, certain of our in-license agreements provide for a one-time or
  periodic payment that is not linked to milestones. Periodic payments may be paid until the commercialization of the
  product, either by direct sales or sub-licenses to third parties. Other agreements provide for the continuation of these
  payments even following the commercialization of the licensed drug product.

The royalty and revenue sharing rates we agree to pay in our in-licensing agreements vary from case to case but range from 20% to 29% of the consideration we receive from sublicensing the applicable therapeutic candidate. In some instances we are required to pay a substantially lower percentage, generally less than 5%, if we elect to commercialize the subject therapeutic candidate independently.

The following are descriptions of our in-licensing agreements associated with our therapeutic candidates under clinical development. In addition to the in-licensing agreements discussed herein, we have entered into other in-licensing arrangements in connection with our therapeutic candidates in the advanced preclinical, feasibility and EDP stages.

# BL-1020

In April 2004, we in-licensed the rights to BL-1020 under a research and license agreement with Bar Ilan Research and Development and Ramot. Under the research and license agreement, the licensors granted us an exclusive, worldwide, sublicensable license to develop, manufacture, market and sell certain technology relating to conjugated anti-psychotic drugs and the uses of the technology relating thereto. In addition to BL-1020, this agreement allows us to develop two other earlier stage therapeutic candidates, BL-1021 for the treatment of neuropathic pain and a second candidate for which development has been terminated. Under the research and license agreement, we agreed to fund further research in respect of the licensed technology during a specified research period, subject to certain exceptions. In addition, we have the right to grant sublicenses for the licensed technology, subject to certain restrictions.

Under the research and license agreement, we are obligated to use commercially reasonable efforts to develop, commercialize and market the licensed technology. We pay an annual license fee of \$25,000 and are required to make low, single digit royalty payments on the net sales of the licensed technology, subject to certain limitations. To date, we have paid \$175,000 under the BL-1020 in-license agreement in connection with our obligations to make annual payments. Our royalty payment obligations are payable on a product-by-product and country-by-country basis, for the longer of 15 years from the date of first commercial sale in such country, the last expiration of any patent in such country, and the expiration of the licensed product's "orphan drug" status in such country. If we sublicense our rights under the research and license agreement, we are required to pay the licensors a low, double digit royalty payment based on any amounts we receive from any third-party sublicensees, subject to certain limitations.

We are required to consult the licensors regarding the preparation, filing and prosecution of all patent applications, and the maintenance of all patents included within the licensed patent rights. We have the right to take action in the prosecution, prevention, or termination of any patent infringement of the licensed technology. We are responsible for the expenses of any patent infringement suit that we bring, including the expenses incurred by the licensors in connection with the prosecution of such suits or the settlement thereof. We are entitled to reimbursement from any sums recovered in such suit for all costs and expenses involved in its prosecution. After such reimbursement, we and the licensors are each entitled to a certain percentage of any remaining sums.

The research and license agreement remains in effect until the expiration of all of our royalty and sublicense revenue obligations to licensors, determined on a product-by-product and country-by-country basis, unless we terminate the license agreement earlier. We may terminate the license agreement by providing 60 days' prior written notice to Ramot. If we materially breach any of our obligations under the agreement and fail to cure such breach within 30 days after receiving written notice of the material breach from Ramot, Ramot may terminate the agreement immediately. If either Bar Ilan Research and Development or Ramot materially breach their respective obligations under the agreement and fail to cure such breach within 30 days after receiving written notice of the material breach from us, we may terminate the agreement immediately. With respect to any termination for material breach, if the breach is not susceptible to cure within the stated period and the breaching party uses diligent, good faith efforts to cure such breach, the stated period will be extended by an additional 30 days. In addition, we and Ramot may terminate the agreement upon notice to the other upon the occurrence of certain bankruptcy events.

Termination of the agreement will result in a loss of all of our rights to the licensed technology, which will revert to the licensors. In addition, any sublicense of the licensed technology will terminate provided that, upon termination, at the request of the sublicensee, licensors are required to enter into a license agreement with the sublicensee on substantially the same terms as those contained in the sublicense agreement.

#### BL-1040

In January 2005, we in-licensed the rights to BL-1040 under a license agreement with B.G. Negev Technologies. Under the agreement, B.G. Negev Technologies granted us an exclusive, worldwide, sublicensable license to develop, manufacture, market and sell certain technology relating to injectable alginate biomaterials and the uses thereof. Upon execution of the agreement, we were obligated to make an initial payment and to make annual payments equal to \$30,000, subject to certain conditions. To date we have paid \$700,000 under the BL-1040 in-license agreement, to cover the initial fee and annual fees. We are obligated to make a low, single digit royalty payment on net sales, subject to certain limitations if we manufacture and sell products developed under the agreement on our own. We also have the right to grant sublicenses for the licensed technology and are required to pay B.G. Negev Technologies a royalty payment of 28% of the net revenues (after giving effect to withholding taxes and other deductions) we receive as consideration in connection with any sublicensing, co-marketing or co-promotion, or a permitted assignment, of BL-1040, which includes those under our licensing agreement with Ikaria. We have agreed to pay Ramot a portion of the payments we make to B.G. Negev Technologies in connection with the in-license arrangement to satisfy contractual obligations between B.G. Negev Technologies and Ramot with respect to certain intellectual property rights to the licensed technology. We have also agreed to indemnify Ramot and certain of its related parties in connection with our use of the technology we in-licensed from B.G. Negev Technologies.

Under the license agreement, we are obligated to use commercially reasonable efforts to develop the licensed technology in accordance with a specified development plan. We have paid to B.G. Negev Technologies initial payments and are required to pay an annual license fee, subject to certain exceptions. In addition, we are required to make a one-time milestone payment upon the achievement of specified milestones. We are required to make certain royalty payments on the net sales of the licensed technology, subject to certain limitations. Our royalty payment obligations are payable on a product-by-product and country-by-country basis, for the period that a valid patent on the licensed technology remains in force in such country, subject to certain exceptions for abandonment.

The license agreement remains in effect until the expiration of all of our royalty and sublicense revenue obligations to B.G. Negev Technologies, determined on a product-by-product and country-by-country basis. We may terminate the license agreement for any reason on 60 days' prior written notice to B.G. Negev Technologies. Either party may terminate the agreement for material breach by the other party if the breaching party is unable to cure the breach within 60 days after receiving written notice of the breach from the non-breaching party. With respect to any termination for material breach, if the breach is not susceptible to cure within the stated period and the breaching party uses diligent, good faith efforts to cure such breach, the stated period will be extended by an additional 30 days. In addition, either party may terminate the agreement upon the occurrence of certain bankruptcy events.

Termination of the agreement will result in a loss of all of our rights to the licensed technology, which will revert to B.G. Negev Technologies. In addition, any sublicense of the licensed technology will terminate provided that, upon termination, at the request of the sublicensee, B.G. Negev Technologies is required to enter into a license agreement with the sublicensee on substantially the same terms as those contained in the sublicense agreement.

We have the first right to prepare, file, prosecute and maintain any patent applications and patents, in respect of the licensed technology and any part thereof, at our expense. We are required to consult with B.G. Negev Technologies regarding patent prosecution and patent maintenance. In addition, we have the right to take action in the prosecution, prevention, or termination of any patent infringement of the licensed technology. We are responsible for the expenses of any patent infringement suit that we bring, including the expenses incurred by B.G. Negev Technologies in connection with such suits. We are entitled to reimbursement from any sums recovered in such suit or in the settlement thereof for all costs and expenses

involved in the prosecution of any such suit. After such reimbursement, if any funds remain, we and B.G. Negev Technologies are each entitled to a certain percentage of any remaining sums.

### BL-5010

In November 2007, we in-licensed the rights to develop and commercialize BL-5010 under a license agreement with IPC. Under the agreement, IPC granted us an exclusive, worldwide, sublicensable license to develop, manufacture, market and sell certain technology relating to an acid-based formulation for the non-surgical removal of skin lesions and the uses thereof. We are obligated to use commercially reasonable efforts to develop the licensed technology in accordance with a specified development plan, including meeting certain specified diligence goals. We are required to pay to IPC a license fee, which we have paid, equal to \$400,000 in the aggregate, subject to certain specifications. We are also required to make low, single digit royalty payments on the net sales of the licensed technology if we manufacture and sell it on our own, subject to certain limitations. Our royalty payment obligations are payable on a product-by-product and country-by-country basis, until the last to expire of any patent included within the licensed technology in such country. We also have the right to grant sublicenses for the licensed technology and are required to pay IPC a royalty payment in the low, double digits based on the revenues we receive as consideration in connection with any sublicensing, development, manufacture, marketing, distribution or sale of the licensed technology.

The license agreement remains in effect until the expiration of all of our license, royalty and sublicense revenue obligations to IPC, determined on a product-by-product and country-by-country basis, unless we terminate the license agreement earlier. We may terminate the license agreement for any reason on 30 days' prior written notice. If we terminate the agreement without cause, we may be required to fund the completion of certain clinical trials of the licensed technology in an amount not to exceed \$600,000. We may also terminate the license agreement upon 60 days' prior written notice to IPC for scientific, regulatory or medical reasons which, as determined by our Scientific Advisory Board, would prevent us from continuing the development of the licensed technology pursuant to the development plan. Either party may terminate the agreement for material breach if the breach is not cured within 30 days after written notice from the non-breaching party. If the breach is not susceptible to cure within the stated period and the breaching party uses diligent, good faith efforts to cure such breach, the stated period will be extended by an additional 30 days. In addition, either party may terminate the agreement upon the occurrence of certain bankruptcy events.

Termination of the agreement will result in a loss of all of our rights to the licensed technology, which will revert to IPC. In addition, any sublicense of the licensed technology will terminate provided that, upon termination, at the request of the sublicensee, IPC is required to enter into a license agreement with the sublicensee on substantially the same terms as those contained in the sublicense agreement.

We have the first right to prepare, file, prosecute and maintain any patent applications and patents, in respect of the licensed technology and any part thereof, at our expense, provided that such patent applications and patents are registered in the name of IPC. We are required to make all future payments necessary to prosecute and maintain all patent applications and/or patents in respect of the licensed technology. We are required to consult with IPC regarding the preparation, filing and prosecution of all patent applications, and the maintenance of all patents included within the licensed patents. In addition, we have the right to take action in the prosecution, prevention, or termination of any patent infringement of the licensed patents. We are responsible for the expenses of any patent infringement suit that we bring, including the expenses incurred by IPC in connection with such suits. We are entitled to reimbursement from any sums recovered in such suit for all costs and expenses involved in the prosecution of any such suit. After such reimbursement, we and IPC are each entitled to a certain percentage of any remaining sums.

# **Other Material Agreements**

The following are summary descriptions of certain material agreements to which we are a party, in addition to the in-licensing agreements and the licensing agreements described in other sections of this prospectus. The descriptions provided below do not purport to be complete and are qualified in their entirety by the complete agreements, which are attached as exhibits to the registration statement of which this prospectus forms a part.

#### Incubator Agreement

We entered into an incubator agreement with the OCS in January 2005 to operate a biotechnology incubator. Our wholly-owned subsidiaries, BIJ Ltd. and BIJ L.P., operate the incubator. Under the arrangement, the OCS agreed to loan funds to the incubator in connection with in-licensing the rights to the therapeutic candidates. We in-license, through the incubator, certain, but not all, of the therapeutic candidates that we eventually incorporate into our pipeline. As of June 30, 2010, we received approximately \$11.4 million in loans from the OCS under the incubator agreement, which does not include \$5.0 million we have received from the OCS outside of the incubator agreement, as of that date. The OCS funds have been used to initiate 19 different development projects, 14 of which have terminated. Four of our current development projects have been funded under the incubator agreement, including BL-1021, BL-1040, BL-2030 and BL-4040. Other projects may be funded by the OCS outside of the incubator agreement.

The incubator agreement has a six-year term and we are entitled to apply for a three-year extension to the agreement. The incubator agreement is currently scheduled to terminate on December 31, 2010. We applied for an extension to the agreement in June 2010 and are waiting for notification from the OCS of its approval of the extension. If the incubator agreement terminates, we will no longer be eligible for funding from the OCS through the incubator for new projects in the incubator, but existing projects and the terms of any outstanding loans will not be affected by the termination.

Under the incubator program, the Biotechnology Incubators Committee of the OCS is required to approve each project we intend to perform through the incubator and has broad discretionary powers with respect to approving equipment purchases and the general operation of the incubator. All of the restrictions placed on OCS-funded technology apply as well to all intellectual property derived from the incubator project. See "Government Funding for Development Programs — Israel Office of the Chief Scientist — Research and Development Grants."

If we elect to terminate an incubator project for drug development, we are required to provide to the OCS the reasons that led to the termination of the project together with a financial and technical report relating to the drug development. We are also obligated to send notice to the entity that in-licensed to us the technology used for developing the drug. If the licensor is interested in continuing the development of the therapeutic candidate, the licensor is required to execute an agreement with the OCS and us to assume all rights and obligations relating to the funding received from the OCS. We expect that upon termination of a project and fulfillment of all OCS requirements for such termination, all loans associated with such project will be forgiven by the OCS.

The funding provided to us under the incubator agreement is in the form of a separate loan for each project, which is to be repaid solely out of the revenues generated by such project, with interest, until the full repayment of the loan. Revenue derived from a product developed in the incubator is subject to royalty payments at the same rates as set forth in the Research Law, as described in this prospectus, and until the loans provided for that project are repaid. However, if a loan is not repaid within two years following the completion of the applicable incubator project the interest rate for that loan will be doubled for the third through fifth years after completion of the project. The loan and all accrued interest is repayable upon demand if we violate the terms of the incubator agreement, with accrued interest. We initially provided the OCS with a bank guarantee in the sum of approximately NIS 8.1 million to cover all of our undertakings made under the agreement. The amount of the guarantee was reduced and is currently approximately NIS 3.0 million. Every year, the amount of the guarantee is reduced by an amount equivalent to 50% of the incubator operating costs, subject to a minimum guarantee of approximately NIS 1.5 million. Our obligation to maintain the bank guarantee terminates three months after the expiration of the term of the incubator agreement. In addition, all intellectual property held or developed by the incubator in connection with the incubator program is pledged as security for our obligations under the agreement. The intellectual property rights pledged may be realized by the State of Israel eight years after the date of approval of the relevant incubator program, or earlier in the event of a breach of the incubator agreement by us, or in the event liquidation or dissolution of our biotechnology incubator.

We operate a "type-2" technological incubator, also known as a "project incubator," in which the incubator itself operates the project, and the intellectual property of the project is owned by the incubator. There are restrictions regarding the transfer of rights to intellectual property held by the incubator to any third party, and transfers of intellectual property must comply with the requirements of the Research Law, including those published by the Director-General of the OCS. There is a floating charge in favor of the OCS covering all of the assets and equipment of the incubator. Type-2 incubators may sell the incubator's assets, but at least 25% of the earnings from the sale must be used to repay the loan. If there is a sale of all of the technology, or an exclusive license for all of the intellectual property assets, of a particular project, the loan must be repaid in full. In all cases, the amount used to repay any loan shall not exceed the full principal amount of the loan plus accrued interest and adjustments to the principal amount based on the common price index. In addition, the transfer of any intellectual property by any project company remains subject to the restrictions on transfers of OCS-funded technology out of Israel. See "— Government Regulation and Funding — Israeli Government Programs — Israel Office of the Chief Scientist."

### Early Development Program Agreement

We have entered into an agreement with our shareholder, Pan Atlantic Bank and Trust Limited, or Pan Atlantic, pursuant to which Pan Atlantic committed to provide us with up to \$5.0 million to be used in connection with the in-licensing and development of early development stage therapeutic candidates, our Early Development Program. At least 70% of the research projects performed under the Early Development Program must originate inside Israel. We operate our Early Development Program independently from our biotechnology incubator. Pursuant to our Early Development Program, we are entitled to request from Pan Atlantic, twice a year, up to \$625,000 for an aggregate of up to \$1.25 million per year, unless otherwise agreed by Pan Atlantic, for our early development research projects, provided that we match the program funds at a rate of \$0.20 per every dollar invested by Pan Atlantic does not have any rights to any products developed through our early development projects. As part of the agreement, Pan Atlantic has the right to invest up to \$5.0 million in our first public offering outside of Israel, including this offering. Currently, there is a liability on our balance sheet of \$0.72 million, representing cumulative amounts received from Pan Atlantic in excess of the cumulative amounts spent on our Early Development Program as of June 30, 2010.

The term of the Early Development Program Agreement continues through the earlier of (i) the completion of the disbursement of all of the funds provided in the agreement and the completion of all research programs funded thereby and (ii) the termination of the agreement by either party. Each party to the agreement may terminate the agreement due to the default of the other party with respect to a material term of the agreement, which default is not cured within 30 days of the defaulting party's receipt of notice of default, or to the occurrence of specified bankruptcy events with respect to the other party to the agreement or if the other party engages in a sale of all or substantially all of its assets as would cause that party to be unwilling to fulfill its obligations under the agreement.

# **Intellectual Property**

Our success depends in part on our ability to obtain and maintain proprietary protection for our therapeutic candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position.

*Patents.* As of September 1, 2010, we owned or exclusively licensed for uses within our field of business 13 patent families that, collectively contain over 12 issued patents and over 60 patent applications relating to our three clinical candidates. We are also pursuing patent protection for other drug candidates in our pipeline. Patents related to our therapeutic candidates may provide future competitive advantages by providing exclusivity related to the composition of matter, formulation, and method of administration of the applicable compounds and could materially improve the value of our therapeutic candidates. The patent positions for our three leading therapeutic candidates are described below and include both patents and patent

applications we own or exclusively license. We vigorously defend our intellectual property to preserve our rights and gain the benefit of our investment.

- With respect to BL-1020, we have an exclusive license to three patent families that relate to the molecule that is the active ingredient of our proprietary anti-psychotic drug, pharmaceutical compositions and methods of use, such as in the treatment of schizophrenia. Patents and patent applications corresponding to the international patent applications have been granted or are pending in the United States, Israel, Europe, Australia, Japan, Canada, China, India, South Korea and Mexico. The patents and any patents to issue in the future based on pending patent applications in these families will expire, without extension, beginning in 2022. In addition, three provisional patent applications have been recently filed claiming (i) the use of BL-1020 for improving cognitive functions, (ii) a novel crystalline form of BL-1020 and (iii) a method of production of the crystalline form.
- With respect to BL-1040, we have an exclusive license to a patent family directed to the BL-1040 composition, methods of production and methods of use, such as uses for the treatment of myocardial infarction. Patents and patent applications corresponding to the international patent application have been granted or are pending in the United States, Israel, Europe, Japan, Canada, Australia, Mexico, China, South Korea and India. The issued patents and any patents to issue in the future based on pending patent applications in these families will expire in 2024.
- With respect to BL-5010, we have an exclusive license to a patent family directed to the BL-5010 composition or methods of its use, such as the treatment of skin lesions. Patents and patent applications corresponding to the international patent application have been granted or are pending in the United States, Israel and Europe. The issued patents and any patents to issue in the future based on pending patent applications in these families will expire beginning in the end of 2021.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, narrowed, circumvented or found to be invalid or unenforceable, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. Neither we nor our licensors can be certain that we were the first to invent the inventions claimed in our owned or licensed patents or patent applications. In addition, our competitors may independently develop similar technologies or duplicate any technology developed by us, and the rights granted under any issued patents may not provide us with any meaningful competitive advantages against these competitors. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

*Trade Secrets.* We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and assignment of inventions agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, such agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

# **Scientific Advisory Board**

Our Scientific Advisory Board, which consists of a number of leading scientists and physicians, plays an active role in the evaluation of in-licensing opportunities, the development of our pipeline, and in the rejection of in-licensing opportunities that do not meet our licensing criteria. We also seek advice from our Scientific Advisory Board on scientific and medical matters generally. Our Scientific Advisory Board meets approximately every six weeks to, among other things:

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- screen all potential in-licensing and current therapeutic candidates; •
- oversee our research and development programs; and
- address specific scientific and technical issues relevant to our business. .

The following table sets forth information for our scientific advisory board members. n ...

Name	Position/Institutional Affiliation			
J. Aaron Ciechanover, M.D., Ph.D.	Professor Ciechanover is a Nobel Prize laureate in Chemistry (2004) and			
	a recipient of the Israel Prize (2000) in Biological Research and the			
	prestigious Lasker Award (2000). Professor Ciechanover is a			
	Distinguished Research Professor at the Technion — Israel Institute of			
	Technology. Professor Ciechanover is a member of, among many			
	institutions, the following: the Israeli National Academy of Sciences and			
	Humanities, the American Academy of Arts and Sciences (Foreign			
	Fellow), the American Philosophical Society, the Pontifical Academy of			
	Sciences of the Vatican, the National Academy of Sciences of the USA			
	(Foreign Associate) and the Institute of Medicine of the National			
	Academies of the USA (Foreign Associate).			
Aliza Eshkol, Ph.D.	Dr. Eshkol is Vice President for Scientific Affairs, Serono International			
	SA, Geneva, Switzerland.			
David Ladkani, M.D.	Dr. Ladkani is the Chief Scientific Officer, Global Products Division, of			
	Teva. Dr. Ladkani has received the prestigious Rothschild Award for			
	innovation, and is widely published in the field of multiple sclerosis			
	treatments.			
Yaakov Naparstek, M.D.	Professor Naparstek is the Chairman of Medicine of Hadassah University			
	Hospital. His main research interests are in the field of autoimmunity,			
	systemic lupus erythematosus and autoimmune arthritis.			
Moshe Phillip, M.D.	Professor Phillip has been our Vice President of Medical Affairs and			
	Senior Clinical Advisor and a member of our Scientific Advisory Board			
	since 2004. Professor Phillip is the Director of the Institute for			
	Endocrinology and Diabetes of the Israel National Center for Childhood			
	Diabetes at Schneider Children's Medical Center of Israel and the Vice			
	Dean for Research and Development at the Sackler School of Medical			
Itamar Shalit MD	Education at Tel Aviv University. Professor Shalit is the Director of the Pediatric Infectious Disease Unit at			
Itamar Shalit, M.D.	the Schneider Children's Medical Center in Israel. Dr. Shalit is the author			
	of over 70 publications in scientific journals and chapters in textbooks			
	and currently serves as the Chairman of the Israeli Society for Infectious			
	Diseases.			
Yosef Yarden, Ph.D.	Professor Yarden is the Dean of the Feinberg Graduate School of the			
Toser Tarden, Th.D.	Weizmann Institute of Science. He serves on numerous national and			
	international boards and the scientific advisory committees of several			
	organizations, both academic and commercial, including serving as a			
	Council Member of the European Association for Cancer Research.			
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### Manufacturing

We do not currently own or operate manufacturing facilities and have no experience in manufacturing pharmaceutical products or medical devices. We rely on, and expect to continue to rely on, outside parties to produce all clinical and commercial quantities of our therapeutic candidates. However, we have the option to manufacture at least 20% of BL-1040 products pursuant to the terms of a supply agreement to be negotiated in good faith with Ikaria. See "— Material Agreements — Ikaria Agreement." There can be no assurance that our therapeutic candidates, if approved, can be manufactured in sufficient commercial quantities, in compliance with regulatory requirements and at an acceptable cost. We and our contract manufacturers are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products or medical devices. We and our contract manufacturers must ensure that all of the processes, methods and equipment are compliant with the current Good Manufacturing Practices, or cGMP, for drugs or Quality System Regulations, or QSR, for devices on an ongoing basis, mandated by the FDA and other regulatory authorities, and conduct extensive audits of vendors, contract laboratories and suppliers.

# **Contract Research Organizations**

We outsource certain preclinical and clinical development activities to contract research organizations, or CROs, which meet FDA or European Medicines Agency regulatory standards. We create and implement the drug development plans and, during the preclinical and clinical phases of development, manage the CROs according to the specific requirements of the therapeutic candidate under development.

#### Competition

The pharmaceutical, medical device and biotechnology industries are intensely competitive. Several of our therapeutic candidates, if commercialized, would compete with existing drugs and therapies. In addition, there are many pharmaceutical companies, biotechnology companies, medical device companies public and private universities, government agencies and research organizations actively engaged in research and development of products targeting the same markets as our therapeutic candidates. Many of these organizations have substantially greater financial, technical, manufacturing and marketing resources than we have. Our competitors may also be able to use alternative technologies that do not infringe upon our patents to formulate the active materials in our therapeutic candidates. They may, therefore, bring to market products that are able to compete with our candidates, or other products that we may develop in the future.

# BL-1020

If approved, BL-1020 will compete with currently marketed atypical anti-psychotics from Johnson & Johnson, Eli Lilly and Company, AstraZeneca, Bristol-Myers Squibb/Otsuka Pharmaceutical Co., Ltd., Pfizer Inc. and others, as well as with generic brands of typical and atypical anti-psychotics. We are also aware of a number of potentially competitive compounds under development including: Cariprazine, which is being developed by Forest Laboratories, Inc.; Bifeprunox, which is being developed by Solvay Pharmaceuticals, Inc., and Lurasidone, which is being developed by Dainippon Sumitomo Pharma Co., Ltd. None of these anti-psychotics are indicated to improve cognition.

# BL-1040

We are not aware of any marketed products for the prevention of cardiac remodeling following an AMI that, like BL-1040, are injectable and form a protective scaffold that supports the heart muscle during recovery and repair. BL-1040 faces competition from a number of therapies currently in development that treat cardiac remodeling in different ways. Other treatments for cardiac remodeling include BioHeart, Inc.'s MyoCell® implantation procedure, Paracor Medical, Inc.'s HeartNet<sup>TM</sup> and Acorn Cardiovascular, Inc.'s CorCap<sup>TM</sup> device. These devices are indicated for different patient populations than BL-1040 and require surgery. For example, CorCap<sup>TM</sup> is indicated for patients suffering from congestive heart failure (CHF) and requires surgery to apply the device.

# BL-5010

There are a variety of approved destructive and non-destructive treatments for skin lesions. Surgery is currently the most common approved non-destructive treatment for skin lesions but is invasive and painful, and generally results in cosmetically undesirable outcomes. Destructive treatments are associated with pain.



Metvix® is a non-destructive, non-surgical, cream-based treatment for skin lesions developed by Galderma Pharma SA which involves exposure of the skin lesion to red light after the application of the cream. It has been approved in many countries. BL-5010 does not require the use of any equipment.

### Insurance

We maintain insurance programs for our offices and laboratory in Israel and our office in the United States. Our Israeli insurance program covers approximately \$3.7 million of equipment, stock and lease improvements against risk of fire, lightning, natural perils and burglary and \$1.5 million of consequential damages. We also maintain a \$10.0 million employer liability insurance policy and \$5.0 million of third party liability. We maintain an all-risk policy that provides coverage of approximately \$1.5 million for electronic equipment and boiler and machinery insurance for laboratory refrigerators. For our U.S. office, we maintain a workers compensation policy with \$1.0 million employers liability coverage, property insurance and a \$2.0 million comprehensive general liability policy, a \$1.0 million auto liability policy and a \$1.0 million umbrella policy, all of which are necessary for our compliance with the requirements under our lease agreement. We also maintain a \$20.0 million directors and officers liability insurance policy.

We procure cargo marine coverage when we ship substances for our clinical studies. Such insurance is custom-fit to the special requirements of the applicable shipment, such as temperature and/or climate sensitivity. If required, we insure the substances to the extent they are stored in central depots and at clinical sites.

We believe that the amounts of our insurance policies are adequate and customary for a business of our kind. However, because of the nature of our business, we cannot assure you that we will be able to maintain insurance on a commercially reasonable basis or at all, or that any future claims will not exceed our insurance coverage.

# **Environmental Matters**

We are subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal of hazardous, radioactive and biological materials and wastes and the cleanup of contaminated sites. We believe that our business, operations and facilities are being operated in compliance in all material respects with applicable environmental and health and safety laws and regulations. Based on information currently available to us, we do not expect environmental costs and contingencies to have a material adverse effect on us. The operation of our facilities, however, entails risks in these areas. Significant expenditures could be required in the future if we are required to comply with new or more stringent environmental or health and safety laws, regulations or requirements. See "Government Regulation — Israel Ministry of Environment — Toxin Permit."

### **Property and Infrastructure**

We are headquartered in Jerusalem, Israel. We lease one facility pursuant to a lease agreement with Caps-Pharma Ltd. that expires on December 15, 2010, with options to renew through December 2016. The facility consists of approximately 1,700 square meters of space and lease payments are approximately \$20,400 per month. This facility houses our administrative and research operations and our central laboratory. The central laboratory consists of approximately 600 square meters and includes an analytical chemistry laboratory, a formulation laboratory, and a tissue culture laboratory. We are currently outfitting a section of the central laboratory as a Class 1000 Clean Room for the synthesis of compounds that require a clean environment for development. Substantially all of our employees are based in this facility.

# **Corporate Structure**

Our corporate structure consists of BioLineRx and three wholly-owned subsidiary entities: BioLine Innovations Jerusalem Limited Partnership, or BIJ L.P.; BioLine Innovations Jerusalem Ltd., or BIJ Ltd.; and BioLineRx USA Inc. BIJ Ltd. and BIJ L.P. are engaged in the operation of our biotechnology incubator. See "— Material Agreements — Incubator Agreement." BioLineRx USA was formed in connection with our operations in the United States.



### Employees

As of June 30, 2010, we had 55 employees, all but one of which are employed in Israel. As of such date, 19 employees were employed in management and administrative positions and 36 were employed in research and development positions. Of our employees, 21 hold M.D. or Ph.D. degrees.

While none of our employees are party to any collective bargaining agreements, certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Associations) are applicable to our employees by order of the Israel Ministry of Labor. These provisions primarily concern the length of the workday, minimum daily wages for professional workers, pension fund benefits for all employees, insurance for work-related accidents, procedures for dismissing employees, determination of severance pay and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimums.

We have never experienced any employment-related work stoppages and believe our relationship with our employees is good.

# Legal Proceedings

We are not involved in any material legal proceedings.

# GOVERNMENT REGULATION AND FUNDING

We operate in a highly controlled regulatory environment. Stringent regulations establish requirements relating to analytical, toxicological and clinical standards and protocols in respect of the testing of pharmaceuticals and medical devices. Regulations also cover research, development, manufacturing and reporting procedures, both pre- and post-approval. In many markets, especially in Europe, marketing and pricing strategies are subject to national legislation or administrative practices that include requirements to demonstrate not only the quality, safety and efficacy of a new product, but also its cost-effectiveness relating to other treatment options. Failure to comply with regulations can result in stringent sanctions, including product recalls, withdrawal of approvals, seizure of products and criminal prosecution.

Before obtaining regulatory approvals for the commercial sale of many of our therapeutic candidates, we or our licensees must demonstrate through preclinical studies and clinical trials that our therapeutic candidates are safe and effective. Historically, the results from preclinical studies and early clinical trials often have not accurately predicted results of later clinical trials. In addition, a number of pharmaceutical products have shown promising results in clinical trials but subsequently failed to establish sufficient safety and efficacy results to obtain necessary regulatory approvals. We have incurred and will continue to incur substantial expense for, and devote a significant amount of time to, preclinical studies and clinical trials. Many factors can delay the commencement and rate of completion of clinical trials, including the inability to recruit patients at the expected rate, the inability to follow patients adequately after treatment, the failure to manufacture sufficient quantities of materials used for clinical trials, and the emergence of unforeseen safety issues and governmental and regulatory delays. If a therapeutic candidate fails to demonstrate safety and efficacy in clinical trials, this failure may delay development of other therapeutic candidates and hinder our ability to conduct related preclinical studies and clinical trials. Additionally, as a result of these failures, we may also be unable to find additional licensees or obtain additional financing.

Governmental authorities in all major markets require that a new pharmaceutical product or medical device be approved or exempted from approval before it is marketed, and have established high standards for technical appraisal, which can result in an expensive and lengthy approval process. The time to obtain approval varies by country. In the past, it generally took from six months to four years from the application date, depending upon the quality of the results produced, the degree of control exercised by the regulatory authority, the efficiency of the review procedure and the nature of the product. Some products are never approved. In recent years, there has been a trend towards shorter regulatory review times in the United States as well as certain European countries, despite increased regulation and higher quality, safety and efficacy standards.

Historically, different requirements by different countries' regulatory authorities have influenced the submission of applications. However, the past 10 years have shown a gradual trend toward harmonization of drug and medical device approval standards, starting in individual territories in Europe and then in the European Union as a whole, in Japan, and in the United States under the aegis of the International Conference on Harmonization, or ICH. In many cases, compliance with ICH standards can help avoid duplication of non-clinical and clinical trials and enable companies to use the same basis for submissions to each of the respective regulatory authorities. The adoption of the Common Technical Document format by the ICH has greatly facilitated use of a single regulatory submission for seeking approval in the ICH regions and certain other countries such as Canada and Australia.

A summary of the United States, European Union and Israeli regulatory process follows below.

# **United States**

In the United States, drugs are subject to rigorous regulation by the FDA. The U.S. Federal Food, Drug and Cosmetic Act, or FDCA, and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, record-keeping, packaging, labeling, adverse event reporting, advertising, promotion, marketing, distribution and import and export of pharmaceutical products. Failure to comply with applicable regulatory requirements may subject us to a variety of administrative or judicially imposed sanctions and/or prevent us from obtaining or maintaining required approvals or to market drugs. Failure to comply with the applicable U.S. requirements may subject us to stringent administrative or

judicial sanctions, such as agency refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions or criminal prosecution.

Unless a drug is exempt from the new drug application process, the steps required before a drug may be marketed in the United States include:

- preclinical laboratory tests, animal studies and formulation studies;
- submission to the FDA of a request for an investigational new drug, or IND, to conduct human clinical testing;
- adequate and well controlled clinical trials to determine the safety and efficacy of the drug for each indication;
- submission to the FDA of a new drug application, or NDA;
- a potential public hearing of an outside advisory committee to discuss the application;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is manufactured; and
- FDA review and approval of the NDA.

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies. For studies conducted in the United States, and certain studies carried out outside the United States, we submit the results of the preclinical studies, together with manufacturing information and analytical results, to the FDA as part of an IND, which must become effective before we may commence human clinical trials. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND does not always result in the FDA allowing clinical trials to commence and the FDA may halt a clinical trial if unexpected safety issues surface or the study is not being conducted in compliance with applicable requirements.

The FDA may refuse to accept an IND for review if applicable regulatory requirements are not met. Moreover, the FDA may delay or prevent the start of clinical trials if the manufacturing of the test drugs fails to meet good manufacturing practice, or GMP, requirements or the clinical trials are not adequately designed. Such government regulation may delay or prevent the study and marketing of potential products for a considerable time period and may impose costly procedures upon a manufacturer's activities. In addition, the FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot continue without FDA authorization and then only under terms authorized by the FDA.

Success in early-stage clinical trials does not assure success in later-stage clinical trials. Results obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a therapeutic candidate receives regulatory approval, later discovery of previously unknown problems with a product may result in restrictions on the product or even withdrawal of marketing approval for the product.

# Clinical Trials

Clinical trials involve the administration of the investigational drug to people under the supervision of qualified investigators. We conduct clinical trials under protocols detailing the trial objectives, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. We must submit each protocol to the FDA as part of the IND.

We conduct clinical trials typically in three sequential phases, but the phases may overlap or be combined. An independent review board, or IRB, must review and approve each trial before it can begin. Phase 1 includes the initial introduction of an IND into a small number of humans. These trials are closely monitored and may be conducted in patients, but are usually conducted in healthy volunteer subjects. These trials are designed to determine the metabolic and pharmacologic actions of the drug in humans and the side effects associated with increasing doses as well as, if possible, to gain early evidence on effectiveness. Phase 2

usually involves trials in a limited patient population to evaluate dosage tolerance and appropriate dosage, identify possible adverse effects and safety risks and preliminarily evaluate the efficacy of the drug for specific indications. Phase 3 trials are large trials used to further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. There can be no assurance that we or our licensees will successfully complete phase 1, phase 2 or phase 3 testing with respect to any therapeutic candidate within any specified period of time, if at all. Furthermore, clinical trials may be suspended at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. We and our licensees perform preclinical and clinical testing outside of the United States. The acceptability of the results of our preclinical and clinical testing by the FDA will be dependent upon adherence to applicable U.S. and foreign standards and requirements, including good laboratory practices, or GLP, Good Clinical Practices, or GCP, and the Declaration of Helsinki for protection of human subjects. Additionally, the FDA may require at least one pivotal clinical study to be conducted in the United States, in order to take into account medical practice and ethical diversity in the United States.

### NDAs and BLAs

After successful completion of the required clinical testing, a New Drug Application, or NDA, or in the case of certain biological products a Biological Product Application, or BLA, is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before product marketing may begin in the United States. The NDA/BLA must include the preclinical and clinical testing results and a compilation of detailed information relating to the product's pharmacology, toxicology, chemistry, manufacture and manufacturing controls. In certain cases, an application for marketing approval may include information regarding the safety and efficacy of a proposed drug that comes from trials not conducted by, or for, the applicant and for which trials the applicant has not obtained a specific right to reference. Such an application, known as a 505(b)(2) NDA, is permitted for new drug products that incorporate previously approved active ingredients, even if the proposed new drug incorporates an approved active ingredient in a novel formulation or for a new indication. A 505(b)(2) type application is not available for drugs subject to BLAs. As interpreted by the FDA, Section 505(b)(2) also permits the FDA to rely for such approvals on literature or on a finding by the FDA of safety and/or efficacy for a previously approved drug product. Under this interpretation, a 505(b)(2) NDA for changes to a previously approved drug product may rely on the FDA's finding of safety and efficacy of the previously approved product coupled with new clinical data and information needed by the FDA to support the change. NDAs submitted under 505(b)(2) are potentially subject to patent and non-patent exclusivity provisions which can block effective approval of the 505(b)(2) application until the applicable exclusivities have expired, which in the case of patents may be several years. The cost of preparing and submitting an NDA may be substantial. Under U.S. federal law, the submission of NDAs, including 505(b)(2) NDAs, is generally subject to substantial application user fees, and the manufacturer and/or sponsor under an NDA approved by the FDA is also subject to annual product and establishment user fees. These fees are typically increased annually. Currently, there are no fees assessed for an Abbreviated New Drug Application, or ANDA.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the FDA threshold determination that the NDA is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under U.S. federal law, the FDA has agreed to certain performance goals in the review of NDAs. Most such applications for non-priority drug products are to be reviewed within 10 months. The review process may be significantly extended by FDA requests for additional information or clarification. The FDA may also refer applications to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. This often, but not exclusively, occurs for novel drug products or drug products that present difficult questions of safety or efficacy. The FDA is not bound by the recommendation of an advisory committee.

Before approving an application, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve the application unless the FDA determines that the product is manufactured in substantial compliance with GMPs. If the FDA determines that the NDA or BLA is supported by adequate data and information, the FDA may issue an approval letter, or, in some cases, when the FDA desires some additional data or information an approvable letter. An approvable letter generally contains a statement of specific conditions that must be met to secure final approval of the application. Upon timely

compliance with the conditions stated in the approvable letter, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of approval, the FDA may require additional trials or post-approval testing and surveillance to monitor the drug's safety or efficacy, the adoption of risk evaluation and mitigation strategies, and may impose other conditions, including labeling and marketing restrictions on the use of the drug, which can materially affect its potential market and profitability. Once granted, product approvals may be withdrawn if compliance with regulatory standards for manufacturing and quality control are not maintained or if additional safety problems are identified following initial marketing.

If the FDA's evaluation of the NDA or BLA submission or manufacturing processes and facilities is not favorable, the FDA may refuse to approve the NDA or BLA and may issue a not approvable letter. The not approvable letter outlines major deficiencies in the submission and often requires substantial additional testing or information for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The Pediatric Research Equity Act, or PREA, requires NDAs (or NDA supplements) for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to contain results assessing the safety and efficacy for the claimed indication in all relevant pediatric subpopulations. Data to support dosing and administration also must be provided for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for the submission of results or full or partial waivers from the PREA requirements (for example, if the product is ready for approval in adults before pediatric studies are complete, if additional safety data is needed, among others).

### Postmarketing Requirements

Once an NDA or BLA is approved, the drug sponsor will be subject to certain post-approval requirements, including requirements for adverse event reporting, submission of periodic reports, manufacturing, labeling, packaging, advertising, promotion, distribution, record-keeping and other requirements. For example, the approval may be subject to limitations on the uses for which the product may be marketed or conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product or require the adoption of risk evaluation and mitigation strategies. In addition, the FDA requires the reporting of any adverse effects observed after the approval or marketing of a therapeutic candidate and such events could result in limitations on the use of such approved product or its withdrawal from the marketplace. Also, some types of changes to the approved product, such as manufacturing changes and labeling claims, are subject to further FDA review and approval. Additionally, the FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, the FDA requires substantiation of any claims of superiority of one product over another including, in many cases, requirements that such claims be proven by adequate and well controlled head-to-head clinical trials. To the extent that market acceptance of our therapeutic candidates may depend on their superiority over existing products, any restriction on our ability to advertise or otherwise promote claims of superiority, or any requirements to conduct additional expensive clinical trials to provide proof of such claims, could negatively affect the sales of our therapeutic candidates and our costs.

# Generic Competition

Once an NDA, including a 505(b)(2) NDA, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA, which relies on bioequivalence studies that compare the generic drug to a reference listed drug to support approval. Currently, ANDAs are not eligible for drugs covered by BLAs. Specifically, a generic drug that is the subject of an ANDA must be bioequivalent and have the same active ingredient(s), route of administration, dosage form, and strength, as well as the same labeling, with certain exceptions, as the listed drug. If the FDA deems that any of these requirements are not met, additional results may be necessary to seek approval.

ANDA applicants do not have to conduct extensive clinical trials to prove the safety or efficacy of the drug product. Rather, they are required to show that their drug is pharmaceutically equivalent to the innovator's drug and also conduct "bioequivalence" testing to show that the rate and extent by which the ANDA applicant's drug is absorbed does not differ significantly from the innovator product. Bioequivalence tests are typically in vivo studies in humans but they are smaller and less costly than the types of phase 3

trials required to obtain initial approval of a new drug. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, are listed as such by the FDA, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

With respect to NDAs, U.S. federal law provides for a period of three years of non-patent market exclusivity following the approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage, dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials, other than bioavailability studies, conducted by or for the sponsor. During this three-year period the FDA cannot grant effective approval of an ANDA or a 505(b)(2) NDA for the same conditions of approval under which the NDA was approved.

U.S. federal law also provides a period of five years following approval of a new chemical entity that is a drug containing no previously approved active ingredients, during which ANDAs for generic versions of such drugs, as well as 505(b)(2) NDAs, cannot be submitted unless the submission contains a certification that the listed patent is invalid or will not be infringed, in which case the submission may be made four years following the original product approval. If an ANDA or 505(b)(2) NDA applicant certifies that it believes one or more listed patents is invalid or not infringed, it is required to provide notice of its filing to the NDA sponsor and the patent holder. If the patent holder or exclusive patent licensee then initiates a suit for patent infringement against the ANDA or 505(b)(2) NDA sponsor within 45 days of receipt of the notice, the FDA cannot grant effective approval of the ANDA or 505(b)(2) NDA until either 30 months have passed or there has been a court decision holding that the patents in question are invalid or not infringed. If an infringement action is not brought within 45 days, the ANDA or 505(b)(2) NDA applicant may bring a declaratory judgment action to determine patent issues prior to marketing. If the ANDA or 505(b)(2) NDA applicant certifies as to the date on which the listed patents will expire, then the FDA cannot grant effective approval of the ANDA or 505(b) (2) NDA until those patents expire. The first ANDA(s) submitting substantially complete application(s) certifying that listed patents for a particular product are invalid or not infringed may qualify for a period of 180 days of marketing exclusivity, starting from the date of the first commercial marketing of the drug by the applicant, during which subsequently submitted ANDAs cannot be granted effective approval. The first ANDA applicant can forfeit its exclusivity under certain circumstances; for example, if it fails to market its product or meet other regulatory requirements within specified time periods.

From time to time, including presently, legislation is drafted and introduced in the U.S. Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of drug products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our therapeutic candidates. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of such changes, if any, may be.

# FDA Approval or Clearance of Medical Devices

In the United States, medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the controls the FDA determines necessary to reasonably ensure their safety and efficacy:

- Class I: general controls, such as labeling and adherence to Quality System Regulations, or QSRs;
- Class II: general controls, pre-market notification (510(k)), and specific controls such as performance standards, patient registries, and postmarket surveillance; and
- Class III: general controls and approval of a PMA.

A PMA application must provide a demonstration of safety and effectiveness, which generally requires extensive preclinical and clinical trial data. Information about the device and its components, device design, manufacturing and labeling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with QSR requirements, which govern testing, control, documentation and other aspects of quality assurance with respect to manufacturing. During the review period, an FDA advisory committee, typically a panel of clinicians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. The FDA is not bound by the advisory panel decision, but the FDA often follows

the panel's recommendation. If the FDA finds the information satisfactory, it will approve the PMA. The PMA can include postapproval conditions including, among other things, restrictions on labeling, promotion, sale and distribution, or requirements to do additional clinical studies post-approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorize certain modifications to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA. During the review of a PMA, the FDA may request more information or additional studies and may decide that the indications for which we seek approval or clearance should be limited.

If human clinical trials of a medical device are required and the device presents a significant risk, the sponsor of the trial must file an investigational device exemption, or IDE, application prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal and/or laboratory testing. If the IDE application is approved by the FDA and one or more institutional review boards, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more institutional review boards without separate approval from the FDA. Submission of an IDE does not give assurance that the FDA will approve the IDE and, if it is approved, the FDA may determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study indication or the rights, safety or welfare of human subjects. The trial also must comply with the FDA's IDE regulations and informed consent must be obtained from each subject.

# European Economic Area

A medicinal product may only be placed on the market in the European Economic Area, or EEA, composed of the 27 EU member states, plus Norway, Iceland and Lichtenstein, when a marketing authorization has been issued by the competent authority of a member state pursuant to Directive 2001/83/EC (as recently amended by Directive 2004/27/EC), or an authorization has been granted under the centralized procedure in accordance with Regulation (EC) No. 726/2004 or its predecessor, Regulation 2309/93. There are essentially three community procedures created under prevailing European pharmaceutical legislation that, if successfully completed, allow an applicant to place a medicinal product on the market in the EEA.

# Centralized Procedure

Regulation 726/2004/EC now governs the centralized procedure when a marketing authorization is granted by the European Commission, acting in its capacity as the European Licensing Authority on the advice of the European Medicines Agency, or EMEA. That authorization is valid throughout the entire community and directly or (as to Norway, Iceland and Liechtenstein) indirectly allows the applicant to place the product on the market in all member states of the EEA. The EMEA is the administrative body responsible for coordinating the existing scientific resources available in the member states for evaluation, supervision and pharmacovigilance of medicinal products. Certain medicinal products, as described in the Annex to Regulation 726/2004, must be authorized centrally. These are products that are developed by means of a biotechnological process in accordance with Paragraph 1 to the Annex to the Regulation. Medicinal products for human use containing a new active substance for which the therapeutic indication is the treatment of acquired immune deficiency syndrome, or AIDS, cancer, neurodegenerative disorder or diabetes must also be authorized centrally. Starting on May 20, 2008, the mandatory centralized procedure was extended to autoimmune diseases and other immune dysfunctions and viral diseases. Finally, all medicinal products that are designated as orphan medicinal products pursuant to Regulation 141/2000 must be authorized under the centralized procedure. An applicant may also opt for assessment through the centralized procedure if it can show that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization centrally is in the interests of patients at the community level. For each application submitted to the EMEA for scientific assessment, the EMEA is required to ensure that the opinion of the Committee for Medicinal Products for Human Use, or CHMP, is given within 210 days after receipt of a valid application. If the opinion is positive, the EMEA is required to send the opinion to the European Commission, which is

responsible for preparing the decision granting a marketing authorization. If the initial opinion of the CHMP is negative, the applicant is afforded an opportunity to seek a re-examination of the opinion. The CHMP is required to re-examine its opinion within 60 days following receipt of the request by the applicant. A refusal of a centralized marketing authorization constitutes a prohibition on placing the given medicinal product on the market in the community.

*Mutual Recognition and Decentralized Procedures.* With the exception of products that are authorized centrally, the competent authorities of the member states are responsible for granting marketing authorizations for medicinal products placed on their markets. If the applicant for a marketing authorization intends to market the same medicinal product in more than one member state, the applicant may seek an authorization progressively in the community under the mutual recognition or decentralized procedure. Mutual recognition is used if the medicinal product has already been authorized in a member state. In this case, the holder of this marketing authorization requests the member state where the authorization has been granted to act as reference member state by preparing an updated assessment report that is then used to facilitate mutual recognition of the existing authorization in the other member states in which approval is sought (the so-called concerned member state(s)). The reference member state must prepare an updated assessment report within 90 days of receipt of a valid application. This report together with the approved Summary of Product Characteristics, or SmPC (which sets out the conditions of use of the product), and a labeling and package leaflet are sent to the concerned member states for their consideration. The concerned member states are required to approve the assessment report, the SmPC and the labeling and package leaflet within 90 days of receipt of these documents. The total procedural time is 180 days.

The decentralized procedure is used in cases where the medicinal product has not received a marketing authorization in the EU at the time of application. The applicant requests a member state of its choice to act as reference member state to prepare an assessment report that is then used to facilitate agreement with the concerned member states and the grant of a national marketing authorization in all of these member states. In this procedure, the reference member state must prepare, for consideration by the concerned member states, the draft assessment report, a draft SmPC and a draft of the labeling and package leaflet within 120 days after receipt of a valid application. As in the case of mutual recognition, the concerned member states are required to approve these documents within 90 days of their receipt.

For both mutual recognition and decentralized procedures, if a concerned member state objects to the grant of a marketing authorization on the grounds of a potential serious risk to public health, it may raise a reasoned objection with the reference member state. The points of disagreement are in the first instance referred to the Co-ordination Group on Mutual Recognition and Decentralized Procedures, or CMD, to reach an agreement within 60 days of the communication of the points of disagreement. If member states fail to reach an agreement, then the matter is referred to the EMEA and CHMP for arbitration. The CHMP is required to deliver a reasoned opinion within 60 days of the date on which the matter is referred. The scientific opinion adopted by the CHMP forms the basis for a binding European Commission decision.

Irrespective of whether the medicinal product is assessed centrally, de-centrally or through a process of mutual recognition, the medicinal product must be manufactured in accordance with the principles of good manufacturing practice as set out in Directive 2003/94/EC and Volume 4 of the rules governing medicinal products in the European community. Moreover, community law requires the clinical results in support of clinical safety and efficacy to be based upon clinical trials conducted in the European community in compliance with the requirements of Directive 2001/20/EC, which implements good clinical practice in the conduct of clinical trials on medicinal products for human use. Clinical trials conducted outside the European community and used to support applications for marketing within the EU must have been conducted in a way consistent with the principles set out in Directive 2001/20/EC. The conduct of a clinical trial in the EU requires, pursuant to Directive 2001/20/EC, authorization by the relevant national competent authority where a trial takes place, and an ethics committee to have issued a favorable opinion in relation to the arrangements for the trial. It also requires that the sponsor of the trial, or a person authorized to act on his behalf in relation to the trial, be established in the community.

There are various types of applications for marketing authorizations:

*Full Applications*. A full application is one that is made under any of the community procedures described above and "stands alone" in the sense that it contains all of the particulars and information required by Article 8(3) of Directive 2001/83 (as amended) to allow the competent authority to assess the quality, safety and efficacy of the product and in particular the balance between benefit and risk. Article 8(3)(1) in particular refers to the need to present the results of the applicant's research on (1) pharmaceutical (physical-chemical, biological or microbiological) tests, (2) preclinical (toxicological and pharmacological) studies and (3) clinical trials in humans. The nature of these tests, studies and trials is explained in more detail in Annex I to Directive 2001/83/EC. Full applications would be required for products containing new active substances not previously approved by the competent authority, but may also be made for other products.

*Abridged Applications.* Article 10 of Directive 2001/83/EC contains exemptions from the requirement that the applicant provide the results of its own preclinical and clinical research. There are three regulatory routes for an applicant to seek an exemption from providing such results, namely (1) cross-referral to an innovator's results without consent of the innovator, (2) well established use according to published literature and (3) consent to refer to an existing dossier of research results filed by a previous applicant.

### Cross-referral to Innovator's Data

Articles 10(1) and 10(2)(b) of Directive 2001/83/EC provide the legal basis for an applicant to seek a marketing authorization on the basis that its product is a generic medicinal product (a copy) of a reference medicinal product that has already been authorized, in accordance with community provisions. A reference product is, in principle, an original product granted an authorization on the basis of a full dossier of particulars and information. This is the main exemption used by generic manufacturers for obtaining a marketing authorization for a copy product. The generic applicant is not required to provide the results of preclinical studies and of clinical trials if its product meets the definition of a generic medicinal product and the applicable regulatory results protection period for the results submitted by the innovator has expired. A generic medicinal product is defined as a medicinal product:

- having the same qualitative and quantitative composition in active substance as the reference medicinal product;
- having the same pharmaceutical form as the reference medicinal product; and
- whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

Applications in respect of a generic medicinal product cannot be made before the expiry of the protection period. Where the reference product was granted a national marketing authorization pursuant to an application made before October 30, 2005, the protection period is either six years or 10 years, depending upon the election of the particular member state concerned. Where the reference product was granted a marketing authorization centrally, pursuant to an application made before November 20, 2005, the protection period is 10 years. For applications made after these dates, Regulation 726/2004 and amendments to Directive 2001/83/EC provide for a harmonized protection period regardless of the approval route utilized. The harmonized protection period is in total 10 years, including eight years of research data protection and two years of marketing protection. The effect is that the originator's results can be the subject of a cross-referral application after eight years, but any resulting authorization cannot be exploited for a further two years. The rationale of this procedure is not that the competent authority does not have before it relevant tests and trials upon which to assess the efficacy and safety of the generic product, but that the relevant particulars can, if the research data protection period can be extended to 11 years where, in the first eight years post-authorization, the holder of the authorization obtains approval for a new indication assessed as offering a significant clinical benefit in comparison with existing products.

If the copy product does not meet the definition of a generic medicinal product or if certain types of changes occur in the active substance(s) or in the therapeutic indications, strength, pharmaceutical form or route of administration in relation to the reference medicinal product, Article 10(3) of Directive 2001/83/EC provides that the results of the appropriate preclinical studies or clinical trials must be provided by the applicant.

#### Well-established Medicinal Use

Under Article 10a of Directive 2001/83/EC, an applicant may, in substitution for the results of its own preclinical and clinical research, present detailed references to published literature demonstrating that the active substance(s) of a product have a wellestablished medicinal use within the community with recognized efficacy and an acceptable level of safety. The applicant is entitled to refer to a variety of different types of literature, including reports of clinical trials with the same active substance(s) and epidemiological studies that indicate that the constituent or constituents of the product have an acceptable safety/efficacy profile for a particular indication. However, use of the published literature exemption is restricted by stating that in no circumstances will constituents be treated as having a well-established use if they have been used for less than 10 years from the first systematic and documented use of the substance as a medicinal product in the community. Even after 10 years' systematic use, the threshold for well established medicinal use might not be met. European pharmaceutical law requires the competent authorities to consider the period over which a substance has been used, the amount of patient use of the substance, the degree of scientific interest in the use of the substance (as reflected in the scientific literature) and the coherence (consistency) of all the scientific assessments made in the literature. For this reason, different substances may reach the threshold for well-established use after different periods, but the minimum period is 10 years. If the applicant seeks approval of an entirely new therapeutic use compared with that to which the published preclinical literature refers, additional preclinical and/or clinical results would have to be provided.

### Informed Consent

Under Article 10c of Directive 2001/83/EC, following the grant of a marketing authorization the holder of such authorization may consent to a competent authority utilizing the pharmaceutical, preclinical and clinical documentation that it submitted to obtain approval for a medicinal product to assess a subsequent application relating to a medicinal product possessing the same qualitative and quantitative composition with respect to the active substances and the same pharmaceutical form.

# Law Relating to Pediatric Research

Regulation (EC) 1901/2006 (as amended by Regulation (EC) 1902/2006) was adopted on December 12, 2006. This Regulation governs the development of medicinal products for human use in order to meet the specific therapeutic needs of the pediatric population. It requires any application for marketing authorization made after July 26, 2008 in respect of a product not authorized in the European Community on January 26, 2007 (the time the Regulation entered into force), to include studies in children conducted in accordance with a pediatric investigation plan agreed to by the relevant European authorities, unless the product is subject to an agreed waiver or deferral. Waivers can be granted in certain circumstances where pediatric studies are not required or desirable. Deferrals can be granted in certain circumstances where the initiation or completion of pediatric studies should be deferred until appropriate studies in adults have been performed. Moreover, this regulation will impose the same obligation from January 26, 2009 on an applicant seeking approval of a new indication, pharmaceutical form or route of administration for a product already authorized and still protected by a supplementary protection certificate granted under Regulation (EEC) 1768/92 or by a patent that qualifies for the granting of such a supplementary protection certificate. The pediatric Regulation 1901/2006 also provides, subject to certain conditions, a reward for performing such pediatric studies, regardless of whether the pediatric results provided resulted in the grant of a pediatric indication. This reward comes in the form of an extension of six months to the supplementary protection certificate granted in respect of the product, unless the product is subject to orphan drug designation, in which case the 10-year market exclusivity period for such orphan products is extended to 12 years. Where the product is no longer covered by a patent or supplementary protection certificate, the applicant may make a separate application for a Pediatric Use Marketing Authorization, which, on approval, will provide 10 years' regulatory results and marketing protection for the pediatric results.

### Post-authorization Obligations

An authorization to market a medicinal product in the EU carries with it an obligation to comply with many post-authorization regulations relating to the marketing and other activities of authorization holders. These include requirements relating to adverse event reporting and other pharmacovigilance requirements, advertising, packaging and labeling, patient package leaflets, distribution and wholesale dealing. The regulations frequently operate within a criminal law framework and failure to comply with the requirements may not only affect the authorization, but also can lead to financial and other sanctions levied on the company in question and responsible officers.

# Approval of Medical Devices

In the 25 member states of the European Union there is a consolidated system for the authorization of medical devices. The European Union requires that manufacturers of medical products obtain the right to affix the CE mark to their products, which shows that the device has a Certificat de Conformité, before selling them in European Union member countries. The CE mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain the right to affix the CE mark to products, a manufacturer must obtain certification that its processes meet certain European quality standards, which vary according to the nature of the device. Compliance with the Medical Device Directive, as certified by a recognized European Notified Body, permits the manufacturer to affix the CE mark on its products and commercially distribute those products throughout the European Union without further conformance tests being required in other member states.

#### Israel

# Israel Ministry of the Environment — Toxin Permit

In accordance with the Israeli Dangerous Substance Law — 1993, the Ministry of the Environment is required to grant a permit in order to use toxic materials. Because we utilize toxic materials in the course of operation of our laboratories, we were required to apply for a permit to use these materials. Our current toxin permit will remain in effect until January 2012.

### Clinical Testing in Israel

In order to conduct clinical testing on humans in Israel, special authorization must first be obtained from the ethics committee and general manager of the institution in which the clinical studies are scheduled to be conducted, as required under the Guidelines for Clinical Trials in Human Subjects implemented pursuant to the Israeli Public Health Regulations (Clinical Trials in Human Subjects), as amended from time to time, and other applicable legislation. In certain circumstances, these regulations may also require authorization from the Israeli Ministry of Health, and in the case of genetic trials, special fertility trials and similar trials, an additional authorization of the overseeing institutional ethics committee. The institutional ethics committee must, among other things, evaluate the anticipated benefits that are likely to be derived from the project to determine if it justifies the risks and inconvenience to be inflicted on the human subjects, and the committee must ensure that adequate protection exists for the rights and safety of the participants as well as the accuracy of the information gathered in the course of the clinical testing. Since we intend to perform a portion of the clinical studies on certain of our therapeutic candidates in Israel, we will be required to obtain authorization from the ethics committee and general manager of each institution in which we intend to conduct our clinical trials, and to the extent required, the Israeli Ministry of Health.

### **Other Countries**

In addition to regulations in the United States, the European Union and Israel, we are subject to a variety of other regulations governing clinical trials and commercial sales and distribution of drugs in other countries. Whether or not our products receive approval from the FDA, approval of such products must be obtained by the comparable regulatory authorities of countries other than the United States before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials and product licensing vary greatly from country to country.

#### **Related Matters**

From time to time, legislation is drafted, introduced and passed in governmental bodies that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA or EMEA and other applicable regulatory bodies to which we are subject. In addition, regulations and guidance are often revised or reinterpreted by the national agency in ways that may significantly affect our business and our therapeutic candidates. It is impossible to predict whether such legislative changes will be enacted, whether FDA or EMEA regulations, guidance or interpretations will change, or what the impact of such changes, if any, may be. We may need to adapt our business and therapeutic candidates and products to changes that occur in the future.

# Israeli Government Programs

# Israel Office of the Chief Scientist

*Research and Development Grants.* A number of our therapeutic products have been financed, in part, through grants from the OCS in accordance with the Israeli Law for the Encouragement of Industrial Research and Development, 1984 and related regulations, or the Research Law. As of June 30, 2010, we have received approximately \$16.4 million in grants and loans from the OCS, including accrued interest, in the aggregate, which amount includes, among other payments, approximately \$5.0 million of OCS research and development grants for particular projects, and approximately \$11.4 million for our biotechnology incubator. Such amounts include approximately \$5.0 million of grants received in connection with terminated programs. We do not expect to be required to repay grants for terminated programs. Under the Research Law and the terms of the grants, royalties on the revenues derived from sales of products developed with the support of the OCS are payable to the Israeli government, generally at the rate of 3.0% during the first three years of repayment and 3.5% subsequently, although these terms are different in the event we out-license the products. The obligation to make these payments terminates upon repayment of the amount of the received grants as adjusted for fluctuation in the U.S. dollar/shekel exchange rate, plus any additional amounts as described below. The amounts received bear interest equal to the 12-month London Interbank Offered Rate applicable to dollar deposits that is published on the first business day of each calendar year.

Pursuant to the Research Law, recipients of grants from the OCS are prohibited from manufacturing products developed using OCS grants or derived from technology developed with OCS grants outside of the State of Israel and from transferring rights to manufacture such products outside of Israel. However, the OCS may, in special cases, approve the transfer of manufacture or of manufacturing rights of a product developed in an approved program or which results therefrom, outside of Israel. If we were to receive approval to manufacture or to transfer the rights to manufacture our products developed with OCS grants outside of Israel, we would be required to pay an increased total amount of royalties (possibly up to 300% of the grant amounts plus interest), depending on the portion of total manufacturing that is performed outside of Israel. In addition, the royalty rate applicable to us could possibly increase. Such increased royalties constitute the total repayment amount required in connection with the transfer of manufacturing rights of OCS funded products outside Israel. The Research Law does enable companies to seek prior approval for conducting manufacturing activities outside of Israel without being subject to increased royalties; however, the OCS rarely grants such approval.

In addition, under the Research Law, we are prohibited from transferring our OCS financed technologies, technologies derived therefrom and related intellectual property rights outside of Israel except under limited circumstances and only with the approval of the OCS. We may not receive the required approvals for any proposed transfer and, if received, we may be required to pay the OCS a portion of the consideration that we receive upon any sale of such technology to a non-Israeli entity. The scope of the support received, the royalties that we may have already paid to the OCS, the amount of time that has elapsed between the date on which the technology was transferred and the date on which the OCS grants were received and the sale price and the form of transaction will be taken into account in order to calculate the amount of the payment to the OCS. In addition, approval of the transfer of technology to residents of Israel is required, and may be granted in specific circumstances, only if the recipient agrees to abide by the provisions of applicable laws, including the restrictions on the transfer of know-how and the obligation to pay royalties. No assurances can be made that approval to any such transfer, if requested, will be granted. The out-licensing of OCS-supported technologies may be deemed by the OCS to be a transfer of technology.



The State of Israel does not own intellectual property rights in technology developed with OCS funding and there is no restriction on the export of products manufactured using technology developed with OCS funding. The technology is, however, subject to transfer of technology and manufacturing rights restrictions as described above. For a description of such restrictions, please see "Risk Factors — Risks Relating to Our Operations in Israel." OCS approval is not required for the export of any products resulting from the research or development or for the licensing of any technology in the ordinary course of business.

*Biotechnology Incubator Program.* In 2001, the OCS launched a biotechnology incubator program for advancing Israel's biotechnology industry. The program was significantly changed by the OCS in May 2004, pursuant to which the OCS invited companies to submit proposals to establish and operate OCS-funded biotechnology incubators to provide a physical, organized and professional platform for commercializing biotechnological research and development projects. We submitted a proposal to operate a biotechnology incubator, and our proposal was accepted by the OCS. Accordingly, we entered into the incubator agreement with the OCS in January 2005. We formed BIJ L.P. to act as the incubator entity. Our wholly-owned subsidiary, BIJ Ltd., is the general partner of BIJ L.P. and owns the remaining 99% of BIJ L.P.'s partnership interests.

As of June 30, 2010, we have received approximately \$11.4 million from the OCS under the incubator agreement to fund 19 different development projects, 14 of which have terminated. Of our 10 current development projects, four have been funded under the incubator agreement, including BL-1021, BL-1040, BL-2030 and BL-4040. Other projects may be funded by the OCS outside of the incubator agreement. For additional information on the incubator agreement, see "Business — Other Material Agreements."

### Israel Ministry of Health

Israel's Ministry of Health, which regulates medical testing, has adopted protocols that correspond, generally, to those of the FDA and the European Medicines Agency, making it comparatively straightforward for studies conducted in Israel to satisfy FDA and the European Medicines Agency requirements, thereby enabling medical technologies subjected to clinical trials in Israel to reach U.S. and E.U. commercial markets in an expedited fashion. Many members of Israel's medical community have earned international prestige in their chosen fields of expertise and routinely collaborate, teach and lecture at leading medical centers throughout the world. Israel also has free trade agreements with the United States and the European Union.

# MANAGEMENT

# **Executive Officers and Directors**

The following table sets forth information for our executive officers and directors as of the date of this prospectus. Unless otherwise stated, the address for our directors and officers is c/o BioLineRx Ltd., P.O. Box 45158, 19 Hartum Street, Jerusalem 91450, Israel.

Name	Age	Position(s)
Kinneret Savitsky, Ph.D.	43	Chief Executive Officer, Director
Philip Serlin	50	Chief Financial Officer and Chief Operating Officer
Moshe Phillip, M.D.	56	Vice President of Medical Affairs and Senior Clinical Advisor
Nir Gamliel	43	Vice President of Business Development of BioLineRx USA Inc.
Leah Klapper, Ph.D.	46	General Manager, BioLine Innovations Jerusalem
Aharon Schwartz, Ph.D.	68	Chairman of the Board
Raphael Hofstein, Ph.D.	61	Director
Yakov Friedman	42	Director
Avraham Molcho, M.D.	53	External Director
Nurit Benjamini	43	External Director
Michael J. Anghel, Ph.D.	71	Director

*Kinneret Savitsky*, *Ph.D.*, has served as our Chief Executive Officer and a director since January 2010. Prior to becoming our Chief Executive Officer, from 2004 through 2010, she served as the General Manager of BIJ, our wholly-owned subsidiary. Prior to joining BIJ, Dr. Savitsky served as the Vice President of Biology of Compugen Ltd. (NASDAQ: CGEN), from 2000 to 2004, and held other senior positions at Compugen from 1997 through 2000. Dr. Savitsky received her Ph.D. from Tel Aviv University, a Master's degree in Human Genetics from Tel Aviv University and a B.Sc. in Biology from The Hebrew University of Jerusalem.

*Philip Serlin* has been our Chief Financial Officer and Chief Operating Officer since May 2009. From January 2008 to August 2008, Mr. Serlin served as the Chief Financial Officer and Chief Operating Officer of Kayote Networks Inc. From January 2006 to December 2007, he served as the Chief Financial Officer of Tescom Software Systems Testing Ltd. (TASE:TSCM), an IT services company publicly traded in both Tel Aviv and London. His background also includes senior positions at Chiaro Networks Ltd. and at Deloitte, where he was head of the SEC and U.S. Accounting Department at the National Office in Tel Aviv, as well as seven years at the SEC at its Washington, D.C., headquarters. Mr. Serlin serves on the Board of Directors and audit committee of Vringo, Inc. (AMEX: VRNG). Mr. Serlin is a CPA and holds a B.Sc. in Accounting from Yeshiva University and a Master's degree in Economics and Public Policy from The George Washington University.

*Moshe Phillip, M.D.*, has been our Vice President of Medical Affairs and Senior Clinical Advisor and a member of our Scientific Advisory Board since 2004. Professor Phillip is the Director of the Institute for Endocrinology and Diabetes of the Israel National Center for Childhood Diabetes at the Schneider Children's Medical Center of Israel, has served as the Vice Dean and Head of School for Continuing Medical Education and currently is the Vice Dean for Research and Development at the Sackler School of Medical Education at Tel Aviv University. Professor Phillip served as the Chairman of the Israel Diabetes Association's Committee for Type 1 Diabetes, serves as the Chair of Type 1 Diabetes in the Diabetes National Councils of Health and as a member of the Pediatric National Council of Health. Professor Phillip is also on the editorial board of three medical journals,

including Pediatric Diabetes and Hormone Research. Since 2008, Professor Phillip has served as a director of CGU<sup>3</sup>, a privatelyheld company. Professor Phillip holds an M.D. from the Ben Gurion University of the Negev and received a fellowship in pediatric endocrinology at the University of Maryland School of Medicine.

*Nir Gamliel* has served as Vice President of Business Development of BioLineRx USA since January 2008. Mr. Gamliel brings 16 years of experience in the healthcare industry to BioLineRx USA. Mr. Gamliel was Vice President of Sales and Marketing of the U.S. office of BSP, Inc. (Biological Signal Processing, Inc.), a cardiology diagnostics company (TASE:BSP). From 2001 through 2006, Mr. Gamliel

served as Vice President of Sales at Compugen USA, Inc. (NASDAQ:CGEN), a drug discovery company. He also served as Sales & Marketing Manager for Europe at Voltaire Ltd. (NASDAQ: VOLT), a software company, and held a Franchise Manager position at Johnson & Johnson Medical Israel. Mr. Gamliel holds a B.Sc. in Biology from Bar Ilan University.

*Leah Klapper, Ph.D.*, has served as the General Manager of BIJ since January 2010. Prior to that, from 2004 through 2010, she served as Vice President of Preclinical development of BIJ. From 2001 through 2005, Dr. Klapper served as Vice President of Research and Development at CureTech Ltd., a biotechnology company developing novel immune-modulating molecules, where she founded the research laboratory and led the company from the bench to clinical studies. Dr. Klapper gained extensive post-doctoral training at the Fred Hutchinson Cancer Research Center in Seattle Washington. Dr. Klapper received her Ph.D. from the Weizmann Institute, her M.Sc. from the Department of Pharmacology at Tel Aviv University and a B.Sc. in Life Sciences from Tel Aviv University.

*Aharon Schwartz, Ph.D.*, has served as the Chairman of our Board of Directors since 2003. He has been the Vice President, Strategic Business Planning and New Ventures, of Teva since 1975. Dr. Schwartz also served as Chairman of DenX Ltd. and Immudar. He is currently a non-executive member of the boards of numerous life science companies, including Clal Biotechnology Industries Ltd. (TASE:CBI), Peptor Ltd., Proneuron Biotechnologies, Inc. and TransPharma Medical Ltd. Dr. Schwartz received his Ph.D. in organic chemistry from the Weizmann Institute, his M.Sc. in organic chemistry from the Technion Institute of Technology and a B.Sc. in chemistry and physics from the Hebrew University.

*Raphael Hofstein, Ph.D.*, has served on our Board of Directors since 2004, and has served on our Audit Committee since 2007. Dr. Hofstein served as the President and Chief Executive Officer of MaRS Innovation since June 2009. From 2005 through June 2009, Dr. Hofstein was the President and Chief Executive Officer of Hadasit Ltd., or Hadasit, the technology transfer company of Hadassah Hospital. He has served as chairman of the board of directors of Hadasit since 2006. Prior to joining Hadasit, Dr. Hofstein was the President of Mindsense Biosystems Ltd. and the Business Unit Director of Ecogen Inc. and has held a variety of other positions, including manager of R&D and chief of immunochemistry at the International Genetic Science Partnership. Dr. Hofstein serves on the board of directors of numerous companies, including Hadasit Bio-Holdings Ltd. (TASE:HDST), Evalenz Ltd. (TASE:EXEN) and Evogene Ltd. (TASE:EVGN). Dr. Hofstein received his Ph.D. and M.Sc. from the Weizmann Institute of Science, and his B.Sc. in chemistry and physics from the Hebrew University in Jerusalem. Dr. Hofstein completed postdoctoral training at Harvard Medical School in both the departments of biological chemistry and neurobiology.

*Yakov Friedman* has served on our Board of Directors since 2007. Mr. Friedman has worked as a financial analyst and trader for Friedberg Mercantile Group since 2001. Mr. Friedman serves on the board of directors and as treasurer or secretary of a number of charities and not-for-profit organizations. Mr. Friedman holds an LLB from Osgoode Hall Law School of York University, a BAS in Administrative Studies and an MBA in Finance from York University.

*Avraham Molcho, M.D., MBA*, has served as an external director on our Board of Directors and the Audit Committee of our Board since July 2010. Dr. Molcho is the Founder and Chairman of Biologic Design, a technology platform that encourages human antibody discoveries, and is a venture partner at Forbion Capital Partners, a Dutch life sciences venture capital firm. He currently serves on the board of directors of NiTi Surgical Solutions Ltd., Pathway Medical Technologies, Inc. and Circulite Inc., privatelyheld life science companies. From 2001 through 2006, Dr. Molcho was a managing director and the head of life sciences of Giza Venture Capital and, in that capacity, was involved in the founding of our company. From 2006 through 2008, Dr. Molcho served as the Chief Executive Officer and Chairman of Neovasc Medical, a privately-held Israeli medical device company. He was also the Deputy Director General of Abarbanel Mental Health Center, the largest acute psychiatric hospital in Israel, from 1999 to 2001. Dr. Molcho holds an M.D. from Tel-Aviv University School of Medicine and an MBA from Tel-Aviv University Recanati Business School.

*Nurit Benjamini, MBA*, has served as an external director on our Board of Directors and as the chairman of the Audit Committee of our Board of Directors since July 2010. Since 2007, Ms. Benjamini has served as the Chief Financial Officer of CopperGate Communications Ltd., a system-on-chip company that develops, markets and sells chipsets for the home networking and MDU/MTU Broadband Access markets,

since 2007. CopperGate was acquired by Sigma Designs, Inc. in November 2009. From 2000 through 2007, Ms. Benjamini served as the Chief Financial Officer of Compugen Ltd. (NASDAQ: CGEN). Prior to that, from 1998 through 2000, Ms. Benjamini served as the Chief Financial Officer of Phone-Or Ltd. and from 1993 through 1998, Ms. Benjamini served as the Chief Financial Officer of Aladdin Knowledge Systems Ltd. Ms. Benjamini serves on the board of directors, and as chairperson of the audit committee, of Allot Communications Ltd. (NASDAQ:ALLT). Ms. Benjamini holds a B.A. in Economics and Business and an M.B.A. in Finance, both from Bar Ilan University, Israel.

Michael J. Anghel, Ph.D., has served on our Board of Directors since September 2010. From 1977 to 1999, he led the Discount Investment Corporation Ltd. (of the IDB Group) activities in the fields of technology and communications. Dr. Anghel was instrumental in founding Tevel, one of the first Israeli cable television operators and later in founding Cellcom Israel Ltd. (NYSE:CEL) — the second Israeli cellular operator. In 1999, he founded CAP Ventures, an advanced technology investment company. From 2004 to 2005, Dr. Anghel served as CEO of DCM, the investment banking arm of the Israel Discount Bank (TASE:DSCT). He has been involved in various technology enterprises and has served on the Boards of Directors of various major Israeli corporations and financial institutions including Elron Electronic Industries Ltd. (TASE:ELRN), Elbit Systems Ltd. (NASDAQ:ESLT, TASE:ESLT), Nice Systems (NASDAQ: NICE), Gilat Satellite Networks Ltd. (NASDAQ:GILT), American Israeli Paper Mills (now Hadera Paper Ltd. (AMEX:AIP)), Maalot (the Israeli affiliate of Standard and Poor's) and Hapoalim Capital Markets. He currently serves on the Boards of Directors of Partner Communications Company, Ltd. (NASDAQ:PTNR, TASE:PTNR), Syneron Medical Ltd. (NASDAO:ELOS), Evogene Ltd. (TASE:EVGN), Gravity Visual Effects and Design Ltd., Dan Hotels Ltd. (TASE:DANH), Orbotech Ltd. (NASDAQ:ORBK, GSM:ORBK) and the Strauss-Group Ltd. (TASE:STRS). He is also the chairman of the Center for Educational Technology. Prior to launching his business career, Dr. Anghel served as a full-time member of the Recanati Graduate School of Business Administration of the Tel Aviv University, where he taught finance and corporate strategy. He currently serves as Chairman of the Tel Aviv University's Executive Program. Dr. Anghel holds a B.A. (Economics) from the Hebrew University in Jerusalem and an MBA. and Ph.D. (Finance) from Columbia University, New York.

# **Compensation of Executive Officers and Directors**

# **Employment Agreements**

We have entered into written employment agreements with each of our executive officers. All of these agreements contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable law.

In addition, we have entered into agreements with each executive officer and director pursuant to which we have agreed to indemnify each of them to the fullest extent permitted by law, including with respect to liabilities resulting from this offering, to the extent that these liabilities are not covered by directors and officers insurance.

# Director Compensation

Under the Israeli Companies Law, 5754-1999, or the Israeli Companies Law, external directors are entitled to fixed annual compensation and to an additional payment for each meeting attended. We currently pay our external directors, Avraham Molcho, M.D. and Nurit Benjamini, an annual fee of NIS 77,000 or \$19,871, and a per meeting fee of NIS 3,850, or \$994. For the year ended December 31, 2009, the aggregate direct compensation that we paid to Gil Bianco and Ilan Leviteh, then our external directors, for their services as our directors, as a group was NIS 339,000, or \$87,484. In addition, in 2010, each of Avraham Molcho, M.D. and Nurit Benjamini received a grant of 50,000 options to purchase ordinary shares, which options were subject to shareholder approval which was duly obtained. These fees are subject to the approval of our shareholders in accordance with the Israeli Companies Law and are currently the maximum fees allowed pursuant to applicable regulations under the Israeli Companies Law. The compensation of our external directors is determined at the time of their election. In November 2009, we began paying Raphael Hofstein for his services as a director and in September 2010, we began paying Michael Anghel for his services as a director. The aggregate direct compensation that we paid all of our directors, as a group, for the year ended December 31, 2009, was NIS 464,000, or \$119,742.

There are no service contracts between our directors and us. We have employment agreements with certain of our executive officers, as described herein.

Under applicable Israeli regulations, a publicly-traded Israeli company is required to disclose the annual compensation paid by or on behalf of the company to each of the five highest paid senior officers of the company or its subsidiaries. In addition, the company is required to disclose the compensation paid by the company to interested parties (including directors). We have disclosed such information in our annual report for the year 2009, published on March 25, 2010 and filed with the Tel Aviv Stock Exchange, and reported that other than Gil Bianco and Ilan Leviteh (each of which served as our directors until July 2010), Tamar Howson (who served as a director until June 10, 2009), Raphael Hofstein and Morris Laster (who served as a director until August 17, 2010), no other directors received compensation from us for their services. The following is a table showing the compensation received by each of the above-mentioned directors during the year ended December 31, 2009:

Name of Director	Remuneration	Monetary Value of the Options/ Shares Granted	Salary and Related Payments	Bonus
		(amounts in		
Morris C. Laster <sup>(1)</sup>	_	1,773,000	1,136,000	150,000 <sup>(1)</sup>
Gil Bianco	170,000	145,000		
Ilan Leviteh	169,000	145,000		
Tamar Howson	73,000	—		
Raphael Hofstein	10,000	_		

### (1) Dr. Laster served on our Board of Directors until August 17, 2010.

In addition to the above, we have granted Raphael Hofstein options to purchase 200,000 of our ordinary shares. In 2010, our Board of Directors had approved, subject to shareholder approval, the grant of options to purchase 200,000 of our ordinary shares to each of Gil Bianco and Ilan Leviteh, subject to their reelection for a new three-year term as external directors. The shareholders reelected Gil Bianco and Ilan Leviteh in May 2010 but did not approve the option grants. Gil Bianco and Ilan Leviteh resigned in July 2010 and Dr. Molcho and Ms. Benjamini were subsequently elected to serve as external directors.

### Employment Agreement with Kinneret Savitsky

Dr. Savitsky began serving as our Chief Executive Officer on January 2, 2010. Prior to becoming our Chief Executive Officer, from 2004 through 2010, she served as the general manager of BIJ L.P., our wholly-owned subsidiary. In connection with her appointment as Chief Executive Officer, we amended Dr. Savitsky's employment agreement. In accordance with the amended employment agreement, Dr. Savitsky is entitled to a gross monthly salary of approximately NIS 70,000, an allocation to a manager's insurance policy equivalent to 13.33% of her gross monthly salary and 7.5% of her gross monthly salary (but not to exceed approximately NIS 1,150 per month) for a study fund. Five percent of her gross monthly salary is deducted for the manager's insurance policy and 2.5% (but not to exceed approximately NIS 400 per month) is deducted for the study fund. Dr. Savitsky is also entitled to reimbursement for vehicle maintenance costs and reasonable expenses. Dr. Savitsky's annual salary, including all accompanying benefits, was approximately NIS 1,011,000 during the year ended December 31, 2009. In addition to the foregoing, under the amended employment agreement, BioLineRx is the employer, not BIJ L.P.

On November 24, 2009, we granted Dr. Savitsky new options to purchase 500,000 ordinary shares, which grant was approved by our shareholders on January 14, 2010. In addition, pursuant to her employment agreement, and in accordance with our stock option plan, Dr. Savitsky is also entitled to receive grants of restricted shares and/or options exercisable into our ordinary shares from time to time. As of August 31, 2010, we have granted to Dr. Savitsky options to purchase 1,525,288 ordinary shares, 980,534 of which have vested or will vest within 60 days of such date. On February 24, 2010, our Board of Directors, upon the recommendation of our Audit Committee, approved the payment to Dr. Savitsky of a bonus for 2009 equal to NIS 125,000, which payment was approved by our shareholders in May 2010.

In accordance with our stock option plan, Dr. Savitsky's options vest over a period of four years from the applicable grant date. If we terminate the employment relationship with Dr. Savitsky for cause, all of Dr. Savitsky's vested and unvested options shall terminate immediately. Upon termination of employment for any other reason (other than death or disability), vested options may be exercised within 90 days of termination of employment, unless otherwise determined by the Audit Committee or the Board of Directors. If Dr. Savitsky is no longer able to work due to death or permanent disability, then 50% of all of her unvested options shall be deemed fully vested, and any vested options shall be exercisable by Dr. Savitsky or her estate for 12 months following her death or disability. In the event of a merger, consolidation, reorganization, sale or transfer of all or substantially all of our ordinary shares, or sale or transfer of all or substantially all of our assets, Dr. Savitsky's outstanding options may be assumed by the successor company or an affiliate thereof or securities of such company may be substituted for the options. If the successor company does not assume or substitute for Dr. Savitsky's outstanding options, then Dr. Savitsky's unvested options will immediately vest as of the date which is 10 days before the effective date of the applicable transaction, provided that Dr. Savitsky commits to remain employed with the successor company for one year following the effective date of the transaction. Assumed or substituted options that are scheduled to vest more than one year after the closing of the applicable transaction shall have their vesting schedules accelerated by one year, provided that if any such acceleration would result in an option becoming vested prior to the one year from the closing date of the applicable transaction, such option will vest on the first anniversary of the closing of the applicable transaction. If Dr. Savitsky's employment with the successor company (or an affiliate) is terminated by the successor company (or an affiliate) without cause within one year of the closing of a transaction, all outstanding options assumed or substituted by the successor company shall immediately vest in full. If we effect a voluntary liquidation or dissolution, all of Dr. Savitsky's unexercised vested options and any unvested options will automatically terminate.

# Employment Agreement with Philip Serlin

Philip Serlin began serving as our Chief Financial Officer and Chief Operating Officer on May 24, 2009. Mr. Serlin's current gross monthly salary is NIS 47,250. In accordance with his employment agreement, Mr. Serlin is entitled to an allocation to a manager's insurance policy equivalent to 13.33% of his gross monthly salary and 7.5% of his gross monthly salary for a study fund. Five percent of his gross monthly salary is deducted for the manager's insurance policy and 2.5% is deducted for the study fund. Mr. Serlin is also entitled to reimbursement for vehicle maintenance costs and reasonable expenses.

In addition, pursuant to his employment agreement, and in accordance with our stock option plan, Mr. Serlin is also entitled to receive options exercisable into our ordinary shares from time to time. As of August 31, 2010, we have granted him options to purchase 554,200 ordinary shares in the aggregate. In accordance with our stock option plan, Mr. Serlin's options vest over a period of four years from the applicable grant date. If we terminate the employment relationship with Mr. Serlin for cause, all of Mr. Serlin's vested and unvested options shall terminate immediately. Upon termination of employment for any other reason (other than death or disability), vested options may be exercised within 90 days of termination of employment, unless otherwise determined by the Audit Committee or the Board of Directors. If Mr. Serlin is no longer able to work due to death or permanent disability, then 50% of all of his unvested options shall be deemed fully vested, and any vested options shall be exercisable by Mr. Serlin or his estate for 12 months following his death or disability. If we complete a merger, consolidation, reorganization, sale or transfer of all or substantially all of our ordinary shares, or sale or transfer of all or substantially all of our assets, Mr. Serlin's outstanding options may be assumed by the successor company or an affiliate thereof or securities of such company may be substituted for the options. If the successor company does not assume or substitute for Mr. Serlin's outstanding options, then Mr. Serlin's unvested options will immediately vest as of the date which is 10 days before the effective date of the applicable transaction, provided that Mr. Serlin commits to remain employed with the successor company for one year following the effective date of the transaction. Assumed or substituted options that are scheduled to vest more than one year after the closing of the applicable transaction shall have their vesting schedules accelerated by one year, provided that if any such acceleration would result in an option becoming vested prior to the one year from the closing date of the applicable transaction, such option will vest on the first anniversary of the closing of the applicable transaction. If Mr. Serlin's employment with the successor company (or an affiliate) is terminated by the successor company (or an affiliate) without cause within one year of the closing of a transaction, all

outstanding options assumed or substituted by the successor company shall immediately vest in full. If we effect a voluntary liquidation or dissolution, all of Mr. Serlin's unexercised vested options and any unvested options will automatically terminate.

On February 24, 2010, our Board of Directors approved the payment to Mr. Serlin of a bonus for 2009 equal to NIS 105,000.

# Employment Agreement with Moshe Phillip

Moshe Phillip has served as our Vice President of Medical Affairs and Senior Clinical Advisor since January 7, 2004. Dr. Phillip's current gross monthly salary is NIS 51,500. In accordance with his employment agreement, Dr. Phillip is entitled to an allocation to a manager's insurance policy equivalent to 13.33% of his gross monthly salary and 7.5% of his gross monthly salary for a study fund. Five percent of his gross monthly salary is deducted for the manager's insurance policy. Dr. Phillip is also entitled to reimbursement for vehicle maintenance costs and reasonable expenses.

In addition, pursuant to his employment agreement, and in accordance with our stock option plan, Dr. Phillip is also entitled to receive options exercisable into our ordinary shares from time to time. As of August 31, 2010, we have granted to Dr. Phillip options to purchase 1,104,474 ordinary shares in the aggregate, 696,755 of which have vested or will vest within 60 days of such date. In accordance with our stock option plan, Dr. Phillip's options vest over a period of four years from the applicable grant date. If we terminate the employment relationship with Dr. Phillip for cause, all of Dr. Phillip's vested and unvested options shall terminate immediately. Upon termination of employment for any other reason (other than death or disability), vested options may be exercised within 90 days of termination of employment, unless otherwise determined by the Audit Committee or the Board of Directors. If Dr. Phillip is no longer able to work due to death or permanent disability, then 50% of all of his unvested options shall be deemed fully vested, and any vested options shall be exercisable by Dr. Phillip or his estate for 12 months following his death or disability. In the event of a merger, consolidation, reorganization, sale or transfer of all or substantially all of our ordinary shares, or sale or transfer of all or substantially all of our assets, Dr. Phillip's outstanding options may be assumed by the successor company or an affiliate thereof or securities of such company may be substituted for the options. If the successor company does not assume or substitute for Dr. Phillip's outstanding options, then Dr. Phillip's unvested options will immediately vest as of the date which is 10 days before the effective date of the applicable transaction, provided that Dr. Phillip commits to remain employed with the successor company for one year following the effective date of the transaction. Assumed or substituted options that are scheduled to vest more than one year after the closing of the applicable transaction shall have their vesting schedules accelerated by one year, provided that if any such acceleration would result in an option becoming vested prior to the one year from the closing date of the applicable transaction, such option will vest on the first anniversary of the closing of the applicable transaction. If Dr. Phillip's employment with the successor company (or an affiliate) is terminated by the successor company (or an affiliate) without cause within one year of the closing of a transaction, all outstanding options assumed or substituted by the successor company shall immediately vest in full. If we effect a voluntary liquidation or dissolution, all of Dr. Phillip's unexercised vested options and any unvested options will automatically terminate.

On February 24, 2010, our Board of Directors approved the payment to Dr. Phillip of a bonus for 2009 equal to NIS 105,000.

### Employment Agreement with Nir Gamliel

Nir Gamliel has served as the Vice President of Business Development of BioLineRx USA Inc., our wholly-owned subsidiary, since January 2, 2007. Mr. Gamliel's current gross annual salary is \$178,500. In accordance with his employment agreement, Mr. Gamliel is also entitled to reimbursement for vehicle maintenance costs and reasonable expenses.

Mr. Gamliel is entitled to an additional bonus plan that is based upon milestones and is under the discretion of our Board of Directors. The bonus terms are as follows: a bonus for 2008 of up to 25% of his base salary if Mr. Gamliel achieves certain milestones, including, among others, creating potentially lasting connections with global pharmaceutical companies. For 2009, Mr. Gamliel is entitled to a bonus to be determined by our Board of Directors of up to 25% of his base salary if Mr. Gamliel achieves certain

milestones as determined by our Board of Directors. In addition, Mr. Gamliel is entitled to a bonus of up to 35% of his base salary for his contribution to "deal execution," as this term is defined from time to time by us and Mr. Gamliel. In accordance with his bonus plan, Mr. Gamliel received a bonus of \$42,500 in 2008 and \$102,000 in 2009. Mr. Gamliel is also entitled to the bonuses granted to all of our employees, from time to time. We or Mr. Gamliel may terminate Mr. Gamliel's employment upon 30 days' notice. If we terminate his employment, Mr. Gamliel will be entitled to severance pay equal to three months' base salary.

In addition, pursuant to his employment agreement, and in accordance with our stock option plan, Mr. Gamliel is also entitled to receive options exercisable into our ordinary shares from time to time. As of August 31, 2010, we have granted him options to purchase 605,390 ordinary shares, in the aggregate, 75,000 of which have vested or will vest within 60 days of such date. In accordance with our stock option plan, Mr. Gamliel's options vest over a period of four years from the applicable grant date. If we terminate the employment relationship with Mr. Gamliel for cause, all of Mr. Gamliel's vested and unvested options shall terminate immediately. Upon termination of employment for any other reason (other than death or disability), vested options may be exercised within 90 days of termination of employment, unless otherwise determined by the Audit Committee or the Board of Directors. If Mr. Gamliel is no longer able to work due to death or permanent disability, then 50% of all of his unvested options shall be deemed fully vested, and any vested options shall be exercisable by Mr. Gamliel or his estate for 12 months following his death or disability. If we complete a merger, consolidation, reorganization, sale or transfer of all or substantially all of our ordinary shares, or sale or transfer of all or substantially all of our assets, Mr. Gamliel's outstanding options may be assumed by the successor company or an affiliate thereof or securities of such company may be substituted for the options. If the successor company does not assume or substitute for Mr. Gamliel's outstanding options, then Mr. Gamliel's unvested options will immediately vest as of the date which is 10 days before the effective date of the applicable transaction, provided that Mr. Gamliel commits to remain employed with the successor company for one year following the effective date of the transaction. Assumed or substituted options that are scheduled to vest more than one year after the closing of the applicable transaction shall have their vesting schedules accelerated by one year, provided that if any such acceleration would result in an option becoming vested prior to the one year from the closing date of the applicable transaction, such option will vest on the first anniversary of the closing of the applicable transaction. If Mr. Gamliel's employment with the successor company (or an affiliate) is terminated by the successor company (or an affiliate) without cause within one year of the closing of a transaction, all outstanding options assumed or substituted by the successor company shall immediately vest in full. If we effect a voluntary liquidation or dissolution, all of Mr. Gamliel's unexercised vested options and any unvested options will automatically terminate.

On February 24, 2010, our Board of Directors approved the payment to Mr. Gamliel of a bonus for 2009 equal to NIS 105,000. The bonus was part of a company-wide bonus allocation. In addition, on August 31, 2010, our Board of Directors approved the payment to Mr. Gamliel of a cash bonus equal to \$62,475 due to his efforts in connection with our out-licensing agreement with Cypress Bioscience.

### Employment Agreement with Leah Klapper, Ph.D.

Leah Klapper began serving as the General Manager of BIJ in January 2010. Dr. Klapper's current gross monthly salary is NIS 45,000. In accordance with her employment agreement, Dr. Klapper is entitled to an allocation to a manager's insurance policy equivalent to 13.33% of her gross monthly salary and 7.5% of her gross monthly salary (but not to exceed approximately NIS 1,150 per month) for a study fund. Five percent of her gross monthly salary is deducted for the manager's insurance policy and 2.5% (but not to exceed approximately NIS 400 per month) is deducted for the study fund. Dr. Klapper is also entitled to reimbursement for vehicle maintenance costs and reasonable expenses.

In addition, pursuant to her employment agreement, and in accordance with our stock option plan, Dr. Klapper is also entitled to receive options exercisable into our ordinary shares from time to time. As of August 31, 2010, we have granted her options to purchase 393,062 ordinary shares in the aggregate, 126,049 of which have vested or will vest within 60 days of April 1, 2010. In accordance with our stock, option plan, Dr. Klapper's options vest over a period of four years from the applicable grant date. If we terminate the employment relationship with Dr. Klapper for cause, all of Dr. Klapper's vested and unvested options shall terminate immediately. Upon termination of employment for any other reason (other than death or disability), vested options may be exercised within 90 days of termination of employment, unless otherwise determined

by the Audit Committee or the Board of Directors. If Dr. Klapper is no longer able to work due to death or permanent disability, then 50% of all of her unvested options shall be deemed fully vested, and any vested options shall be exercisable by Dr. Klapper or her estate for 12 months following her death or disability. If we complete a merger, consolidation, reorganization, sale or transfer of all or substantially all of our ordinary shares, or sale or transfer of all or substantially all of our assets, Dr. Klapper's outstanding options may be assumed by the successor company or an affiliate thereof or securities of such company may be substituted for the options. If the successor company does not assume or substitute for Dr. Klapper's outstanding options, then Dr. Klapper's unvested options will immediately vest as of the date which is 10 days before the effective date of the applicable transaction, provided that Dr. Klapper commits to remain employed with the successor company for one year following the effective date of the transaction. Assumed or substituted options that are scheduled to vest more than one year after the closing of the applicable transaction shall have their vesting schedules accelerated by one year, provided that if any such acceleration would result in an option becoming vested prior to the one year from the closing date of the applicable transaction, all outstanding options assumed or substituted by the successor company shall immediately vest in full. If we effect a voluntary liquidation or dissolution, all of Dr. Klapper's unexercised vested options and any unvested options will automatically terminate.

# Executive Compensation

The following table presents information for our fiscal year ended December 31, 2009 regarding compensation paid to or accrued for our Chief Executive Officer, our Chief Financial and Operating Officer and each of our three other most highly compensated executive officers who were serving as executive officers as of the end of December 31, 2009, who we refer to as our named executive officers. Compensation includes long-term awards granted in the fiscal year ended December 31, 2009. The compensation table excludes other compensation in the form of perquisites and other personal benefits that constituted less than 10% of the total annual salary and bonus for the executive officer in the fiscal year ended December 31, 2009. Two of our officers were awarded options exercisable for 630,000 ordinary shares, in the aggregate, during the fiscal year ended December 31, 2009. Otherwise, no options were granted to our named executive officers during the fiscal year ended December 31, 2009.

# **Summary Compensation Table**

	Annual Co	Long-Term	
Name and Position(s) <sup>(1)</sup>	Salary and related benefits	Bonus	Compensation Shares Underlying Options*
		(NIS in thousands)	-
Morris C. Laster, M.D. <sup>(2)</sup> Chief Executive Officer (Former) and Director	1,136	150	1,773
Kinneret Savitsky, Ph.D. <sup>(2)</sup> Chief Executive Officer (Current) and Director	880	125	463
Philip Serlin <sup>(3)</sup> Chief Financial and Operating Officer	487	105	64
Moshe Phillip, M.D. Vice President, Medical Affairs and Senior Clinical Advisor	736	105	376
Nir Gamliel Vice President of Business Development of BioLineRx USA Inc.	606	654	122

- \* The value of the ordinary shares underlying the options has been calculated in accordance with the Black-Scholes option pricing model under IFRS.
- (1) Leah Klapper, Ph.D., began serving as an Executive Officer in January 2010 and, therefore, her salary and benefits do not appear in the above table.
- (2) Dr. Laster resigned from his position as Chief Executive Officer, effective as of January 1, 2010 and was replaced by Dr. Savitsky. Dr. Savitsky served as the General Manager of BIJ L.P. from August 1, 2004 through December 31, 2009. Dr. Laster did not stand for re-election to our Board of Directors at our shareholders meeting in August 2010.
- (3) We hired Mr. Serlin as our Chief Financial Officer and Chief Operating Officer on May 24, 2009. The amounts in the table represent Mr. Serlin's compensation from that date through December 31, 2009.

We set aside or accrued NIS 327,415, in the aggregate, for pension or other retirement benefits for the named executive officers in 2009.

# **Stock Option Plans**

# 2003 Share Option Plan

In 2003, we adopted the BioLineRx Ltd. 2003 Share Option Plan, or the Plan. The Plan provides for the granting of options and ordinary shares to our directors, employees, consultants and service providers, and to the directors, employees, consultants and service providers of our subsidiaries and affiliates. The Plan provides for options to be issued at the determination of our Board of Directors in accordance with applicable law. As of June 30, 2010, there were 7,084,160 ordinary shares issuable upon the exercise of outstanding options under the Plan.

# Administration of Our Share Option Plan

Our share option plan is administered by our Audit Committee, which makes recommendations to our Board of Directors regarding the granting of options and the terms of option grants, including exercise price, method of payment, vesting schedule, acceleration of vesting and the other matters necessary in the administration of these plans. Options granted under the Plan to eligible employees and office holders are granted under Section 102 of the Israel Income Tax Ordinance pursuant to which the options or the ordinary shares issued upon their exercise must be allocated or issued to a trustee and be held in trust for two years from the date upon which such options were granted, provided that options granted prior to January 1, 2006, or the ordinary shares issued upon their exercise, are subject to being held in trust for two years from the end of the year in which the options are granted. Under Section 102, any tax payable by an employee from the grant or exercise of the options is deferred until the transfer of the options or ordinary shares by the trustee to the employee or upon the sale of the options or ordinary shares, and gains may qualify to be taxed as capital gains at a rate equal to 25%, subject to compliance with specified conditions.

Options granted under our share option plan generally vest over four years, and they expire between seven to 10 years from the grant date. If we terminate an employee for cause, all of the employee's vested and unvested options expire immediately from the time of delivery of the notice of discharge, unless determined otherwise by the Audit Committee or the Board of Directors. Upon termination of employment for any other reason, including due to death or disability of the employee, vested options may be exercised within three months of the termination date, unless otherwise determined by the Audit Committee or the Board of Directors. Vested options which are not exercised and unvested options return to the pool of reserved ordinary shares under the Plan for reissuance.

In the event of a merger, consolidation, reorganization or similar transaction or our voluntary liquidation or dissolution, all of our unexercised vested options and any unvested options will be automatically terminated. However, in the event of a change of control, or merger, consolidation, reorganization or similar transaction resulting in the acquisition of at least 50% of our voting power, or the sale of all or substantially all of our assets, each option holder will be entitled to purchase the number of shares of the other corporation the option holder would have received if he or she had exercised the options immediately prior to such transaction or may sell or exchange their shares received pursuant to the exercise of an option.

# **Corporate Governance Practices**

As an Israeli corporation we are subject to various corporate governance requirements under Israeli law relating to such matters as external directors, the audit committee and an internal auditor. These matters are in addition to the Marketplace Rules of The NASDAQ Stock Market and other applicable provisions of U.S. securities laws. Under the Marketplace Rules of The NASDAQ Stock Market, a foreign private issuer may generally follow its home country rules of corporate governance in lieu of the comparable requirements of the Marketplace Rules of The NASDAQ Stock Market, except for certain matters including (among others) the composition and responsibilities of the audit committee and the independence of its members within the meaning of the rules and regulations of the SEC. For further information, see "Risk Factors" and "NASDAQ Listing Rules and Home Country Practices."

## **Board Practices**

### Board of Directors

According to the Israeli Companies Law, the management of our business is vested in our Board of Directors. Our Board of Directors may exercise all powers and may take all actions that are not specifically granted to our shareholders. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our Board of Directors. Executive officers are appointed by and serve at the discretion of our Board of Directors, subject to any applicable employment agreements we have entered into with the executive officers.

According to our Articles of Association, our Board of Directors must consist of at least five and not more than 10 directors, including external directors. Currently, our Board of Directors consists of six directors, including two external directors as required by the Israeli Companies Law. Pursuant to our Articles of Association, other than the external directors, for whom special election requirements apply under the Israeli Companies Law as detailed below, our directors are elected at a general or special meeting of our shareholders and serve on the Board of Directors until they are removed by the majority of our shareholders at a general or special meeting of our shareholders or upon the occurrence of certain events, in accordance with the Israeli Companies Law and our Articles of Association. In addition, our Articles of Association allow our Board of Directors to appoint directors to fill vacancies on the Board of Directors to serve until the next general meeting or special meeting, or earlier if required by our Articles of Association or applicable law. We have held elections for each of our non-external directors at each annual meeting of our shareholders since our initial public offering in Israel. External directors are elected for an initial term of three years and may be removed from office pursuant to the terms of the Israeli Companies Law. See "— External Directors."

The Israeli Companies Law provides that an Israeli company may, under certain circumstances, exculpate an office holder from liability with respect to a breach of his duty of care toward the company if appropriate provisions are included in its articles of association. See "— Exculpation, Insurance and Indemnification of Directors and, Officers." Our Articles of Association contain such provisions, and we have entered into

agreements with each of our office holders undertaking to indemnify them to the fullest extent permitted by law, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance.

In accordance with the exemption available to foreign private issuers under applicable NASDAQ rules, we do not intend to follow the requirements of the NASDAQ rules with regard to the process of nominating directors, and instead, will follow Israeli law and practice, in accordance with which our Board of Directors is authorized to recommend to our shareholders director nominees for election, and our shareholders may nominate candidates for election as directors by the shareholders' general meeting.

The term office holder is defined in the Israeli Companies Law as a director, general manager, chief business manager, deputy general manager, vice general manager, executive vice president, vice president, any other manager directly subordinate to the general manager or any other person assuming the responsibilities of any of the foregoing positions, without regard to such person's title. Each person listed above under "Executive Officers and Directors" is an office holder.

*Chairman of the Board.* A person cannot hold both the role of chairman of both the board of directors and chief executive officer of a company, without shareholder approval, under the Israeli Companies Law.

#### External Directors

Under Israeli law, the boards of directors of companies whose shares are publicly traded are required to include at least two members who qualify as external directors. Each of our current external directors, Dr. Avraham Molcho and Ms. Nurit Benjamini, was elected as an external director by our shareholders in July 2010. Their initial terms expire in July 2013. External directors must be elected by majority vote of the shares present and voting at a shareholders meeting, provided that either:

- such majority includes at least one-third of the shares held by all non-controlling shareholders present and voting at such meeting; or
- the total number of shares of non-controlling shareholders voted against the election of the external director does not exceed 1.0% of the aggregate voting rights in the company.

After an initial term of three years, external directors may be reelected to serve in that capacity for an additional term of three years. The term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including The NASDAQ Global Market, may be extended beyond the initial two terms permitted under the Israeli Companies Law indefinitely in increments of additional three-year terms, provided in each case that the following conditions are met: (a) the audit committee and the board of directors confirm that, in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the reelection for such additional period(s) is beneficial to the company; (b) the reelection is approved by the shareholders by a special majority required for the election of external directors; and (c) the proposed terms of compensation of the external directors, and the considerations of the audit committee and the Board of Directors in deciding to recommend reelection of the external directors, are presented to the shareholders prior to the vote on reelection. External directors may be removed from office by the same percentage of shareholders required for their election or by a court, in each case, only under limited circumstances, including ceasing to meet the statutory qualification for appointment or violating the duty of loyalty to the company. If an external directorship becomes vacant and there are less than two external directors on the board of directors at the time, then the board of directors is required under the Israeli Companies Law to call a shareholders' meeting immediately to appoint a replacement external director. Each committee of the board of directors that exercises the powers of the board of directors must include at least one external director, except that the audit committee must include all external directors then serving on the board of directors. Under the Israeli Companies Law external directors of a company are prohibited from receiving, directly or indirectly, any compensation from the company other than for their services as external directors pursuant to the provisions and limitations set forth in regulations promulgated under the Israeli Companies Law.

The Israeli Companies Law provides that a person is not qualified to serve as an external director if, as of the appointment date or at any time during the two years preceding his or her appointment, that person or a relative, partner or employer of that person, any person to which that person is subordinate (whether directly or indirectly), or any entity under that person's control, had any affiliation or business relationship with the company, any entity controlling the company or an entity that, as of the appointment date, or at any time during the two years preceding that date, is controlled by the company or by any entity controlling the company.

The term affiliation includes:

- an employment relationship;
- a business or professional relationship maintained on a regular basis;
- control; and
- service as an office holder, excluding service as a director in a private company prior to the first offering of its shares to the
  public if such director was appointed as a director of the private company in order to serve as an external director following
  the public offering.

In addition, no person may serve as an external director if that person's professional activities create, or may create, a conflict of interest with that person's responsibilities as a director or otherwise interfere with that person's ability to serve as an external director. Until the lapse of two years after termination of an external director's membership on a board of directors, such company may not engage an external director to serve as an executive officer or director and cannot employ or receive services from that person for pay, either directly or indirectly, including through a corporation controlled by that person. If at the time an external director is appointed all members of the board of directors are of the same gender, the external director must be of the other gender. A director of one company may not be appointed as an external director of another company if a director of the other company is acting as an external director of the first company at such time.

Under the regulations promulgated under the Israeli Companies Law, a person may be appointed as an external director if he or she has professional qualifications or if he or she has accounting and financial expertise. In addition, at least one of the external directors must be determined by our Board of Directors to have accounting and financial expertise. In determining the number of directors required to have such expertise, the members of our Board of Directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our Board of Directors has determined that Nurit Benjamini possesses "accounting and financial" expertise, and that both of our external directors possess the requisite professional qualifications.

#### Audit Committee

Under the Israeli Companies Law, the board of directors of a public company must appoint an audit committee. The audit committee must be comprised of at least three directors, including all of the external directors. The audit committee may not include the chairman of the board, any director employed by the company or that regularly provides services to the company (other than as a board member), a controlling shareholder or any relative, as each term is defined in the Israeli Companies Law, of such person.

The members of our Audit Committee are Nurit Benjamini (Chairman), Dr. Avraham Molcho and Dr. Raphael Hofstein. Prior to the listing of our ordinary shares for trading on The NASDAQ Global Market, we will evaluate whether the members of our Audit Committee meet the independence requirements set forth in the Marketplace Rules of The NASDAQ Stock Market. Pursuant to the Marketplace Rules of The NASDAQ Stock Market, our Board of Directors may appoint one director to our Audit Committee who (1) is not an Independent Director as defined in NASDAQ Marketplace Rule 5605(a)(2), (2) meets the criteria set forth in Section 10A(m)(3) under the Exchange Act, and (3) is not one of our current officers or employees or "family member," as defined in NASDAQ Marketplace Rule 5605(a)(2), of an officer or employee, if our Board of Directors, under exceptional and limited circumstances, determines that the appointment is in our best interests and the best interest of our shareholders, and our Board of Directors discloses, in our next annual report subsequent to the determination, the nature of the relationship and the reasons for that determination.

Our Board of Directors has determined that Nurit Benjamini (Chairman) qualifies as an audit committee financial expert as defined by rules of the SEC.

Our Board of Directors intends to adopt an audit committee charter that will add to the responsibilities of the audit committee under the Israeli Companies Law, setting forth the responsibilities of the audit committee consistent with the rules of the SEC and the Marketplace Rules of the NASDAQ Stock Market, including the following:

- oversight of the company's independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of the company's independent registered public accounting firm to the board of directors in accordance with Israeli law;
- · recommending the engagement or termination of the office of the company's internal auditor; and
- recommending the terms of audit and non-audit services provided by the independent registered public accounting firm for pre-approval by the board of directors.

Our audit committee provides assistance to our Board of Directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. The audit committee also oversees the audit efforts of our independent accountants and takes those actions as it deems necessary to satisfy itself that the accountants are independent of management. Under the Israeli Companies Law, the audit committee is also required to identify deficiencies in the administration of the company, including by consulting with the internal auditor, and recommending remedial actions with respect to such deficiencies, and is responsible for reviewing and approving related party transactions.

Under the Israeli Companies Law, the approval of the audit committee is required for specified actions and transactions with office holders and controlling shareholders. See "— Approval of Related Party Transactions under Israeli Law." However, an audit committee may not approve an action or a transaction with a controlling shareholder or with an office holder unless at the time of approval the two external directors were serving as members of the audit committee and at least one of them was present at the meeting at which the approval was granted.

#### Compensation Committee

Our Board of Directors does not currently have a compensation committee.

### Nominating Committee

Our Board of Directors does not currently have a nominating committee. Prior to listing our ordinary shares on The NASDAQ Global Market, our Board of Directors will determine whether it will form a nominating committee or avail our company of the exemption available to foreign private issuers under The NASDAQ Listing Rules. See "— NASDAQ Listing Rules and Home Country Practices."

We do not have personal services contracts with any of our directors, except Dr. Laster. See "Certain Relationship and Related Party Transactions."

#### Internal Auditor

Under the Israeli Companies Law, the board of directors of an Israeli public company must appoint an internal auditor recommended by the audit committee and nominated by the board of directors. An internal auditor may not be:

- a person (or a relative of a person) who holds more than 5% of the company's shares;
- a person (or a relative of a person) who has the power to appoint a director or the general manager of the company;
- an executive officer or director of the company; or
- a member of the company's independent accounting firm.

The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures. Our internal auditor is Linur Dloomy, CPA (Israel) a partner of Brightman Almagor Zohar & Co. (a member firm of Deloitte).

# NASDAQ Listing Rules and Home Country Practices

The Sarbanes-Oxley Act, as well as related rules subsequently implemented by the SEC, requires foreign private issuers, such as us, to comply with various corporate governance practices. In complying with the Marketplace Rules of The NASDAQ Stock Market, we may elect to follow certain corporate governance practices permitted under the Israeli Companies Law and the rules of the TASE in lieu of compliance with certain corporate governance requirements otherwise required by the Marketplace Rules of The NASDAQ Stock Market.

In accordance with Israeli law and practice and subject to the exemption set forth in Rule 5615 of the Marketplace Rules of The NASDAQ Stock Market, if we list on The NASDAQ Global Market we intend to follow the provisions of the Israeli Companies Law, rather than the Marketplace Rules of The NASDAQ Stock Market, with respect to the following requirements:

- Distribution of annual and quarterly reports to shareholders. Under Israeli law we are not required to distribute annual and quarterly reports directly to shareholders and the generally accepted business practice in Israeli is not to distribute such reports to shareholders but to make such reports available through the website of the Israeli Securities Authority. In addition, we plan to make our audited financial statements available to our shareholders at our offices and to mail such reports to shareholders upon request. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules.
- *Quorum.* Under Israeli law, a company is entitled to determine in its articles of association the number of shareholders and percentage of holdings required for a quorum at a shareholders meeting. Our Articles of Association provide that a quorum of two or more shareholders holding at least 25% of the voting rights in person or by proxy is required for commencement of business at a general meeting. However, the quorum set forth in our articles of association with respect to an adjourned meeting consists of any number of shareholders present in person or by proxy.
- *Independent Directors*. Our Board of Directors has two external directors in accordance with the provisions contained in Sections 239 249 of the Israeli Companies Law and Rule 10A-3 of the general rules and regulations promulgated under the Securities Act of 1933, rather than a majority of external directors. Israeli law does not require, nor do our independent directors conduct, regularly scheduled meetings at which only they are present.
- *Audit Committee*. Our Audit Committee complies with all of the requirements under Israeli law, and is composed of two external directors, which are all of our external directors, and one other director. Consistent with Israeli law, the independent auditors are elected at a meeting of shareholders instead of being appointed by the Audit Committee.
- Nomination of our Directors. With the exception of our external directors and directors elected by our Board of Directors due to vacancy, our directors are elected by a general or special meeting of our shareholders, to hold office until they are removed from office by the majority of our shareholders at a general or special meeting of our shareholders. See "— Board of Directors." The nominations for directors, which are presented to our shareholders, are generally made by our directors, but nominations may be made by one or more of our shareholders as provided in our Articles of Association, under the Israeli Companies law or in an agreement between us and our shareholders. Currently, there is no agreement between us and any shareholder regarding the nomination of directors. In accordance with our Articles of Association, under the Israeli Companies Law, any one or more shareholders holding, in the aggregate, either (1) 5% of our outstanding shares and 1% of our outstanding voting power or (2) 5% of our outstanding voting power, may nominate one or more persons for election as directors at a general or special meeting by delivering

a written notice of such shareholder's intent to make such nomination or nominations to our registered office. Each such notice must set forth all of the details and information as required to be provided in our Articles of Association.

- Compensation of Officers. Provided that the executive officer does not serve on our board, Israeli law does not require and
  we do not require that independent members of our Board of Directors determine the compensation of an executive officer.
- Approval of Related Party Transactions. All related party transactions are approved in accordance with the requirements and procedures for approval of interested party acts and transactions, set forth in sections 268 to 275 of the Israeli Companies Law, and the regulations promulgated thereunder, which require the approval of the audit committee, board of directors and shareholders, for specified transactions, rather than approval by the audit committee or other independent body of our Board of Directors as required under NASDAQ Listing Rules. See also "— Approval of Related Party Transactions.
- Shareholder Approval. We seek shareholder approval for all corporate actions requiring such approval in accordance with
  the requirements of the Israeli Companies Law, which are different or in addition to the requirements for seeking
  shareholder approval under NASDAQ Listing Rule 5635, rather than seeking approval for corporation actions in
  accordance with such listing rules.

# Approval of Related Party Transactions Under Israeli Law

## Fiduciary Duties of Directors and Executive Officers

The Israeli Companies Law codifies the fiduciary duties that directors and executive officers owe to a company. An office holder is defined in the Israeli Companies Law as any director, general manager, chief business manager, deputy general manager, vice general manager, other manager directly subordinate to the general manager or any other person assuming the responsibilities of any of these positions regardless of that person's title. Each person listed in the table under "Management — Executive Officers and Directors" is an office holder under the Israeli Companies Law.

An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care requires an office holder to act with the level of care with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of loyalty requires that an office holder act in good faith and in the best interests of the company. The duty of care includes a duty to use reasonable means to obtain:

- information on the appropriateness of a given action brought for his or her approval or performed by virtue of his or her position; and
- all other important information pertaining to these actions.

The duty of loyalty of an office holder includes a duty to:

- refrain from any conflict of interest between the performance of his or her duties in the company and his or her personal affairs;
- refrain from any activity that is competitive with the company;
- refrain from exploiting any business opportunity of the company to receive a personal gain for himself or herself or others; and
- disclose to the company any information or documents relating to a company's affairs which the office holder received as a result of his or her position as an office holder.

# Disclosure of Personal Interests of an Office Holder.

Israeli law requires that an office holder promptly disclose to the board of directors any personal interest that he or she may have and all related material information known to him or her concerning any existing or proposed transaction with the company. A personal interest includes an interest of any person in an act or transaction of a company, including a personal interest of one's relative or of a corporate body in which such person or a relative of such person is a 5% or greater shareholder, director or general manager or in which he or she has the right to appoint at least one director or the general manager, but excluding a personal interest is stemming from one's ownership of shares in the company. If it is determined that an office holder has a personal interest in a transaction, board approval is required for the transaction, unless the company's articles of association provide for a different method of approval. No transaction that is adverse to the company's interest may be approved by the board of directors. Approval first by the company's audit committee and subsequently by the board of directors is required for an extraordinary transaction, meaning any transaction that is not in the ordinary course of business, not on market terms or that is likely to have a material impact on the company's profitability, assets or liabilities. A director who has a personal interest in a matter which is considered at a meeting of the board of directors or the audit committee may generally not be present at this meeting or vote on this matter unless a majority of the directors or members of the audit committee have a personal interest in the matter. In the event of an extraordinary transaction, if a majority of the board of directors has a personal interest in the transaction, shareholder approval is also required.

Pursuant to the Israeli Companies Law, all compensation arrangements for executive officers and office holders who are not directors require approval by our Board of Directors, unless the Company's articles of association provide for a different method of approval. Extraordinary transactions with, or insurance, indemnification or exculpation of, executive officers or office holders who are not directors require Audit Committee approval and subsequent approval of our Board of Directors. Compensation arrangements with directors, including compensation arrangements with directors in their capacities as executive officers, as well as transactions relating to insurance, indemnification of directors, require the approval of our Audit Committee, our Board of Directors and our shareholders, in that order.

*Disclosure of Personal Interests of Controlling Shareholders.* Pursuant to Israeli law, the disclosure requirements regarding personal interests that apply to directors and executive officers also apply to a controlling shareholder of a public company. A controlling shareholder is a shareholder who has the ability to direct the activities of a company, including a shareholder who owns 25% or more of the voting rights if no other shareholder owns more than 50% of the voting rights. Two or more shareholders with a personal interest in the approval of the same transaction are deemed to be one shareholder.

Under the Israeli Companies Law, the disclosure requirements that apply to an office holder also apply to each controlling shareholder of a public company. An extraordinary transaction between a public company and a controlling shareholder, or in which a controlling shareholder has a personal interest, and the terms of any compensation of a controlling shareholder who is an office holder, require the approval of the company's audit committee, board of directors and shareholders. In addition, the shareholder approval must fulfill one of the following requirements:

- at least one-third of the shares held by shareholders who have no personal interest in the transaction and who are present and voting, in person, by proxy or by written ballot at the meeting, must be voted in favor of approving the transaction (for this purpose, abstentions are disregarded); or
- the shareholders who have no personal interest in the transaction and who are present and voting, in person, by proxy or by written ballot at the meeting, and who vote against the transaction may not represent more than 1% of the voting rights of the company.

*Shareholder Duties.* Pursuant to the Israeli Companies Law, a shareholder has a duty to act in good faith and in a customary manner toward the company and other shareholders and to refrain from abusing his or her power in the company, including, among other things, in voting at the general meeting of shareholders and at class shareholder meetings with respect to the following matters:

- an amendment to the company's articles of association;
- an increase of the company's authorized share capital;



- a merger; or
- interested party transactions that require shareholder approval.

In addition, certain shareholders have a duty of fairness toward the company. These shareholders include any controlling shareholder, any shareholder who knows that it has the power to determine the outcome of a shareholder vote and any shareholder who has the power to appoint or to prevent the appointment of an office holder of the company or other power towards the company. The Israeli Companies Law does not define the substance of this duty of fairness, except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness.

# Exculpation, Insurance and Indemnification of Directors and Officers

The Israeli Companies Law allows us to indemnify or insure our office holders against the following liabilities incurred for acts performed as an office holder:

- a breach of duty of loyalty to the company, to the extent the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach of duty of care to the company or to a third party; and
- subject to certain limitation as set forth below, a financial liability imposed on or incurred by the office holder in favor of a third party.

Under the Israeli Companies Law, an Israeli company may not exculpate an office holder from liability for a breach of the duty of loyalty of the office holder. The company may, however, approve an office holder's act performed in breach of the duty of loyalty, provided that the office holder acted in good faith, the act or its approval does not prejudice the company and the office holder discloses the nature of his or her personal interest in the act and all material facts and documents a reasonable time before discussion of the approval. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for a breach of duty of care, but only if a provision authorizing such exculpate a director for liability arising out of a prohibited dividend or distribution to shareholders.

Pursuant to the Israeli Companies Law, a company may indemnify an office holder only for judgments, settlements or arbitrators' awards approved by a court that were rendered in connection with events that the company's board of directors deemed foreseeable based on the company's actual activities at the time of the approval by its board of directors of the indemnification, provided that the indemnification is limited to an amount or criteria determined by the board of directors as reasonable under the circumstances and that the indemnification undertaking expressly indicates the foreseeable activities and the amount or criteria for indemnification.

In addition to the foregoing, a company's audit committee and board of directors must approve the procurement of insurance coverage for office holders, the company's undertaking to indemnify or indemnification of an office holder and the decision to exculpate an office holder from liability. If an office holder is a director or a controlling shareholder or a relative of a controlling shareholder, such decisions must also be approved by a general meeting of shareholders. See "— Approval of Related Party Transactions Under Israeli Law."

We cannot indemnify, exculpate or insure our office holders with respect to any of the following:

- a breach by the office holder of his duty of loyalty, except with respect to insurance coverage or indemnification if the office holder acted in good faith and had reasonable grounds to assume that the act would not prejudice the company;
- a breach by the office holder of his duty of care if such breach was committed intentionally or recklessly, unless the breach was committed only negligently;
- any act or omission committed with intent to derive an unlawful personal gain; and
- any fine or forfeiture imposed on the office holder.

# **Code of Business Conduct and Ethics**

We intend to adopt a Code of Business Conduct and Ethics applicable to all of our directors and employees, including our Chief Executive Officer, Chief Financial Officer, comptroller or principal accounting officer, or other persons performing similar functions, which is a "code of ethics" as defined by applicable SEC rules. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the code of ethics, we will disclose the nature of such amendment or waiver on our website to the extent required by applicable law.

# CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of some of the transactions with related parties to which we, or our subsidiaries, are party. The descriptions provided below are summaries and do not purport to be complete.

We believe that we have executed all of our transactions with related parties on terms no less favorable to us than those we could have obtained from unaffiliated third parties. We are required by Israeli law to ensure that all future transactions between us and our officers, directors and principal shareholders and their affiliates are approved by a majority of our Board of Directors, including a majority of the independent and disinterested members of our Board of Directors, and that they are on terms no less favorable to us than those that we could obtain from unaffiliated third parties.

#### Agreement with Morris Laster, M.D.

According to the employment agreement we entered into with Dr. Laster, dated May 1, 2003, Dr. Laster, our former Chief Executive Officer and director, was entitled to a separation payment equal to four months' salary and related social benefits upon the end of his employment as Chief Executive Officer, which occurred on January 1, 2010. From January 1, 2010 through August 2010, Dr. Laster provided consulting services to the Company and served as a member of our Scientific Advisory Board. As required under Israeli law, the terms of Dr. Laster's engagement with the Company were approved by our Audit Committee and Board of Directors and were approved by our shareholders in May 2010. In consideration for the services provided, Dr. Laster was entitled to NIS 30,000 per month, for the period commencing January 1, 2010 and ending June 30, 2010, and NIS 15,000 per month for the subsequent six-month period, against presentation of a valid VAT invoice. Dr. Laster's tenure as a director ended in August 2010. Dr. Laster has agreed to provide us with consulting services from time to time.

On February 24, 2010, our Board of Directors, upon recommendation of our Audit Committee, approved the payment to Dr. Laster of a bonus for his services as our chief executive officer during the year ended December 31, 2009 equal to NIS 150,000, which payment was approved by our shareholders in May 2010.

# Pan Atlantic Bridge Loan Agreement

On January 10, 2007, we entered into a convertible bridge loan agreement with Pan Atlantic Investments Limited, or Pan Atlantic, pursuant to which Pan Atlantic provided us with a \$9.0 million convertible loan. Pursuant to the terms of the bridge loan agreement, the \$9.0 million loan converted into 6,716,418 of our ordinary shares at a price per share of \$1.34 immediately prior to our initial public offering on the TASE.

# **Early Development Program Agreement**

We entered into an agreement with Pan Atlantic pursuant to which Pan Atlantic committed to provide up to \$5.0 million of funding for us to in-license and develop early development stage therapeutic candidates. Pursuant to this early development program, we are entitled to request from Pan Atlantic twice a year up to \$625,000 for an aggregate of up to approximately \$1.25 million per year, unless otherwise agreed by Pan Atlantic, for our early development research projects, provided that we match the program funds at a rate of \$0.20 per every dollar invested by Pan Atlantic. Pan Atlantic is not obligated to transfer any funds under this program for any request made after April 1, 2011. Pan Atlantic does not have any rights to any products developed through our early development projects. As part of the agreement, Pan Atlantic will have the right to invest up to \$5.0 million in our first public offering outside of Israel.

# **Registration Rights Agreement**

On January 25, 2007, we entered into a registration rights agreement with Teva, the Jerusalem Development Authority, Pitango, Hadasit, Giza, the Star Group, Mr. Yehuda Zisapel and Pan Atlantic, which contains provisions regarding registration rights as follows:

# Demand Registration Rights

Since August 8, 2007, we have been required to, at the request of the holders of a majority of the outstanding registrable securities held by our founders and investors, use our best efforts to register any or all of these shareholders' ordinary shares as follows:



- we are required to effect up to two such registrations, but only if the aggregate market value of the shares to be registered in each such registration is at least \$5.0 million at the time of the request; and
- we will not be required to effect a second demand registration within six months after the effective date of the first demand registration or any other registration statement pertaining to our ordinary shares, or such shorter periods if such shorter periods are acceptable to the underwriters of such offering.

# Piggyback Registration Rights

All of our founders and investors also have the right to request that we include their ordinary shares in any registration statement we file in the future for the purposes of a public offering, subject to specified limitations.

# Shelf Registration Rights

At the request of any holder of registrable securities, we must use, subject to certain limitations, our best efforts to register any or all of these shareholders' ordinary shares on a "shelf" registration statement under the Securities Act. We shall not be obligated to effect or take any action to effect a shelf registration:

- if, within the 12 months proceeding such request we have already effected two shelf registrations;
- during the period ending 90 days after the effective date of any registration statement pertaining to our ordinary shares, or such shorter periods if such shorter periods are acceptable to the underwriters of such offering; and
- if such request does not cover shares representing an aggregate market value of the shares to be registered in each such registration of at least \$1.0 million.

#### Cutbacks

In connection with demand registrations, the managing underwriters may limit the number of shares offered for marketing reasons. In such case, the managing underwriter must first exclude any shares to be registered by us, and, second, any shares to be registered by the founders and investors prior to the offering.

In connection with piggyback registrations, the managing underwriters of an underwritten offering may limit the number of shares offered for marketing reasons. In such case, the managing underwriter must exclude first any shares not held by the founders and investors, and second, any share held by the founders and investors prior to the offering.

# Termination

All registration rights terminate on the fifth anniversary of our initial public offering on the TASE (February 8, 2012), and with respect to any individual shareholder, at such time as all registrable securities of such shareholder may be sold pursuant to Rule 144 under the Securities Act during any 90-day period without restriction.

## Expenses

We have agreed to pay all expenses incurred in carrying out the above registrations. However, each shareholder participating in such registration or sale is responsible for its pro rata portion of the customary and standard discounts or commissions payable to any underwriter.

# In-License Agreement with B.G. Negev Technologies

In January 2005, we in-licensed the rights to BL-1040 under a license agreement with B.G. Negev Technologies. Under the agreement, B.G. Negev Technologies granted to us an exclusive, worldwide, sublicensable license to develop, manufacture, market and sell technology relating to our BL-1040 therapeutic candidate. We are required to pay B.G. Negev Technologies 28% of the revenues we receive as consideration in connection with any sublicensing, co-marketing or co-promotion, or a permitted assignment, of BL-1040, which includes the revenues we have and will receive under our licensing agreement with Ikaria. B.G. Negev Technologies may terminate this agreement upon a material breach on our part, including a failure to meet all of the progress milestones using commercially reasonable efforts. See "Business — In-Licensing Agreements — BL-1040."

We may in-license other technologies from B.G. Negev Technologies in the course of our business, from time to time. However, we have not in-licensed any other technologies from B.G. Negev Technologies in connection with any other therapeutic candidate in our current pipeline.

# In-License Agreement with Gene Vector Technologies Ltd.

In August 2007, BIJ L.P. in-licensed the rights to BL-4040 under a license agreement with Gene Vector Technologies, Ltd., or Gene Vector Technologies. Under the agreement, Gene Vector granted to us an exclusive, worldwide, sublicensable license to develop, manufacture, market and sell technology relating to our BL-4040 therapeutic candidate. Gene Vector Technologies may terminate this agreement upon a material breach on our part, including a failure to meet all of the progress milestones using commercially reasonable efforts. Raphael Hofstein, one of our directors, was the Chairman of Gene Vector Technologies when we entered into the license agreement.

# Agreements with Directors and Officers

# **Employment Agreements**

We have entered into employment agreements with each of our executive officers. See "Management — Compensation of Directors and Officers — Employment Agreements."

# Indemnification Agreements

Our Articles of Association permit us to exculpate, indemnify and insure our directors and officeholders to the fullest extent permitted by the Israeli Companies Law. We have entered into agreements with each of our office holders undertaking to indemnify them to the fullest extent permitted by law, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance. We have obtained Directors & Officers insurance for each of our officers and directors. See "Management — Compensation of Directors and Officers — Employment Agreements."

# PRINCIPAL SHAREHOLDERS

The following table sets forth information regarding the beneficial ownership of our outstanding ordinary shares as of the date of this registration statement:

- each person or group of affiliated persons that, to our knowledge, beneficially owns more than 5.0% of our ordinary shares;
- each of our directors and executive officers individually; and
- all of our directors and executive officers as a group.

The beneficial ownership of ordinary shares is determined in accordance with the rules of the SEC and generally includes any ordinary shares over which a person exercises sole or shared voting or investment power. For purposes of the table below, we deem shares subject to options or warrants that are currently exercisable or exercisable within 60 days of August 31, 2010, to be outstanding and to be beneficially owned by the person holding the options or warrants for the purposes of computing the percentage ownership of that person but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. The percentage of shares beneficially owned prior to offering is based on the 123,519,170 ordinary shares outstanding as of August 31, 2010 and the percentage of shares beneficially owned after offering assumes ordinary shares outstanding upon the completion of this offering. Except where otherwise indicated, we believe, based on information furnished to us by such owners, that the beneficial owners of the ordinary shares listed below have sole investment and voting power with respect to such ordinary shares. To our knowledge, none of our shareholders of record are U.S. holders. Our principal shareholders do not have different or special voting rights. Unless otherwise noted below, each shareholder's address is c/o BioLineRx Ltd., P.O. Box 45158, 19 Hartum Street, Jerusalem 91450, Israel.

	Shares Beneficially Owned Prior To Offering		Shares Beneficially Owned After Offering	
	Number	Percent	Number	Percent
Directors and executive officers:				
Aharon Schwartz, Ph.D.	—	—		
Raphael Hofstein, Ph.D. <sup>(1)</sup>	37,500	*		
Yakov Friedman	—	—		
Kinneret Savitsky, Ph.D. <sup>(2)</sup>	1,127,448	*		
Moshe Phillip, M.D. <sup>(3)</sup>	746,755	*		
Philip Serlin <sup>(4)</sup>	_	_		
Nir Gamliel <sup>(5)</sup>	75,000	*		
Leah Klapper <sup>(6)</sup>	205,746	*		
Avraham Molcho, M.D. <sup>(7)</sup>		_		
Nurit Benjamini <sup>(8)</sup>		_		
All directors and executive officers as a group	2,192,449	2.0		
(10 persons) <sup>(9)</sup>				
Principal shareholders:				
Pan Atlantic Investments Limited <sup>(10)</sup>	18,007,162	13.3		
Teva Pharmaceutical Industries Ltd. <sup>(11)</sup>	11,889,535	9.6		
Clal Insurance Group <sup>(12)</sup>	11,170,764	9.0		
•				

<sup>\*</sup> Less than 1.0%.

<sup>(2)</sup> Includes 211,416 ordinary shares issuable upon exercise of outstanding options within 60 days of August 31, 2010. Does not include 544,754 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of August 31, 2010.



Includes 37,500 ordinary shares issuable upon exercise of outstanding options within 60 days of August 31, 2010. Does not include 162,500 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of August 31, 2010.

- (3) Includes 171,792 ordinary shares issuable upon exercise of outstanding options within 60 days of August 31, 2010. Does not include 407,719 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of August 31, 2010.
- (4) Mr. Serlin holds options to purchase 554,200 ordinary shares, none of which are exercisable within 60 days of August 31, 2010.
- (5) Includes 75,000 ordinary shares issuable upon exercise of outstanding options within 60 days of August 31, 2010. Does not include 530,390 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of August 31, 2010.
- (6) Includes 14,472 ordinary shares issuable upon exercise of outstanding options within 60 days of August 31, 2010. Does not include 267,013 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of August 31, 2010.
- (7) Dr. Molcho holds options to purchase 50,000 ordinary shares, none of which are exercisable within 60 days of August 31, 2010.
- (8) Ms. Benjamini holds options to purchase 50,000 ordinary shares, none of which are exercisable within 60 days of August 31, 2010.
- (9) Includes 510,180 ordinary shares issuable upon exercise of outstanding options within 60 days of August 31, 2010. Does not include 2,566,576 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of August 31, 2010.
- (10)Based upon information provided by the shareholder, includes 7,327,244 shares held by Pan Atlantic Investments Limited, 9,094,518 shares held by Pan Atlantic Bank and Trust Limited and Series 2 warrants to purchase 1,585,400 shares held by Pan Atlantic Bank and Trust Limited. Based upon information provided by the shareholder, Pan Atlantic Investments Limited is a company organized under the laws of Barbados. Pan Atlantic is a wholly owned subsidiary of Friedberg Mercantile Group, Ltd., a Canadian corporation controlled by Mr. Albert D. Friedberg and his family. The principal executive offices of Pan Atlantic are at Musson Building, Third Floor, Hincks Street, P.O. Box 982, Bridgetown, Barbados, West Indies.
- (11)Teva is a publicly-traded Israeli company. Its principal executive offices are at 5 Basel Street, PO Box 3190, Petach Tikva, Israel 49131.
- (12)Based upon information provided by the shareholder, the Clal Insurance Group is comprised of Clal Insurance Enterprises Holdings Ltd., which is comprised of (1) Clal Insurance Enterprises Holdings Ltd. Pensions, which holds 5,204,933 ordinary shares; and (2) Clal Insurance Enterprises Holdings Ltd. Participants, which holds 4,175,559 ordinary shares; and Clal Insurance Enterprises Holdings Ltd.'s wholly owned subsidiary, Clal Finances Ltd., which is deemed to be a major shareholder and comprised of (1) Clal Finances Ltd. Funds, which holds 1,113,890 ordinary shares; (2) Clal Finances Ltd. Nostro, which holds 676,382 ordinary shares; and (3) Epsilon Investment House Ltd. Funds. The Clal Insurance Group's address is 48 Menachem Begin Road, Clal Development Bldg., Tel Aviv, Israel.

# **DESCRIPTION OF SHARE CAPITAL**

The following description of our share capital and provisions of our Articles of Association are summaries and do not purport to be complete.

# **Ordinary Shares**

Our authorized share capital consists of ordinary shares, par value NIS 0.01 per share, of which shares are issued and outstanding as of the date of this prospectus.

All of our outstanding ordinary shares will be validly issued, fully paid and non-assessable. Our ordinary shares are not redeemable and do not have any preemptive rights. Pursuant to Israeli securities laws, a company whose shares are traded on the TASE may not have more than one class of shares for a period of one year following its registration, after which it is permitted to issue preferred shares (which shall bear dividend preference and shall not have any voting rights), and all outstanding shares must be validly issued and fully paid. Shares and convertible securities may not be issued without the consent of the Israeli Securities Authority and all outstanding shares must be registered for trading on the TASE.

# **Registration Number and Purposes of the Company**

Our number with the Israeli Registrar of Companies is 513398750. Our purpose appears in our Articles of Association and includes every lawful purpose.

## **Transfer of Shares**

Our ordinary shares that are fully paid for are issued in registered form and may be freely transferred under our Articles of Association, unless the transfer is restricted or prohibited by applicable law or the rules of a stock exchange on which the shares are traded. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our Articles of Association or the laws of the State of Israel, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

## **Election of Directors**

Our ordinary shares do not have cumulative voting rights in the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors, subject to the special approval requirements for external directors described under "Management — Board Practices — External Directors."

Pursuant to our Articles of Association, other than the external directors, for whom special election requirements apply under the Israeli Companies Law, our directors are elected at a general or special meeting of our shareholders and serve on the Board of Directors until they are removed by the majority of our shareholders at a general or special meeting of our shareholders or upon the occurrence of certain events, in accordance with the Israeli Companies Law and our Articles of Association. In addition, our Articles of Association allow our Board of Directors to appoint directors to fill vacancies on the Board of Directors to serve until the next general meeting or special meeting, or earlier if required by our Articles of Association or applicable law. We have held elections for each of our non-external directors at each annual meeting of our shareholders since our initial public offering in Israel. External directors are elected for an initial term of three years and may be removed from office pursuant to the terms of the Israeli Companies Law. See "Management — Board Practices — External Directors."

# **Dividend and Liquidation Rights**

We may declare a dividend to be paid to the holders of our ordinary shares in proportion to their respective shareholdings. Under the Israeli Companies Law, dividend distributions are determined by the board of directors and do not require the approval of the shareholders of a company unless the company's articles of association provide otherwise. Our Articles of Association do not require shareholder approval of a dividend distribution and provide that dividend distributions may be determined by our Board of Directors.

Pursuant to the Israeli Companies Law, we may only distribute dividends from, our profits accrued over the previous two years, as defined in the Israeli Companies Law, according to our then last reviewed or audited financial reports, provided that the date of the financial reports is not more than six months prior to



the date of distribution, or we may distribute dividends with court approval. In each case, we are only permitted to pay a dividend if there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of our ordinary shares in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

## **Shareholder Meetings**

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year that must be no later than 15 months after the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to as special meetings. Our Board of Directors may call special meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Israeli Companies Law and our Articles of Association provide that our Board of Directors is required to convene a special meeting upon the written request of (a) any two of our directors or one quarter of our Board of Directors or (b) one or more shareholders holding, in the aggregate, either (1) 5% of our outstanding shares and 1% of our outstanding voting power or (2) 5% of our outstanding voting power.

Subject to the provisions of the Israeli Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which may be between four and 40 days prior to the date of the meeting. Furthermore, the Israeli Companies Law and our Articles of Association require that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- amendments to our Articles of Association;
- appointment or termination of our auditors;
- appointment of directors and appointment and dismissal of external directors;
- approval of acts and transactions requiring general meeting approval pursuant to the Israeli Companies Law;
- director compensation, indemnification and change of the principal executive officer;
- increases or reductions of our authorized share capital;
- a merger; and
- the exercise of our Board of Director's powers by a general meeting, if our Board of Directors is unable to exercise its powers and the exercise of any of its powers is required for our proper management.

The Israeli Companies Law requires that a notice of any annual or special shareholders meeting be provided at least 21 days prior to the meeting and if the agenda of the meeting includes the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, notice must be provided at least 35 days prior to the meeting.

The Israeli Companies Law does not allow shareholders of publicly traded companies to approve corporate matters by written consent. Consequently, our Articles of Association does not allow shareholders to approve corporate matters by written consent.

#### Voting Rights

#### Quorum Requirements

Pursuant to our Articles of Association, holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting. The quorum required for our general meetings of shareholders consists of at least two shareholders present in person, by proxy or written ballot who hold or represent between them at least 25% of the total outstanding voting rights.

A meeting adjourned for lack of a quorum is adjourned to the same day in the following week at the same time and place or on a later date if so specified in the summons or notice of the meeting. At the reconvened meeting, any number of our shareholders present in person or by proxy shall constitute a lawful quorum.

# Vote Requirements

Our Articles of Association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by applicable law.

Israeli law provides that a shareholder of a public company may vote in a meeting and in a class meeting by means of a written ballot in which the shareholder indicates how he or she votes on resolutions relating to the following matters:

- an appointment or removal of directors;
- an approval of transactions with office holders or interested or related parties;
- an approval of a merger or any other matter in respect of which there is a provision in the articles of association providing that decisions of the general meeting may also be passed by written ballot; and
- other matters which may be prescribed by Israel's Minister of Justice.

The provision allowing the vote by written ballot does not apply where the voting power of the controlling shareholder is sufficient to determine the vote. Our Articles of Association provides that our Board of Directors may prevent voting by means of a written ballot and this determination is required to be stated in the notice convening the general meeting.

The Israeli Companies Law provides that a shareholder, in exercising his or her rights and performing his or her obligations toward the company and its other shareholders, must act in good faith and in a customary manner, and avoid abusing his or her power. This is required when voting at general meetings on matters such as changes to the articles of association, increasing the company's registered capital, mergers and approval of related party transactions. A shareholder also has a general duty to refrain from depriving any other shareholder of its rights as a shareholder. In addition, any controlling shareholder, any shareholder who knows that its vote can determine the outcome of a shareholder vote and any shareholder who, under the company's articles of association, can appoint or prevent the appointment of an office holder, is required to act with fairness towards the company. The Israeli Companies Law does not describe the substance of this duty except to state that the remedies generally available upon a breach of contract will also apply to a breach of the duty to act with fairness, and, to the best of our knowledge, there is no binding case law that addresses this subject directly.

# Resolutions

An ordinary resolution at a shareholders meeting requires approval by a simple majority of the voting rights represented at the meeting, in person, by proxy or written ballot, and voting on the resolution. Under the Israeli Companies Law, unless otherwise provided in a company's articles of association or under applicable law, all resolutions of the shareholders of a company require a simple majority. A resolution for the voluntary winding up of the company requires the approval of holders of 75% of the voting rights represented at the meeting, in person, by proxy or by written ballot and voting on the resolution. For information regarding the majority required for approval of related party transactions, see "Management — Approval of Related Party Transactions Under Israeli Law."

#### Access to Corporate Records

Under the Israeli Companies Law, all shareholders of a company generally have the right to review minutes of the company's general meetings, its shareholders register and principal shareholders register, articles of association, financial statements and any document it is required by law to file publicly with the Israeli Companies Registrar and the Israeli Securities Authority. Any of our shareholders may request access to review any document in our possession that relates to any action or transaction with a related party, interested party or office holder that requires shareholder approval under the Israeli Companies Law. We may deny a request to review a document if we determine that the request was not made in good faith, that the document contains a commercial secret or a patent or that the document's disclosure may otherwise prejudice our interests.

## **Modification of Class Rights**

The rights attached to any class of share, such as voting, liquidation and dividend rights, may be amended by written consent of the holders of a majority of the issued shares of that class, or by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting.

# **Registration Rights**

For a discussion of registration rights we have granted to shareholders, please see "Certain relationships and related party transactions — Registration Rights."

# Acquisitions Under Israeli Law

# Full Tender Offer

A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Israeli Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the same class for the purchase of all of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a shareholder that had its shares so transferred may petition the court within three months from the date of acceptance of the full tender offer, whether or not such shareholder agreed to the tender, to determine whether the tender offer was for less than fair value and whether the fair value should be paid as determined by the court. If the shareholders who did not accept the tender offer hold 5% or more of the issued and outstanding share capital of the company or of the applicable class from shareholders who accepted the tender offer.

# Special Tender Offer

The Israeli Companies Law provides that an acquisition of shares of a public Israeli company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company, unless one of the exemptions in the Israeli Companies Law is met. This rule does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Israeli Companies Law provides that an acquisition of shares in a public company must be made by means of a tender offer if as a result of the acquisition the purchaser would become a holder of 45% or more of the voting rights in the company, if there is no other shareholder of the company who holds 45% or more of the voting rights in the company, if there is no other shareholder of the company who holds 45% or more of the voting rights in the company, in the Israeli Companies Law is met.

A special tender offer must be extended to all shareholders of a company but the offeror is not required to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer.

If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

#### Merger

The Israeli Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Israeli Companies Law are met, a majority of each party's shares voted on the proposed merger at a Shareholders' meeting called with at least 35 days' prior notice.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person who holds 25% or more of the outstanding shares or the right to appoint 25% or more of the directors of the other party, vote against the merger. If the transaction would have been approved but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value of the parties to the merger and the consideration offered to the shareholders.

Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of any of the parties to the merger, and may further give instructions to secure the rights of creditors.

In addition, a merger may not be completed unless at least 50 days have passed from the date that a proposal for approval of the merger was filed by each party with the Israeli Registrar of Companies and 30 days have passed from the date the merger was approved by the shareholders of each party.

#### Anti-Takeover Measures Under Israeli Law

The Israeli Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights, distributions or other matters and shares having preemptive rights. As of the date of this prospectus, we do not have any authorized or issued shares other than our ordinary shares. In the future, if we do create and issue a class of shares other than ordinary shares, such class of shares, depending on the specific rights that may be attached to them, may delay or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization of a new class of shares will require an amendment to our Articles of Association which requires the prior approval of the holders of a majority of our shares at a general meeting. In addition, the rules and regulations of the TASE also limit the terms permitted with respect to a new class of shares and prohibit any such new class of shares from having voting rights. Shareholders voting in such meeting will be subject to the restrictions provided in the Israeli Companies Law as described above in "— Voting Rights."

#### **Borrowing Powers**

Pursuant to the Israeli Companies Law and our Articles of Association, our Board of Directors may exercise all powers and take all actions that are not required under law or under our Articles of Association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

#### **Changes in Capital**

Our Articles of Association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Israeli Companies Law and must be approved by a resolution duly passed by our shareholders at a general or special meeting by voting on such change in the capital. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings and profits and an issuance of shares for less than their nominal value, require a resolution of our Board of Directors and court approval.

# **Transfer Agent and Registrar**

The transfer agent and registrar for our ordinary shares in Israel is Bank Leumi Nominee Company Ltd. (Hevra Le-Rishumim of Bank Leumi Le-Israel Ltd.). Prior to listing our ordinary shares for trading on The NASDAQ Global Market we will appoint a transfer agent in the United States.

# **Reverse Stock Split**

At a special meeting of our shareholders held on August 17, 2010, our shareholders authorized our Board of Directors to adopt a reverse stock split, which we intend to effect prior to this offering and which is subject to the completion of this offering. The reverse stock split will be effected at a ratio of up to 10:1, at our Board of Director's discretion. The split was solicited for purposes of allowing us to meet NASDAQ listing requirements relating to the initial listing of our ordinary shares on The NASDAQ Global Market.

# TAXATION

The following description is not intended to constitute a complete analysis of all tax consequences relating to the ownership or disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign, including Israeli, or other taxing jurisdiction.

## Israeli Tax Considerations

The following is a summary of the material Israeli tax laws applicable to us. This section also contains a discussion of material Israeli tax consequences concerning the ownership and disposition of our ordinary shares. This summary does not discuss all the aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of this kind of investor include residents of Israel or traders in securities who are subject to special tax regimes not covered in this discussion. Because certain parts of this discussion are based on new tax legislation that has not yet been subject to judicial or administrative interpretation, we cannot assure you that the appropriate tax authorities or the courts will accept the views expressed in this discussion.

#### General Corporate Tax Structure in Israel

Israeli companies are generally subject to a corporate tax at the rate of 26% of their taxable income in 2009. The corporate tax rate is scheduled to decline to 25% in 2010, to 24% in 2011, 23% in 2012, 22% in 2013, 21% in 2014, 20% in 2015 and 18% in 2016 and thereafter. Capital gains derived by an Israeli company are generally subject to tax at a rate of 25%, or at the prevailing corporate tax rate, whichever is lower.

#### Tax Benefits and Grants for Research and Development

Israeli tax law allows, under certain conditions, a tax deduction for research and development expenditures, including capital expenditures, for the year in which they are incurred. These expenses must relate to scientific research and development projects and must be approved by the relevant Israeli government ministry, determined by the field of research. Furthermore, the research and development must be for the promotion of the company and carried out by or on behalf of the company seeking such tax deduction. The amount of such deductible expenses is reduced by the sum of any funds received through government grants for the funding of the scientific research and development projects. No deduction under these research and development deduction rules is allowed if such deduction is related to an expense invested in an asset depreciable under the general depreciation rules of the Income Tax Ordinance, 1961. Expenditures not so approved are deductible in equal amounts over three years.

We intend to apply to the Office of the Chief Scientist for approval to allow a tax deduction for all research and development expenses during the year incurred. There can be no assurance that our application will be accepted.

## Taxation of our Shareholders

*Capital Gains Taxes Applicable to Non-Israeli Resident Shareholders.* Shareholders that are not Israeli residents are generally exempt from Israeli capital gains tax on any gains derived from the sale, exchange or disposition of our ordinary shares, provided that such shareholders did not acquire their shares prior to our initial public offering on the TASE and such gains were not derived from a permanent establishment or business activity of such shareholders in Israel. However, non-Israeli corporations will not be entitled to the foregoing exemptions if an Israeli resident (a) has a controlling interest of 25% or more in such non-Israeli corporation, whether directly or indirectly.

In addition, under the U.S.-Israel Tax Treaty, the sale, exchange or disposition of our ordinary shares by a shareholder who is a U.S. resident (for purposes of the U.S. — Israel Tax Treaty) holding the ordinary shares as a capital asset is exempt from Israeli capital gains tax unless either (1) the shareholder holds, directly or indirectly, shares representing 10% or more of our voting capital during any part of the 12-month period preceding such sale, exchange or disposition or (2) the capital gains arising from such sale are attributable to



a permanent establishment of the shareholder located in Israel. In either case, the sale, exchange or disposition of ordinary shares would be subject to Israeli tax, to the extent applicable; however, under the U.S. — Israel Tax Treaty, the U.S. resident would be permitted to claim a credit for the tax against the U.S. federal income tax imposed with respect to the sale, exchange or disposition, subject to the limitations in U.S. laws applicable to foreign tax credits. The U.S. — Israel Tax Treaty does not relate to U.S. state or local taxes.

Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale.

*Taxation of Non-Israeli Shareholders on Receipt of Dividends*. Non-residents of Israel are generally subject to Israeli income tax on the receipt of dividends paid on our ordinary shares at the rate of 20%, which tax will be withheld at the source, unless a different rate is provided in a tax treaty between Israel and the shareholder's country of residence. With respect to a person who is a "substantial shareholder" at the time receiving the dividend or on any date in the 12 months preceding such date, the applicable tax rate is 25%. A "substantial shareholder" is generally a person who alone, or together with his relative or another person who collaborates with him on a permanent basis, holds, directly or indirectly, at least 10% of any of the "means of control" of the corporation. "Means of control" generally include the right to vote, receive profits, nominate a director or an officer, receive assets upon liquidation, or order someone who holds any of the aforesaid rights how to act, and all regardless of the source of such right. Under the U.S. — Israel Tax Treaty, the maximum rate of tax withheld in Israel on dividends paid to a holder of our ordinary shares who is a U.S. resident (for purposes of the U.S. — Israel Tax Treaty) is 25%. However, generally, the maximum rate of withholding tax on dividends that are paid to a U.S. corporation holding 10% or more of our outstanding voting capital throughout the tax year in which the dividend is distributed as well as the previous tax year is 12.5%.

A non-resident of Israel who receives dividends from which tax was withheld is generally exempt from the duty to file returns in Israel in respect of such income, provided such income was not derived from a business conducted in Israel by the taxpayer, and the taxpayer has no other taxable sources of income in Israel.

# **U.S. Federal Income Tax Considerations**

The following is a general summary of the material U.S. federal income tax considerations relating to the purchase, ownership and disposition of the ordinary shares by U.S. Investors (as defined below) that purchase ordinary shares pursuant to the public offering and hold such ordinary shares as capital assets. This summary is based on the Internal Revenue Code, or the Code, the regulations of the U.S. Department of the Treasury issued pursuant to the Code, or the Treasury Regulations, and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect, or to different interpretation. This summary is for general information only and does not address all of the tax considerations that may be relevant to specific U.S. Investors in light of their particular circumstances or to U.S. Investors subject to special treatment under U.S. federal income tax law (such as banks, insurance companies, tax-exempt entities, retirement plans, regulated investment companies, partnerships, dealers in securities, brokers, real estate investment trusts, certain former citizens or residents of the United States, persons who acquire ordinary shares as part of a straddle, hedge, conversion transaction or other integrated investment, persons that have a "functional currency" other than the U.S. dollar, persons that own (or are deemed to own, indirectly or by attribution) 10% or more of our shares or persons that generally mark their securities to market for U.S. federal income tax purposes). This summary does not address any U.S. state or local or non-U.S. tax considerations or any U.S. federal estate, gift or alternative minimum tax considerations.

As used in this summary, the term "U.S. Investor" means a beneficial owner of ordinary shares that is, for U.S. federal income tax purposes, (i) a citizen or resident of the United States, (ii) a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income tax regardless of its source or (iv) a trust with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions, or an electing trust that was in existence on August 19, 1996 and was treated as a domestic trust on that date.

If an entity treated as a partnership for U.S. federal income tax purposes holds ordinary shares, the tax treatment of such partnership and each partner thereof will generally depend upon the status and activities of the partnership and such partner. A holder that is treated as a partnership for U.S. federal income tax purposes should consult its own tax adviser regarding the U.S. federal income tax considerations applicable to it and its partners of the purchase, ownership and disposition of ordinary shares.

Prospective investors should be aware that this summary does not address the tax consequences to investors who are not U.S. Investors. Prospective investors should consult their own tax advisers as to the particular tax considerations applicable to them relating to the purchase, ownership and disposition of ordinary shares, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

# Taxation of U.S. Investors

The discussions under "— Distributions" and under "— Sale, Exchange or Other Disposition of Ordinary Shares" below assumes that we will not be treated as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. However, although we were not a PFIC in 2009 and we do not anticipate being a PFIC in 2010, there remains a possibility that we will be a PFIC in 2010 or in any subsequent year. For a discussion of the rules that would apply if we are treated as a PFIC, see the discussion under "— Passive Foreign Investment Company."

*Distributions.* We have no current plans to pay dividends. To the extent we pay any dividends, a U.S. Investor will be required to include in gross income as a taxable dividend the amount of any distributions made on the ordinary shares, including the amount of any Israeli taxes withheld, to the extent that those distributions are paid out of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes. Any distributions in excess of our earnings and profits will be applied against and will reduce the U.S. Investor's tax basis in its ordinary shares and to the extent they exceed that tax basis, will be treated as gain from the sale or exchange of those ordinary shares. If we were to pay dividends, we expect to pay such dividends in NIS. A dividend paid in NIS, including the amount of any Israeli taxes withheld, will be includible in a U.S. Investor's income as a U.S. dollar amount calculated by reference to the exchange rate in effect on the date such dividend is received, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted to U.S. dollars on the date of receipt, a U.S. Investor generally will not recognize a foreign currency gain or loss. However, if the U.S. Investor converts the NIS into U.S. dollars on a later date, the U.S. Investor must include, in computing its income, any gain or loss resulting from any exchange rate fluctuations. The gain or loss will be equal to the difference between (i) the U.S. dollar value of the amount included in income when the dividend was received and (ii) the amount received on the conversion of the NIS into U.S. dollars. Such gain or loss will generally be ordinary income or loss and United States source for U.S. foreign tax credit purposes. U.S. Investor should consult their own tax advisers regarding the tax consequences to them if we pay dividends in NIS or any other non-U.S. currency.

Subject to certain significant conditions and limitations, including potential limitations under the United States-Israel income tax treaty, any Israeli taxes paid on or withheld from distributions from us and not refundable to a U.S. Investor may be credited against the investor's U.S. federal income tax liability or, alternatively, may be deducted from the investor's taxable income. This election is made on a year-by-year basis and applies to all foreign taxes paid by a U.S. Investor or withheld from a U.S. Investor that year. Dividends paid on the ordinary shares generally will constitute income from sources outside the United States and be categorized as "passive category income" or, in the case of some U.S. Investors, as "general category income" for U.S. foreign tax credits are complex, U.S. Investors should consult their own tax adviser regarding the availability of foreign tax credits in their particular circumstances.

Dividends paid on the ordinary shares will not be eligible for the "dividends-received" deduction generally allowed to corporate U.S. Investors with respect to dividends received from U.S. corporations.

For taxable years beginning before January 1, 2011, distributions treated as dividends that are received by an individual U.S. Investor from "qualified foreign corporations" generally qualify for a 15% reduced maximum tax rate so long as certain holding period and other requirements are met. Dividends paid by us in a taxable year in which we are not a PFIC are expected to be eligible for the 15% reduced maximum tax rate.

However, any dividend paid by us in a taxable year in which we are a PFIC will be subject to tax at regular ordinary income rates. Unless the reduced rate provision is extended or made permanent by subsequent legislation, for tax years beginning on or after January 1, 2011, dividends will be taxed at regular ordinary income rates.

Sale, Exchange or Other Disposition of Ordinary Shares. Subject to the discussion under "— Passive Foreign Investment Company" below, a U.S. Investor generally will recognize capital gain or loss upon the sale, exchange or other disposition of ordinary shares in an amount equal to the difference between the amount realized on the sale, exchange or other disposition and the U.S. Investor's adjusted tax basis in such ordinary shares. This capital gain or loss will be long-term capital gain or loss if the U.S. Investor's holding period in the ordinary shares exceeds one year. Preferential tax rates for long-term capital gain (currently, with a maximum rate of 15% for taxable years beginning before January 1, 2011) will apply to individual U.S. Investors. The deductibility of capital losses is subject to limitations. The gain or loss will generally be income or loss from sources within the United States for U.S. foreign tax credit purposes.

U.S. Investors should consult their own tax advisers regarding the U.S. federal income tax consequences of receiving currency other than U.S. dollars upon the disposition of ordinary shares.

#### Passive Foreign Investment Company

In general, a corporation organized outside the United States will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (i) at least 75% of its gross income is "passive income" or (ii) on average at least 50% of its assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in the public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

Under the tests described above, whether or not we are a PFIC will be determined annually based upon the composition of our income and the composition and valuation of our assets, all of which are subject to change.

We believe that we were a PFIC for U.S. federal income tax purposes for years prior to 2009. We believe that we were not a PFIC in 2009. However, because the PFIC determination is highly fact intensive and made at the end of each taxable year, there can be no assurance that we will not be a PFIC in 2010 or in any subsequent year. Upon request, we will annually inform U.S. Investors if we and any of our subsidiaries were a PFIC with respect to the preceding year.

U.S. Investors should be aware of certain tax consequences of investing directly or indirectly in us if we are a PFIC. A U.S. Investor is subject to different rules depending on whether the U.S. Investor makes an election to treat us as a "qualified electing fund", known as a QEF election, for the first taxable year that the U.S. Investor holds ordinary shares, which is referred to in this disclosure as a "timely QEF election," makes a "mark-to-market" election with respect to the ordinary shares (if such election is available) or makes neither election.

*QEF Election.* A U.S. Investor who makes a timely QEF election, referred to in this disclosure as an "Electing U.S. Investor," with respect to us must report for U.S. federal income tax purposes his pro rata share of our ordinary earnings and net capital gain, if any, for our taxable year that ends with or within the taxable year of the Electing U.S. Investor. The "net capital gain" of a PFIC is the excess, if any, of the PFIC's net long-term capital gains over its net short-term capital losses. The amount so included in income generally will be treated as ordinary income to the extent of such Electing U.S. Investor's allocable share of the PFIC's ordinary earnings and as long-term capital gain to the extent of such Electing U.S. Investor's allocable share of the PFIC's net capital gains. Such Electing U.S. Investor generally will be required to translate such income into U.S. dollars based on the average exchange rate for the PFIC's taxable year with respect to the PFIC's functional currency. Such income generally will be treated as income from sources outside the United States for U.S. foreign tax credit purposes. Amounts previously included in income by such

Electing U.S. Investor under the QEF rules generally will not be subject to tax when they are distributed to such Electing U.S. Investor. The Electing U.S. Investor's tax basis in ordinary shares generally will increase by any amounts so included under the QEF rules and decrease by any amounts not included in income when distributed.

An Electing U.S. Investor will be subject to U.S. federal income tax on such amounts for each taxable year in which we are a PFIC, regardless of whether such amounts are actually distributed to such Electing U.S. Investor. However, an Electing U.S. Investor may, subject to certain limitations, elect to defer payment of current U.S. federal income tax on such amounts, subject to an interest charge. If an Electing U.S. Investor is an individual, any such interest will be treated as non-deductible "personal interest."

Any net operating losses or net capital losses of a PFIC will not pass through to the Electing U.S. Investor and will not offset any ordinary earnings or net capital gain of a PFIC recognized by Electing U.S. Investors in subsequent years (although such losses would ultimately reduce the gain, or increase the loss, recognized by the Electing U.S. Investor on its disposition of the ordinary shares).

So long as an Electing U.S. Investor's QEF election with respect to us is in effect with respect to the entire holding period for ordinary shares, any gain or loss recognized by such Electing U.S. Investor on the sale, exchange or other disposition of such ordinary shares generally will be long-term capital gain or loss if such Electing U.S. Investor has held such ordinary shares for more than one year at the time of such sale, exchange or other disposition. Preferential tax rates for long-term capital gain (currently, with a maximum rate of 15% for taxable years beginning before January 1, 2011) will apply to individual U.S. Investors. The deductibility of capital losses is subject to limitations.

A U.S. Investor makes a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. Upon request, we will annually furnish U.S. Investors with information needed in order to complete IRS Form 8621 (which form would be required to be filed with the IRS on an annual basis by the U.S. Investor) and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC. A QEF election will not apply to any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Each U.S. Investor is encouraged to consult its own tax adviser with respect to tax consequences of a QEF election with respect to us.

*Mark-to-Market Election.* Alternatively, if the ordinary shares are treated as "marketable stock," a U.S. Investor would be allowed to make a "mark-to-market" election with respect to our ordinary shares, provided the U.S. Investor completes and files IRS Form 8621 in accordance with the relevant instructions and related Treasury Regulations. If that election is made, the U.S. Investor generally would include as ordinary income in each taxable year the excess, if any, of the fair market value of the ordinary shares at the end of the taxable year over such holder's adjusted tax basis in the ordinary shares. The U.S. Investor would also be permitted an ordinary loss in respect of the excess, if any, of the U.S. Investor's adjusted tax basis in the ordinary shares over their fair market value at the end of the taxable year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. A U.S. Investor's tax basis in the ordinary shares would be treated as ordinary income, and any loss realized on the sale, exchange or other disposition of the ordinary shares would be treated as ordinary loss to the extent that such loss does not exceed the net mark-to-market gains previously included in income by the U.S. Investor, and any loss in excess of such amount will be treated as capital loss. Amounts treated as ordinary income will not be eligible for the favorable tax rates applicable to qualified dividend income or long-term capital gains.

Generally, stock will be considered marketable stock if it is "regularly traded" on a "qualified exchange" within the meaning of applicable Treasury regulations. A class of stock is regularly traded on an exchange during any calendar year during which such class of stock is traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter. Our ordinary shares will be marketable stock as long as they remain listed on the NASDAQ Global Market and are regularly traded. A mark-to-market election will not apply to our ordinary shares held by a U.S. Investor for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election

will not apply to any PFIC subsidiary that we own. Each U.S. Investor is encouraged to consult its own tax adviser with respect to the availability and tax consequences of a mark-to-market election with respect to our ordinary shares.

*Default PFIC Rules.* A U.S. Investor who does not make a timely QEF election or a mark-to-market election, referred to in this disclosure as a "Non-Electing U.S. Investor", will be subject to special rules with respect to (a) any "excess distribution" (generally, the portion of any distributions received by the Non-Electing U.S. Investor on the ordinary shares in a taxable year in excess of 125% of the average annual distributions received by the Non-Electing U.S. Investor in the three preceding taxable years, or, if shorter, the Non-Electing U.S. Investor's holding period for his ordinary shares), and (b) any gain realized on the sale or other disposition of such ordinary shares. Under these rules:

- the excess distribution or gain would be allocated ratably over the Non-Electing U.S. Investor's holding period for the ordinary shares;
- the amount allocated to the current taxable year and any year prior to us becoming a PFIC would be taxed as ordinary income; and
- the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the
  applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with
  respect to the resulting tax attributable to each such other taxable year.

If a Non-Electing U.S. Investor who is an individual dies while owning our ordinary shares, the Non-Electing U.S. Investor's successor would be ineligible to receive a step-up in tax basis of the ordinary shares. Non-Electing U.S. Investors are encouraged to consult their tax advisers regarding the application of the PFIC rules to their specific situation.

A Non-Electing U.S. Investor who wishes to make a QEF election for a subsequent year may be able to make a special "purging election" pursuant to Section 1291(d) of the Code. Pursuant to this election, a Non-Electing U.S. Investor would be treated as selling his or her stock for fair market value on the first day of the taxable year for which the QEF election is made. Any gain on such deemed sale would be subject to tax under the rules for Non-Electing U.S. Investors as discussed above. Non-Electing U.S. Investors are encouraged to consult their tax advisers regarding the availability of a "purging election" as well as other available elections.

To the extent a distribution on our ordinary shares does not constitute an excess distribution to a Non-Electing U.S. Investor, such Non-Electing U.S. Investor generally will be required to include the amount of such distribution in gross income as a dividend to the extent of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) that are not allocated to excess distributions. The tax consequences of such distributions are discussed above under "— Taxation of U.S. Investors — Distributions." Each U.S. Holder is encouraged to consult its own tax adviser with respect to the appropriate U.S. federal income tax treatment of any distribution on our ordinary shares.

If we are treated as a PFIC for any taxable year during the holding period of a Non-Electing U.S. Investor, we will continue to be treated as a PFIC for all succeeding years during which the Non-Electing U.S. Investor is treated as a direct or indirect Non-Electing U.S. Investor even if we are not a PFIC for such years. A U.S. Investor is encouraged to consult its tax adviser with respect to any available elections that may be applicable in such a situation, including the "deemed sale" election of Code Section 1298(b)(1). In addition, U.S. Investors should consult their tax advisers regarding the IRS information reporting and filing obligations that may arise as a result of the ownership of shares in a PFIC.

We may invest in the equity of foreign corporations that are PFICs or may own subsidiaries that own PFICs. U.S. Investors will be subject to the PFIC rules with respect to their indirect ownership interests in such PFICs, such that a disposition of the shares of the PFIC or receipt by us of a distribution from the PFIC generally will be treated as a deemed disposition of such shares or the deemed receipt of such distribution by the U.S. Investor, subject to taxation under the PFIC rules. There can be no assurance that a U.S. Investor will



be able to make a QEF election or a mark-to-market election with respect to PFICs in which we invest. Each U.S. Investor is encouraged to consult its own tax adviser with respect to tax consequences of an investment by us in a corporation that is a PFIC.

The U.S. federal income tax rules relating to PFICs are complex. U.S. Investors are urged to consult their own tax advisers with respect to the purchase, ownership and disposition of ordinary shares, any elections available with respect to such ordinary shares and the IRS information reporting obligations with respect to the purchase, ownership and disposition of ordinary shares.

#### Certain Reporting Requirements

Certain U.S. Investors are required to file IRS Form 926, Return by U.S. Transferor of Property to a Foreign Corporation, and certain U.S. Investors may be required to file IRS Form 5471, Information Return of U.S. Persons With Respect to Certain Foreign Corporations, reporting transfers of cash or other property to us and information relating to the U.S. Investor and us. Substantial penalties may be imposed upon a U.S. Investor that fails to comply. Each U.S. Investor should consult its own tax adviser regarding these requirements.

## Backup Withholding Tax and Information Reporting Requirements

Generally, information reporting requirements will apply to distributions on our ordinary shares or proceeds on the disposition of our ordinary shares paid within the United States (and, in certain cases, outside the United States) to U.S. Investors other than certain exempt recipients, such as corporations. Furthermore, backup withholding (currently at 28%) may apply to such amounts if the U.S. Investor fails to (i) provide a correct taxpayer identification number, (ii) report interest and dividends required to be shown on its U.S. federal income tax return, or (iii) make other appropriate certifications in the required manner. U.S. Investors who are required to establish their exempt status generally must provide such certification on IRS Form W-9.

Backup withholding is not an additional tax. Amounts withheld as backup withholding from a payment may be credited against a U.S. Investor's U.S. federal income tax liability and such U.S. Investor may obtain a refund of any excess amounts withheld by filing the appropriate claim for refund with the IRS and furnishing any required information in a timely manner.

U.S. Investors should consult their own tax advisers concerning the tax consequences relating to the purchase, ownership and disposition of the ordinary shares.

## UNDERWRITING

The underwriters named below, acting through their representative JMP Securities LLC, have severally agreed with us, subject to the terms and conditions of the underwriting agreement, dated , 2010, to purchase the number of ordinary shares provided below opposite their respective names.

Underwriters	Number of Shares
JMP Securities LLC	
Oppenheimer & Co. Inc.	

# Total

The underwriters are offering the ordinary shares subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the ordinary shares offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the ordinary shares if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below.

# **Over-Allotment Option**

We have granted the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to an aggregate of additional ordinary shares to cover over-allotments, if any, at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the ordinary shares offered by this prospectus. If the underwriters exercise this option, each underwriter will be obligated, subject to certain conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above.

# **Commission and Expenses**

The underwriters have advised us that they propose to offer the ordinary shares to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ per share. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of \$ per ordinary share to certain brokers and dealers. After this offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction shall change the amount of proceeds to be received by us as set forth on the cover page of this prospectus. The ordinary shares are offered by the underwriters as stated herein, subject to receipt and acceptance by them and subject to their right to reject any order in whole or in part. The underwriters do not intend to confirm sales to any accounts over which they exercise discretionary authority.

The following table shows the underwriting discounts and commissions payable to the underwriters by us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' over-allotment option to purchase shares.

Total underwriting discounts and commissions to be paid by us

	Total			
Per Share	No Exercise	Full Exercise		
\$	\$	\$		

We estimate that expenses payable by us in connection with the offering of our ordinary shares, other than the underwriting discounts and commissions referred to above, will be approximately \$\$, which includes \$100,000 that we have agreed to reimburse the underwriters for the legal fees incurred by them in connection with the offering.

#### Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act and liabilities arising from breaches of representations and warranties contained in the underwriting agreement, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

#### **Lock-up Agreements**

We, our officers directors and certain of our shareholders have agreed, subject to limited exceptions, for a period of 180 days after the date of the underwriting agreement, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any ordinary shares or any securities convertible into or exchangeable for our ordinary shares either owned as of the date of the underwriting agreement or thereafter acquired without the prior written consent of JMP Securities LLC. This 180-day period may be extended if (1) during the last 17 days of the 180-day period, we issue an earnings release or material news or a material event regarding us occurs or (2) prior to the expiration of the 180-day period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day period, then the period of such extension will be 18-days, beginning on the issuance of the earnings release or the occurrence of the material news or material event. If after any announcement described in clause (2) of the preceding sentence, we announce that we will not release earnings results during the 16-day period shall expire the later of the expiration of the 180-day period and the end of any extension of such period made pursuant to clause (1) of the preceding sentence. JMP Securities LLC may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements. With the exception of the underwriters' over-allotment option, there are no existing agreements between JMP Securities LLC and us or any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

#### Listing

We intend to apply to list our ordinary shares on The NASDAQ Global Market under the trading symbol "BLRX."

# **Electronic Distribution**

A prospectus in electronic format may be made available on websites or through other online services maintained by one or more of the underwriters of this offering, or by their affiliates. Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

## Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the ordinary shares is completed, SEC rules may limit underwriters from bidding for and purchasing shares. However, the representative may engage in transactions that stabilize the market price of the shares, such as bids or purchases to peg, fix or maintain that price so long as stabilizing transactions do not exceed a specified maximum.

In connection with this offering, the underwriters may engage in transactions that stabilize, maintain or otherwise make short sales of our ordinary shares and may purchase our ordinary shares on the open market to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. "Covered" short sales are sales made in an amount not greater than the underwriters' over-allotment option to purchase additional shares in this offering. The underwriters may close out any covered short position by either exercising their over-allotment option or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. "Naked" short sales are sales in excess of the over-allotment option. The underwriters must close out any



naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in this offering. A "stabilizing bid" is a bid for or the purchase of ordinary shares on behalf of the underwriter in the open market prior to the completion of this offering for the purpose of fixing or maintaining the price of the ordinary shares. A "syndicate covering transaction" is the bid for or purchase of ordinary shares on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with this offering.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our stock or preventing or retarding a decline in the market price of our stock. As a result, the price of our stock may be higher than the price that might otherwise exist in the open market.

The representative may also impose a "penalty bid" on underwriters. A "penalty bid" is an arrangement permitting the representative to reclaim the selling concession otherwise accruing to the underwriters in connection with this offering if the ordinary shares originally sold by the underwriters are purchased by the underwriters in a syndicate covering transaction and have therefore not been effectively placed by the underwriters. The imposition of a penalty bid may also affect the price of the ordinary shares in that it discourages resales of those ordinary shares.

Neither we nor any of the underwriters makes any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our ordinary shares. In addition, neither we nor any of the underwriters makes any representation that the representative will engage in these transactions or that any transaction, if commenced, will not be discontinued without notice.

# **No Public Market**

Prior to this offering, there has not been a public market in the United States for our ordinary shares. Consequently, the initial public offering price for our ordinary shares will be between \$ and \$ per share. The offering price will be determined by reference to the closing price of our ordinary shares on the TASE on the pricing date after taking into account prevailing market conditions and through negotiations between us and the underwriters. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the ordinary shares will trade in the public market subsequent to this offering or that an active trading market for the ordinary shares will develop and continue after this offering.

# INDEPENDENT ACCOUNTANTS

The consolidated financial statements as of December 31, 2009 and 2008 and for each of the three years in the period ended December 31, 2009, included in this prospectus, have been so included in reliance on the report of Kesselman and Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm, as stated in their report appearing herein, given on the authority of said firm as experts in auditing and accounting.

# LEGAL MATTERS

The validity of the ordinary shares being offered by this prospectus and other legal matters concerning this offering relating to Israeli law will be passed upon for us by Yigal Arnon & Co., Jerusalem, Israel. Certain legal matters in connection with this offering relating to U.S. law will be passed upon for us by Morrison & Foerster LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by Meitar Liquornik Geva & Leshem Brandwein, Ramat Gan, Israel, with respect to Israeli law, and by Goodwin Procter LLP, New York, New York, with respect to U.S. law.

# ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of the State of Israel. Service of process upon us and upon our directors and officers and the Israeli experts named in this registration statement, substantially all of whom reside outside of the United States, may be difficult to obtain within the United States. Furthermore, because substantially all of our assets and substantially all of our directors and officers are located outside the United States, any judgment obtained in the United States against us or any of our directors and officers may not be collectible within the United States.

We have been informed by our legal counsel in Israel, Yigal Arnon & Co., that it may be difficult to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws because Israel is not the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law.

Subject to specified time limitations and legal procedures, Israeli courts may enforce a United States judgment in a civil matter which, subject to certain exceptions, is non-appealable, including judgments based upon the civil liability provisions of the Securities Act and the Exchange Act and including a monetary or compensatory judgment in a non-civil matter, provided that among other things:

- the judgments are obtained after due process before a court of competent jurisdiction, according to the laws of the state in which the judgment is given and the rules of private international law currently prevailing in Israel;
- the prevailing law of the foreign state in which the judgments were rendered allows for the enforcement of judgments of Israeli courts;
- adequate service of process has been effected and the defendant has had a reasonable opportunity to be heard and to present his or her evidence;
- the judgments are not contrary to public policy of Israel, and the enforcement of the civil liabilities set forth in the judgment is not likely to impair the security or sovereignty of Israel;
- the judgments were not obtained by fraud and do not conflict with any other valid judgments in the same matter between the same parties;
- an action between the same parties in the same matter is not pending in any Israeli court at the time the lawsuit is instituted in the foreign court; and
- the judgment is enforceable according to the laws of Israel and according to the law of the foreign state in which the relief was granted.

If a foreign judgment is enforced by an Israeli court, it generally will be payable in Israeli currency, which can then be converted into non-Israeli currency and transferred out of Israel. The usual practice in an action before an Israeli court to recover an amount in a non-Israeli currency is for the Israeli court to issue a judgment for the equivalent amount in Israeli currency at the rate of exchange in force on the date of the judgment, but the judgment debtor may make payment in foreign currency. Pending collection, the amount of the judgment of an Israeli court stated in Israeli currency ordinarily will be linked to the Israeli consumer price index plus interest at the annual statutory rate set by Israeli regulations prevailing at the time. Judgment creditors must bear the risk of unfavorable exchange rates.

# AVAILABLE INFORMATION

We have filed with the SEC a registration statement on Form F-l under the Securities Act relating to this offering of our ordinary shares. This prospectus does not contain all of the information contained in the registration statement. The rules and regulations of the SEC allow us to omit certain information from this prospectus that is included in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we filed any of these documents as an exhibit to the registration statement, you may read the document itself for a complete description of its terms.

You may read and copy the registration statement, including the related exhibits and schedules, and any document we file with the SEC without charge at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, DC 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains an Internet website that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are also available to the public through the SEC's website at *http://www.sec.gov*.

Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, applicable to foreign private issuers and under those requirements will file reports with the SEC. Those other reports or other information may be inspected without charge at the locations described above. As a foreign private issuer, we will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. However, we will file with the SEC, within 180 days after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and will submit to the SEC, on a Form 6-K, unaudited quarterly financial information. For fiscal years ending after December 31, 2011, we will be required to file an annual report on Form 20-F within 120 days after the end of the fiscal year.

In addition, since our ordinary shares are traded on the TASE, we have filed Hebrew language periodic and immediate reports with, and furnish information to, the TASE and the Israel Securities Authority, or the ISA, as required under Chapter Six of the Israel Securities Law, 1968. Copies of our filings with the Israeli Securities Authority can be retrieved electronically through the MAGNA distribution site of the Israeli Securities Authority (*www.magna.isa.gov.il*) and the TASE website (maya.tase.co.il).

We maintain a corporate website at *www.biolinerx.com*. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

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# BioLineRx Ltd.

			Convenience translation into USD (Note 1b)
	December 31, 2009	June 30, 2010	June 30, 2010
	NIS in th	iousands	In thousands
Assets			
CURRENT ASSETS			
Cash and cash equivalents	105,890	88,489	22,836
Prepaid expenses	1,094	1,102	284
Trade accounts receivable	37,750		
Other receivables	2,313	9,637	2,487
Total current assets	147,047	99,228	25,607
NON-CURRENT ASSETS			
Restricted deposits	3,704	3,719	960
Long-term prepaid expenses	1,150	1,146	296
Property and equipment, net	4,175	4,696	1,212
Intangible assets, net	3,042	1,473	380
Asset in respect of retirement benefit obligations	49	49	12
Total non-current assets	12,120	11,083	2,860
Total assets	159,167	110,311	28,467
Liabilities and equity			
CURRENT LIABILITIES			
Current maturities of long-term loan	_	307	79
Accounts payable and accruals:			
Trade	6,452	3,615	933
OCS	14,005	17,460	4,506
Licensors	10,570	1,628	420
Other	10,203	9,216	2,378
Total current liabilities	41,230	32,226	8,316
LONG-TERM LIABILITIES			
Long-term loan, less current maturities	_	589	152
COMMITMENTS AND CONTINGENT LIABILITIE	S		
Total liabilities	41,230	32,815	8,468
EQUITY			
Ordinary shares	1,235	1,235	319
Warrants	6,549	6,529	1,685
Share premium	412,513	412,533	106,460
Capital reserve	22,963	26,146	6,747
Accumulated deficit	(325,323)	(368,947)	(95,212)
Total equity	117,937	77,496	19,999
Total liabilities and equity	159,167	110,311	28,467

# CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION (UNAUDITED)

The accompanying notes are an integral part of these condensed financial statements.

# F-2

# BioLineRx Ltd.

# CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS (UNAUDITED)

	Three mor June		Convenience translation into USD (Note 1b) Six mont June	Six months ended	
	2009	2010	2009	2010	June 30, 2010
	NIS in th	ousands	NIS in thousands		In thousands
SALES AND MARKETING EXPENSES	(1,054)	(1,225)	(1,477)	(2,184)	(564)
RESEARCH AND DEVELOPMENT EXPENSES, NET	(23,364)	(26,296)	(49,850)	(37,032)	(9,557)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,762)	(3,289)	(4,307)	(6,224)	(1,606)
OPERATING LOSS	(26,180)	(30,810)	(55,634)	(45,440)	(11,727)
FINANCIAL INCOME	9	2,685	3,799	2,878	743
FINANCIAL EXPENSES	(1,710)	(24)	(1,739)	(1,062)	(274)
COMPREHENSIVE LOSS FOR THE PERIOD	(27,881)	(28,149)	(53,574)	(43,624)	(11,258)
	]	NIS		NIS	1
LOSS PER ORDINARY SHARE – BASIC AND DILUTED	(0.35)	(0.23)	(0.68)	(0.35)	(0.09)

The accompanying notes are an integral part of these condensed financial statements.

# BioLineRx Ltd.

# CONDENSED INTERIM STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

Ordinary shares	Warrants	Share premium	Capital reserve	Accumulated deficit	Total
		NIS in t	housands		
625	947	307,658	32,961	(263,805)	78,386
—	—		1,379	—	1,379
*	*	3	—		3
—	(947)	947	_	—	_
29	—	12,996	(12,911)		114
141	—	15,544	—	—	15,685
	—	—	—	(53,574)	(53,574)
795		337,148	21,429	(317,379)	41,993
Ordinary shares	Warrants	Share premium	Capital Reserve	Accumulated deficit	Total
		NIS in t	housands		
1,235	6,549	412,513	22,963	(325,323)	117,937
—	—		3,183		3,183
*	—	20	(20)	—	—
*		20	(20)	 (43,624)	(43,624)
* 	 	20  412,533	(20) 	 (43,624) (368,947)	(43,624) 77,496
	 6,549 Warrants				<u> </u>
1,235 Ordinary shares	Warrants Convenience	412,533 Share premium translation into	26,126 Capital Reserve	(368,947) Accumulated	77,496
1,235 Ordinary	Warrants	412,533 Share premium	26,126 Capital Reserve	(368,947) Accumulated deficit	77,496
1,235 Ordinary shares	Warrants Convenience	412,533 Share premium translation into	26,126 Capital Reserve	(368,947) Accumulated deficit sands (Note 1b)	77,496 Total
1,235 Ordinary shares	Warrants Convenience	412,533 Share premium translation into	26,126 Capital Reserve USD in thou 5,926	(368,947) Accumulated deficit sands (Note 1b)	77,496 Total 30,436
1,235 Ordinary shares 319	Warrants Convenience	412,533 Share premium translation inte 106,455	26,126 Capital Reserve	(368,947) Accumulated deficit sands (Note 1b)	77,496 Total
1,235 Ordinary shares	Warrants Convenience	412,533 Share premium translation into	26,126 Capital Reserve USD in thou 5,926	(368,947) Accumulated deficit sands (Note 1b)	77,496 Total 30,436
1,235 Ordinary shares 319	Warrants Convenience 1,690	412,533 Share premium translation inte 106,455	26,126 Capital Reserve USD in thou 5,926	(368,947) Accumulated deficit sands (Note 1b)	77,496 Total 30,436
	<u>shares</u> 625 	shares	shares         premium           625         947         307,658           625         947         307,658           625         947         307,658           625         947         307,658           625         947         307,658           625         947         307,658           626         -         -           627         -         -           793         -         12,996           141         -         15,544           -         -         -           795         -         337,148           Ordinary         Warrants         Share           premium         NIS in the start	shares         premium         reserve           NIS in thousands         NIS in thousands           625         947         307,658         32,961             1,379           *         *         3             (947)         947            29          12,996         (12,911)           141          15,544                  795          337,148         21,429           Ordinary         Warrants         Share         Capital           premium         Reserve         NIS in thousands           1,235         6,549         412,513         22,963	$ \begin{array}{c c c c c c c c c c c c c c c c c c c $

\* Less than NIS 1,000

The accompanying notes are an integral part of these condensed financial statements.

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# CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS (UNAUDITED)

CASH FLOWS – OPERATING ACTIVITIES     NIS in thousands     I       Loss for the period     (53,574)     (43,624)	une 30, 2010 In thousands (11,258) 6,435
CASH FLOWS – OPERATING ACTIVITIESLoss for the period(53,574)(43,624)	(11,258)
Loss for the period (53,574) (43,624)	
A divertments required to reflect not each used in operating (12,620) 24,029	6,435
Adjustments required to reflect net cash used in operating(13,620)24,938activities (see appendix below)	
Net cash used in operating activities(67,194)(18,686)	(4,823)
CASH FLOWS – INVESTING ACTIVITIES	
Proceeds from sale of financial assets at fair value through profit 30,837 —	—
or loss	
Proceeds from sale of financial assets at fair value through profit 3,767 —	
or loss – restricted	
Investment in restricted deposits (3,219) —	
Purchase of property and equipment (25) (1,282)	(331)
Purchase of intangible assets   (251)   (87)	(22)
Net cash provided by (used in) investing activities31,109(1,369)	(353)
CASH FLOWS – FINANCING ACTIVITIES	
Issuance of share capital and warrants, net of issuance expenses 15,685 —	
Proceeds from exercise of warrants 3 —	—
Proceeds from exercise of employee stock options 114 —	
Proceeds from borrowings — 1,020	263
Repayments of borrowings (124)	(32)
Net cash provided by financing activities15,802896	231
DECREASE IN CASH AND CASH EQUIVALENTS (20,283) (19,159)	(4,945)
CASH AND CASH EQUIVALENTS - BEGINNING OF60,379105,890	27,327
PERIOD	
<b>EXCHANGE DIFFERENCES ON CASH AND CASH</b> 1,920 1,758	454
EQUIVALENTS	
CASH AND CASH EQUIVALENTS - END OF PERIOD42,01688,489	22,836

The accompanying notes are an integral part of the financial statements.

# APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

# (UNAUDITED)

(CINAODII	LD)		
			Convenience translation into USD (Note 1b)
	Six month June		Six months ended June 30, 2010
	2009	2009 2010 NIS in thousands	
	NIS in the	ousands	In thousands
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization	855	867	224
Impairment of intangible assets	148	1,550	400
Retirement benefit obligations			
Long-term prepaid expenses	40	4	1
Exchange differences on cash and cash equivalents	(1,920)	(1,758)	(454)
Gain on fair value adjustments to financial assets at fair value through profit or loss	(98)		
Share-based compensation	1,379	3,183	821
Interest and exchange differences on restricted deposits	(20)	(15)	(4)
	384	3,831	988
Changes in operating asset and liability items:			
Decrease in trade accounts receivable and other receivables	429	30,418	7,850
Decrease in accounts payable and accruals	(14,433)	(9,311)	(2,403)
	(14,004)	21,107	5,447
	(13,620)	24,938	6,435
Supplementary information on interest received in cash	351	416	107

The accompanying notes are an integral part of the financial statements.

# NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED)

# NOTE 1 — GENERAL INFORMATION

# a. General

BioLineRx Ltd. (the "Company") was incorporated and commenced operations in April 2003.

Since incorporation, the Company has been engaged, both independently and through its consolidated entities (collectively, the "Group"), in the development of therapeutics, from early-stage development to advanced clinical trials, for a wide range of medical needs.

In December 2004, the Company registered a limited partnership, BioLine Innovations Jerusalem L.P. (the "Partnership"), which commenced operations on January 1, 2005. The Company holds a 99% interest in the Partnership, with the remaining 1% held by a wholly owned subsidiary of the Company, BioLine Innovations Ltd. The Partnership was established to operate an industrial research and development center in an incubator located in Jerusalem under an agreement with the State of Israel.

In February 2007, the Company listed its securities on the Tel Aviv Stock Exchange (TASE) and they have been traded on the TASE since that time.

In January 2008, the Company established a wholly owned subsidiary, BioLineRx USA Inc., which serves as the Group's business development arm in the United States.

The Company has been engaged in drug development since its incorporation. The Company has not yet generated profits from its activities and cannot determine with reasonable certainty if and when the Company will become profitable.

#### b. Convenience translation into US dollars ("dollars" or "USD")

For the convenience of the reader, the reported New Israeli Shekel ("NIS") amounts as of June 30, 2010 have been translated into dollars, at the representative rate of exchange on June 30, 2010 (USD 1 = NIS 3.875). The dollar amounts presented in these financial statements should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated.

#### c. Approval of condensed consolidated interim financial statements

The condensed consolidated interim financial statements of the Company for the three and six months ended June 30, 2010 were approved by the Board of Directors of the Company on August 31, 2010, and signed on its behalf by the Chairman of the Board, the Company's Chief Executive Officer and the Company's Chief Financial and Operating Officer.

### NOTE 2 — BASIS OF PREPARATION

The Group's condensed consolidated interim financial statements as of June 30, 2010 and for the three and six months then ended (hereinafter — the interim financial statements) have been prepared in accordance with International Accounting Standard No. 34, "Interim Financial Reporting" (hereinafter — IAS 34). These interim financial statements, which are unaudited, do not include all disclosures necessary for a complete presentation of financial position, results of operations, and cash flows in conformity with generally accepted accounting principles. The condensed consolidated interim financial statements should be read in conjunction with the annual financial statements as of December 31, 2009 and for the year then ended and their accompanying notes, which have been prepared in accordance with International Financial Reporting Standards ("IFRS") as published by the International Accounting Standards Board ("IASB"). The results of operations for the three and six months ended June 30, 2010 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

# NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED)

# NOTE 3 — SIGNIFICANT ACCOUNTING POLICIES

The accounting policies and calculation methods applied in the preparation of the interim financial statements are consistent with those applied in the preparation of the annual financial statements as of December 31, 2009 and for the year then ended.

# NOTE 4 — INTANGIBLE ASSETS

The Group wrote off intangible assets in the aggregate amount of NIS 1,550,000 during the six months ending June 30, 2010, relating to two projects (BL-4060 and BL-5020) which were terminated.

#### NOTE 5 — EQUITY

- a. In January 2010, the Company granted to employees a total of 752,100 options exercisable into Ordinary Shares. The exercise prices of the options range from NIS 4.83 to NIS 5.02. The options vest over a four-year period.
- b. In February and March 2010, the Company granted to employees and to members of its Scientific Advisory Board a total of 4,020,300 options exercisable into Ordinary Shares. The exercise price of the options is NIS 4.03 per share. The options vest over a four-year period and expire five years from the date of grant.
- c. During the six months ended June 30, 2010, a total of 15,850 employee options were exercised.

# NOTE 6 - RESEARCH AND DEVELOPMENT

Research and development expenses are reflected net of research grants received from an interested (related) party of the Company, pursuant to a research funding arrangement for early development stage projects, as follows:

	Three months ended June 30,		I Six months end June 30,	
	2009 2010		2009	2010
	NIS in the	ousands	NIS in the	ousands
Grants received from interested party, offset	816	881	1,501	1,636
against research and development				
expenses				

# NOTE 7 — OUT-LICENSING AGREEMENT WITH CYPRESS BIOSCIENCE INC.

In June 2010, the Group entered into an exclusive, royalty-bearing out-licensing agreement with Cypress Bioscience, Inc. ("Cypress Bioscience") for the United States, Canada and Mexico (the "territories"), with regard to BL-1020, a therapeutic candidate for the treatment of schizophrenia. Under the agreement, Cypress Bioscience is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and to commercialize BL-1020 in the territories, and will bear all subsequent costs involved in the continued development of the product, the conduct and funding of its commercialization, and the prosecution and maintenance of patents in the territories.

The effectiveness of the agreement was subject to the consent of the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor ("OCS"), which was received in August 2010. See Note 8.

The total potential payments from the agreement to the Group, not including royalties, are up to USD 365,000,000, as follows: (1) upfront fee of USD 30,000,000, held in escrow until effectiveness of the agreement; (2) up to USD 250,000,000 in connection with the achievement of certain performance-based milestones; (3) up to USD 85,000,000 upon the achievement of certain sales-based milestones.



# NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED)

# NOTE 7 — OUT-LICENSING AGREEMENT WITH CYPRESS BIOSCIENCE INC. – (continued)

With regard to the first performance-based milestone, Cypress Bioscience is entitled to pay a portion of the amount as an investment in the Company's Ordinary Shares.

In addition to the above payments, the Group is also entitled under the agreement to royalties ranging from 12% to 18% of net sales of BL-1020 in the territories.

The Group retained the rights to BL-1020 for the rest of the world outside of the territories. In addition, pursuant to the agreement, the Group has the right to use all regulatory data generated and prepared by Cypress Bioscience in connection with its pursuit of regulatory approval for BL-1020 in Cypress Bioscience's territory, for use by the Group outside Cypress Bioscience's territory, subject to future reimbursement of certain pre-commercialization expenses (as defined) incurred by Cypress Bioscience in generating such data.

The Group is required to pay 22.5% of all consideration received under the agreement to the licensors of BL-1020. In addition, the Group will be obligated to repay grants received from the OCS regarding the BL-1020 project, in accordance with the Israeli R&D Law and as agreed with the OCS.

In light of the Group's progress in developing BL-1020 to the out-licensing stage with a third party, as well as the advanced stage of negotiations with such third party, the Group believes that it is more likely than not that it will be required to repay the grants received from the OCS regarding the BL-1020 project. Accordingly, as of June 30, 2010, the Group recorded a liability to the OCS for the full amount of the grants received in respect of the project, in the total amount of USD 4,500,000.

# NOTE 8 — EVENTS SUBSEQUENT TO THE BALANCE SHEET DATE

- a. In August 2010, the out-licensing transaction with Cypress Bioscience became effective, following receipt of OCS consent to the transaction. Accordingly, the USD 30,000,000 upfront payment was released to the Group from escrow. From such upfront payment, the Group paid USD 6,750,000 to the licensors and USD 3,000,000 to the OCS.
- b. In August 2010, the Company's shareholders formally authorized the Board of Directors to effect a reverse split of the Company's shares, at a ratio to be determined by the Board (but not greater than 10:1), and subject to successful registration of the Company's shares in an initial public offering on The NASDAQ Global Market.

## NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED)

# NOTE 8 — EVENTS SUBSEQUENT TO THE BALANCE SHEET DATE – (continued)

# REPORT OF INDEPENDENT REGISTERED ACCOUNTING FIRM

To the shareholders of **BioLineRx Ltd.** 

We have audited the accompanying consolidated statements of financial position of BioLineRx Ltd. (the "Company") and its consolidated entities as of December 31, 2008 and 2009 and the related consolidated statements of comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2009. These financial statements are the responsibility of the Company's Board of Directors and management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by the Company's Board of Directors and management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company and its consolidated entities as of December 31, 2008 and 2009 and their results of operations and cash flows for each of the three years in the period ended December 31, 2009, in conformity with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). Tel Aviv, Israel **Kesselman & Kesselman** 

March 24, 2010

Kesselman & Kesselman Certified Public Accountants (Isr.) Member of PricewaterhouseCoopers International Ltd.

# CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

				Convenience translation into USD
		Decem	· ·	(Note 1b) December 31,
	Note	2008	2009	2009
		NIS in th	nousands	In thousands
Assets				
CURRENT ASSETS				
Cash and cash equivalents	2h	60,379	105,890	27,325
Financial assets at fair value through profit or loss	2g(1)	30,749	—	_
Financial assets at fair value through profit or loss –	2g(1),	139	—	—
restricted	11b(1)			
Prepaid expenses		5,532	1,094	282
Trade accounts receivable	2j,14		37,750	9,742
Other receivables	13a	5,748	2,313	597
Total current assets		102,547	147,047	37,946
NON-CURRENT ASSETS				
Restricted deposits	2i,11b(1)	604	3,704	956
Financial assets at fair value through profit or loss – restricted	2g(1), 11b(1)	3,618	_	_
Long-term prepaid expenses	13b	270	1,150	297
Property and equipment, net	6	5,484	4,175	1,077
Intangible assets, net	7	3,205	3,042	785
Asset in respect of retirement benefit obligations	2q	—	49	13
Total non-current assets		13,181	12,120	3,128
Total assets		115,728	159,167	41,074
Liabilities and equity				
CURRENT LIABILITIES	3a			
Accounts payable and accruals:				
Trade	13c(1)	31,345	6,452	1,665
OCS			14,005	3,614
Licensors			10,570	2,728
Other	13c(2)	5,983	10,203	2,633
Total current liabilities		37,328	41,230	10,640
NON-CURRENT LIABILITIES			<u> </u>	
Retirement benefit obligations	2q	14	_	_
COMMITMENTS AND CONTINGENT	-4			
LIABILITIES				
Total liabilities		37,342	41,230	10,640
EQUITY	8	07,012	11,200	10,010
Ordinary shares	0	625	1,235	319
Warrants		947	6,549	1,690
Share premium		307,658	412,513	106,455
Capital reserve		32,961	22,963	5,926
Accumulated deficit		(263,805)	(325,323)	(83,956)
Total equity		78,386	117,937	30,434
Total liabilities and equity		115,728	159,167	41,074
בסומו וומטוווווכא מווע פקווונא		110,720	135,107	41,074

The accompanying notes are an integral part of the financial statements.

# CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Note	Yea	r ended December	31,	Convenience translation into USD
		2007	2008	2009	(Note 1b) 2009
			NIS in thousands		In thousands
REVENUES	14			63,909	16,493
COST OF REVENUES	13d		—	(22,622)	(5,838)
GROSS PROFIT				41,287	10,655
RESEARCH AND DEVELOPMENT	13e	(75,863)	(106,156)	(90,302)	(23,304)
EXPENSES, NET					
SALES AND MARKETING EXPENSES	13f	—	—	(3,085)	(796)
GENERAL AND ADMINISTRATIVE	13g	(13,611)	(13,083)	(11,182)	(2,886)
EXPENSES					
GAIN ON ADJUSTMENT OF WARRANTS	2k	27,557	3,658	—	—
TO FAIR VALUE					
OPERATING LOSS		(61,917)	(115,581)	(63,282)	(16,331)
FINANCIAL INCOME	13h	7,875	13,001	3,928	1,013
FINANCIAL EXPENSES	13i	(5,377)	(12,269)	(2,164)	(558)
LOSS AND COMPREHENSIVE LOSS FOR		(59,419)	(114,849)	(61,518)	(15,876)
THE YEAR					
			NIS		USD
LOSS PER ORDINARY SHARE – BASIC AND	10a	(0.88)	(1.44)	(0.63)	(0.16)
DILUTED					

The accompanying notes are an integral part of the financial statements.

# STATEMENTS OF CHANGES IN EQUITY

		Share capita	1	Warrants	Share			Total
	Ordinary shares		Preferred A-1 shares		premium	reserve	deficit	
				NIS is	n thousands			
BALANCE AT JANUARY 1, 2007	*	136	71	—	92,221	9,852	(89,537)	12,743
CHANGES IN 2007:								
Issuance of preferred A-1 shares		—	19	—	7,977	—		7,996
Conversion of preferred A-1 shares	90		(90)	—	—	_		
Conversion of preferred A shares	136	(136)	—	—		—		
Issuance of share capital	393	—	—	—	205,801	—		206,194
Employee stock options exercised	6	—	—	—	1,659	(1,642)		23
Share-based compensation		_	—	—	—	15,716		15,716
Comprehensive loss for the year							(59,419)	(59,419)
BALANCE AT DECEMBER 31, 2007	625				307,658	23,926	(148,956)	183,253
CHANGES IN 2008:								
Warrants reclassified from liabilities to				947				947
equity								
Share-based compensation	—			—	—	9,035		9,035
Comprehensive loss for the year							(114,849)	(114,849)
BALANCE AT DECEMBER 31, 2008	625			947	307,658	32,961	(263,805)	78,386
CHANGES IN 2009:								
Exercise of warrants	*			*	3			3
Expiration of warrants				(947)	947			
Employee stock options exercised	30				13,143	(13,057)		116
Employee stock options forfeited					340	(340)		
Issuance of share capital and warrants	580			6,549	90,422			97,551
Share-based compensation	_				—	3,399		3,399
Comprehensive loss for the year							(61,518)	(61,518)
BALANCE AT DECEMBER 31, 2009	1,235			6,549	412,513	22,963	(325,323)	117,937

\* Represents an amount less than NIS 1,000.

The accompanying notes are an integral part of the financial statements.

# STATEMENTS OF CHANGES IN EQUITY

	Share capital		Warrants	Share	Capital	Accumulated	Total	
	Ordinary shares	Preferred A shares	Preferred A-1 shares		premium	reserve	deficit	
			Convenience	translation in	to USD in the	usands (Not	e 1b)	
BALANCE AT JANUARY 1, 2009	161			244	79,395	8,507	(68,080)	20,227
CHANGES IN 2009:								
Exercise of warrants	*			*	1	—		1
Expiration of warrants				(244)	244			_
Employee stock options exercised	8			_	3,392	(3,370)	_	30
Employee stock options forfeited	_				88	(88)	_	—
Issuance of share capital and warrants	150			1,690	23,335	_		25,175
Share-based compensation	_					877	_	877
Comprehensive loss for the year	_				—		(15,876)	(15,876)
BALANCE AT DECEMBER 31, 2009	319			1,690	106,455	5,926	(83,956)	30,434

The accompanying notes are an integral part of the financial statements.

# CONSOLIDATED CASH FLOW STATEMENTS

CONSOLIDATED CASH FLOW STATEMENTS Convenience					
		ended Decembe	· · · ·	into USD (Note 1b)	
	2007	2008	2009	2009	
		NIS in thousands		In thousands	
CASH FLOWS – OPERATING ACTIVITIES					
Comprehensive loss for the year	(59,419)	(114,849)	(61,518)	(15,876)	
Adjustments required to reflect net cash used in operating	1,150	21,080	(22,978)	(5,930)	
activities (see appendix below)					
Net cash used in operating activities	(58,269)	(93,769)	(84,496)	(21,806)	
CASH FLOWS – INVESTING ACTIVITIES					
Proceeds from sale of financial assets at fair value through profit or loss	_	27,851	30,837	7,958	
Proceeds from sale of financial assets at fair value through profit or loss – restricted			3,767	972	
Purchase of financial assets at fair value through profit or loss	—	(58,327)	—	—	
Purchase of financial assets at fair value through profit or loss – restricted	—	(3,757)	—	—	
Investment in restricted deposits		_	(3,147)	(812)	
Withdrawal of restricted deposits	1,613	5,977	251	65	
Purchase of property and equipment	(1,341)	(3,255)	(235)	(61)	
Grants received in respect of property and equipment	325	28			
Proceeds from sale of property and equipment			3	1	
Purchase of intangible assets	(1,011)	(1,790)	(628)	(162)	
Net cash provided by (used in) investing activities	(414)	(33,273)	30,848	7,961	
CASH FLOWS – FINANCING ACTIVITIES					
Shareholders' loans convertible into shares	38,142	_	_	_	
Issuance of share capital and warrants, net of issuance	200,069		97,551	25,174	
expenses					
Proceeds from exercise of warrants			3	1	
Issuance of preferred A-1 shares, net of issuance expenses	7,996		—		
Proceeds from exercise of employee stock-options	23		116	30	
Net cash provided by financing activities	246,230		97,670	25,205	
INCREASE (DECREASE) IN CASH AND CASH	187,547	(127,042)	44,022	11,360	
EQUIVALENTS					
CASH AND CASH EQUIVALENTS – BEGINNING OF YEAR	6,498	193,798	60,379	15,581	
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(247)	(6,377)	1,489	384	
CASH AND CASH EQUIVALENTS – END OF YEAR	193,798	60,379	105,890	27,325	

The accompanying notes are an integral part of the financial statements.

# CONSOLIDATED CASH FLOW STATEMENTS

CONSOLIDATED C.	ASH FLOW		Convenience translation into USD	
	2007	2008	(Note 1b) 2009	
	ľ	NIS in thousand	S	In thousands
APPENDIX				
Adjustments required to reflect net cash used in operating activities:				
Income and expenses not involving cash flows:				
Depreciation and amortization	1,077	1,676	1,754	453
Impairment of intangible assets	—	603	584	151
Retirement benefit obligations	(28)	_	(63)	(17)
Interest on a loan convertible into shares	145	—		
Long-term prepaid expenses	(44)	(103)	(880)	(227)
Gain on adjusting warrants to fair value	(27,557)	(3,658)		
Loss on sale of property and equipment	_	_	1	_
Exchange differences on cash and cash equivalents	247	6,377	(1,489)	(384)
Gain on fair value adjustments to financial assets at fair value through profit or loss		(273)	(98)	(25)
Share-based compensation	15,716	9,035	3,399	877
Interest and exchange differences on restricted deposits	554	156	(204)	(53)
	(9,890)	13,813	3,004	775
Changes in operating asset and liability items:				
Increase in trade accounts receivable and other receivables	(679)	(9,812)	(29,877)	(7,710)
Increase in accounts payable and accruals	11,719	17,079	3,895	1,005
	11,040	7,267	(25,982)	(6,705)
	1,150	21,080	(22,978)	(5,930)
Supplementary information on investing and financing activities not involving cash flows:				
Convertible loans converted into ordinary shares	38,287	_	_	_
Credit received in connection with purchase of intangible assets		238	245	63
Warrants reclassified from liabilities to equity		947		
Supplementary information on interest received in cash	7,233	3,901	443	114

The accompanying notes are an integral part of the financial statements.

# NOTES TO THE FINANCIAL STATEMENTS

## NOTE 1 — GENERAL INFORMATION

#### a. General

BioLineRx Ltd. (the "Company") was incorporated and commenced operations in April 2003.

Since incorporation, the Company has been engaged, both independently and through its consolidated entities (collectively, the "Group"), in the development of therapeutics, from early-stage development to advanced clinical trials, for a wide range of medical needs.

In December 2004, the Company formed a limited partnership, BioLine Innovations Jerusalem L.P. (the "Partnership"), which commenced operations on January 1, 2005. The Company holds a 99% interest in the Partnership, with the remaining 1% held by a wholly-owned subsidiary of the Company, BioLine Innovations Ltd. (the "Subsidiary"). The Partnership was established to operate an industrial research and development center in an incubator located in Jerusalem (the "Incubator") under an agreement with the State of Israel. See Note 11a(1).

In February 2007, the Company listed its securities on the Tel Aviv Stock Exchange ("TASE") — see Note 8.

In January 2008, the Company established a wholly-owned subsidiary, BioLineRx USA Inc., which serves as the Group's business development arm in the United States.

The Company has been engaged in drug development since its incorporation. The Company has not yet generated profits from its activities and cannot determine with reasonable certainty if and when the Company will become profitable.

## b. Convenience translation into US dollars ("dollars" or "USD")

For the convenience of the reader, the reported New Israeli Shekel (NIS) amounts as of December 31, 2009 have been translated into dollars, at the representative rate of exchange on June 30, 2010 (USD 1 = NIS 3.875). The dollar amounts presented in these financial statements should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated.

#### c. Approval of consolidated financial statements

The consolidated financial statements of the Company for the year ended December 31, 2009 were approved by the Board of Directors of the Company on March 24, 2010, and signed on its behalf by the Chairman of the Board, the Company's Chief Executive Officer and the Company's Chief Financial and Operating Officer.

# NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES

#### a. Basis of presentation

The Company's consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the IASB.

The consolidated financial statements have been prepared on the basis of historical cost, subject to adjustment of financial assets and liabilities to their fair value through profit or loss and adjustment of assets and liabilities in connection with retirement benefit obligations.

The Company classifies its expenses on the statement of comprehensive loss based on the operating characteristics of such expenses. The Company's annual operating cycle consists of a standard 12-month period.

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the

### NOTES TO THE FINANCIAL STATEMENTS

# NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)

Group's accounting policies. Areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in Note 4. Actual results may differ materially from estimates and assumptions used by the Group's management.

#### b. Consolidation of the financial statements

Consolidated entities are all entities over which the Company has the power to govern the financial and operating policies, which generally involves holding of more than 50% of the shares or interests conferring voting rights of the applicable entity. The existence and effect of potential voting rights that are currently exercisable or convertible are considered when assessing whether the Company controls an entity. Consolidated entities are fully consolidated from the date on which control of such entities is transferred to the Company and they are de-consolidated from the date that control ceases. The purchase method of accounting is used to account for the acquisition of subsidiaries by the Group.

#### c. Functional and presentation currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which each entity operates (the "functional currency"). The consolidated financial statements are presented in NIS, which is the Company's functional currency and the Group's presentation currency.

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the date of each transaction. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at yearend exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement within the relevant line items to which the gains and losses are related.

# d. Property and equipment

Property and equipment are stated at historical cost less depreciation and related grants received from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor (the "OCS"). Historical cost includes expenditures that are directly attributable to the acquisition of the items. Assets are depreciated by the straight-line method over the estimated useful lives of the assets, provided that the Group's management believes the residual values of the assets to be negligible, as follows:

	70
Computers and communications equipment	20 - 33
Office furniture and equipment	6 - 15
Laboratory equipment	15 – 20

The assets' residual values and useful lives are reviewed, and adjusted, if appropriate, at each balance sheet date. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Leasehold improvements are amortized by the straight-line method over the term of the lease, which is shorter than the estimated useful life of the improvements.

Grants received from the OCS are recognized in profit or loss over the life of a depreciable asset as a reduction in depreciation expense.

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)

#### e. Intangible assets

The Group applies the cost method of accounting in subsequent measurements of intangible assets. Under this method of accounting, intangible assets are carried at cost less any accumulated amortization and any accumulated impairment losses.

## Intellectual property

The Group recognizes in its financial statements intangible assets developed by the Group to the extent that the conditions stipulated in o. below are met. Intellectual property acquired by the Group is initially measured at cost. Intellectual property acquired by the Group, which is used in subsequent research and development for projects still under development, is not amortized and is tested annually for impairment. See f. below.

#### Computer software

Acquired computer software licenses are capitalized on the basis of the costs incurred to acquire and bring to use the specific software. These costs are amortized over the estimated useful lives of the software programs (3 - 5 years).

#### f. Impairment of non-financial assets

Intangible assets are tested annually for impairment, except for computer software that is amortized, as detailed in 2e above. In addition, impairment testing of intellectual property is required when the Group decides to terminate or suspend the development of a project based on such intellectual property. Property and equipment, as well as computer software, are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized equal to the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and the asset's value in use to the Group.

### g. Financial assets

The Group classifies its financial assets in the following categories: at fair value through profit or loss and loans and receivables. The classification depends on the purpose for which each financial asset was acquired. The Group's management determines the classification of financial assets at initial recognition:

1) Financial assets at fair value through profit or loss

A financial asset is classified in this category if management has designated it as such, because it is managed and its performance is evaluated on a fair-value basis in accordance with a documented risk management or investment strategy, and information about these assets is provided internally on that basis to the Group's key management personnel. Assets in this category are classified as current assets if they are expected to be sold within one year from the balance sheet date.

#### 2) Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. These assets are included in current assets. The Group's loans and receivables include "accounts receivable," "cash and cash equivalents" and "restricted deposits" in the balance sheet. See Notes 2h, 2i and 2j.

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)

#### h. Cash equivalents

The Group considers all highly liquid investments, which include short-term bank deposits (up to three months from date of deposit) that are not restricted as to withdrawal or use, to be cash equivalents.

## i. Restricted deposits

The Company has placed a lien on NIS and dollar deposits in banks to secure its liabilities to various parties. Those deposits are presented separately as current or non-current assets, depending on the timing of the restriction. See Note 11b(1).

## j. Trade receivables

Trade receivable balances relate to amounts receivable from customers of the Group in respect of sub-licenses granted, or services that have been provided, during the normal course of business. If collection of these amounts is expected within one year or less, they are classified in current assets; otherwise, they are reflected in non-current assets.

Trade receivables are initially recognized at their fair value. Thereafter, they are measured at amortized cost, based on the effective interest method, less any allowance for doubtful accounts.

## k. Warrants

Receipts in respect of warrants are classified as equity to the extent that they confer the right to purchase a fixed number of shares for a fixed exercise price. As part of the Company's initial public offering on the TASE in February 2007, the Company issued Series 1 warrants with an exercise price linked to the Israeli Consumer Price Index ("CPI"). Accordingly, the exercise price was not deemed to be fixed and, as such, the Series 1 warrants did not qualify for equity classification. As long as the exercise price was linked to the CPI, the Series 1 warrants were classified as liabilities and carried at fair value, with changes in their fair value recognized in profit or loss. The issuance costs of the Series 1 warrants were also directly charged to profit or loss. Following amendment of the terms of the Series 1 warrants, whereby linkage of the exercise price to the CPI was cancelled, the warrants were classified in equity.

#### I. Share capital

Ordinary Shares are classified as equity. Incremental costs directly attributable to the issuance of new shares are shown in equity as a deduction from the issuance proceeds.

#### m. Deferred taxes

Deferred taxes are recognized using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred income tax assets are recognized only to the extent that it is probable that future taxable income will be available against which the temporary differences can be utilized.

As the Group is currently engaged solely in development activities and is not expected to generate taxable income in the foreseeable future, no deferred tax assets are included in the financial statements.

#### n. Revenue recognition

The Group recognizes revenue in accordance with International Accounting Standard ("IAS") 18 — "Revenue," including guidance regarding arrangements with multiple deliverables. Pursuant to this guidance, the Group applies revenue recognition criteria to the separately identifiable components of a single transaction. The consideration from the arrangement is allocated among the separately identifiable components by reference to their fair value.

## NOTES TO THE FINANCIAL STATEMENTS

# NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)

Revenues incurred in connection with the out-licensing of the Group's patents and other intellectual property are recognized when all of the following criteria have been met as of the balance sheet date:

- The Group has transferred to the buyer the significant risks and rewards of ownership of the patents and intellectual property.
- The Group does not retain either the continuing managerial involvement to the degree usually associated with ownership or the effective control over the patent and intellectual property.
- The amount of revenue can be measured reliably.
- It is probable that the economic benefits associated with the transaction will flow to the Group.
- The costs incurred or to be incurred in respect of the sale can be measured reliably.

Revenues in connection with rendering of services are recognized by reference to the stage of completion of the transaction as of the balance sheet date, if and when the outcome of the transaction can be estimated reliably.

Revenues from royalties are recognized on an accrual basis in accordance with the substance of the relevant agreement.

#### o. Research and development expenses

Research expenses are charged to operations as incurred.

An intangible asset arising from development (or from the development phase of an internal project) is recognized if all of the following conditions are fulfilled:

- technical feasibility exists for completing development of the intangible asset so that it will be available for use or sale.
- it is management's intention to complete development of the intangible asset for use or sale.
- the Company has the ability to use or sell the intangible asset.
- it is probable that the intangible asset will generate future economic benefits, including existence of a market for the output
  of the intangible asset or the intangible asset itself or, if the intangible asset is to be used internally, the usefulness of the
  intangible asset.
- adequate technical, financial and other resources are available to complete development of the intangible asset, as well as the use or sale thereof.
- the Company has the ability to reliably measure the expenditure attributable to the intangible asset during its development.

Other development costs that do not meet the foregoing conditions are charged to operations as incurred. Development costs previously expensed are not recognized as an asset in subsequent periods. As of December 31, 2009, the Group has not yet capitalized development expenses.

#### p. Government participation in research and development expenses

The Group receives participation in research and development expenses from the State of Israel through the OCS, both in the form of loans extended to the Incubator for research and development, as described in Note 11a(1), and in the form of grants, as described in Note 11a(2).



#### NOTES TO THE FINANCIAL STATEMENTS

# NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)

Despite the formal difference between the two types of support from the OCS, there is no material financial difference between them. Each loan and grant qualifies as a "forgivable loan" in accordance with IAS 20, "Accounting for Government Grants and Disclosure of Government Assistance," since the loans and grants are repayable only if the Group generates revenues related to the project that is the subject of the loan or grant.

The Company recognizes each forgivable loan on a systematic basis at the same time the Company records, as an expense, the related development costs for which the grant/loan is received, provided that there is reasonable assurance that (a) the Company complies with the conditions attached to the grant/loan, and (b) the grant/loan will be received. The amount of the forgivable loan is recognized based on the participation rate approved by the OCS.

The Company accounts for each forgivable loan as a liability unless it is more likely than not that the Company will meet the terms of forgiveness, in which case the forgivable loan is accounted for as a government grant and carried to income as a reduction of research and development expenses.

Government grants received in respect of investments in property and equipment are presented as a reduction of the cost of such assets.

If forgivable loans are initially carried to income, as described above, and, in subsequent periods, it appears more likely than not that the project will be successful and that the loans will be repaid or royalties paid to the OCS, the Group recognizes a liability on the balance sheet, which is measured in accordance with the provisions of IAS 37, "Provisions, Contingent Liabilities and Contingent Assets." The liability is measured based on the Group's best estimate of the amount required to settle the Group's obligation at the end of each reporting period.

# q. Employee benefits

#### 1) Pension and severance pay obligations

Israeli labor laws and the Group's agreements require the Group to pay retirement benefits to employees terminated or leaving their employ in certain other circumstances. Most of the Group's employees are covered by a defined contribution plan under Section 14 of the Israel Severance Pay Law.

The amount recorded as an employee benefit expense in respect of defined contribution plans for the years 2007, 2008 and 2009 was NIS 1,252,000, NIS 1,884,000 and NIS 1,887,000, respectively.

With respect to the remaining employees, the Company records a liability on its balance sheet for defined benefit plans that represents the present value of the defined benefit obligation as of balance sheet date, net of the fair value of plan assets, and adjustments for unrecognized actuarial gains or losses. The defined benefit obligation is computed annually by independent actuaries, using the corridor method. The present value of the defined benefit liability is determined by discounting the anticipated future cash outflows, using interest rates that are denominated in the currency in which the benefits will be payable.

Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are charged to income.

Past-service costs are recognized immediately in income, unless the changes to the pension plan are conditional on the employees remaining in service for a specified period of time (the vesting period). In such cases, the past-service costs are amortized on a straight-line basis over the vesting period.

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)

#### 2) Vacation days and recreation pay

Labor laws in Israel entitle every employee to vacation days and recreation pay, both of which are computed annually. The entitlement with respect to each employee is based on the employee's length of service at the Company. The Group recognizes a liability and an expense in respect of vacation and recreation pay based on the individual entitlement of each employee.

## 3) Share-based payments

The Group operates a number of equity-settled, share-based compensation plans, under which it receives services from employees as consideration for equity instruments (options) of the Group. The fair value of the employee services received in exchange for the grant of the options is recognized as an expense. The total amount to be expensed is determined by reference to the fair value of the options granted:

- including any market performance conditions;
- excluding the impact of any service and non-market performance vesting conditions (for example, profitability, sales growth targets and the employee remaining with the entity over a specified time period); and
- excluding the impact of any non-vesting conditions.

Non-market vesting conditions are included in assumptions about the number of options that are expected to vest. The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied. At the end of each reporting period, the Group revises its estimates of the number of options that are expected to vest based on the non-marketing vesting conditions. It recognizes the impact of the revision to original estimates, if any, in the income statement, with a corresponding adjustment to equity.

When the options are exercised, the Company issues new shares. The proceeds received, net of any directly attributable transaction costs, are credited to share capital (at par value) and share premium when the options are exercised.

#### r. Loss per share

1) Basic

The basic loss per share is calculated by dividing the loss attributable to the holders of Ordinary Shares by the weighted average number of outstanding Ordinary Shares during the year.

#### 2) Diluted

The diluted loss per share is calculated by adjusting the weighted average number of outstanding Ordinary Shares, assuming conversion of all dilutive potential shares. The Company's dilutive potential shares consist of preferred shares, convertible loans, warrants and options granted to employees and service providers. The dilutive potential shares were not taken into account in computing loss per share, as their effect would not have been dilutive.

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)

#### s. Changes in accounting policy and disclosures

1) New and amended standards adopted during 2009

The Group has adopted the following new and amended accounting standards as of January 1, 2009, which did not have a material effect on the financial statements of the Group:

- a) IFRS 7 "Financial instruments Disclosures" (amendment), effective January 1, 2009. This amendment requires enhanced disclosures about fair value measurement and liquidity risk. In particular, the amendment requires disclosure of fair value measurements in accordance with a fair value measurement hierarchy.
- b) IAS 1 (revised) "Presentation of financial statements," effective January 1, 2009. This revised standard establishes overall requirements for presentation of the financial statements, as well as guidelines for their structure and minimal requirements for their content. Among other things, the revised standard prohibits the presentation of items of income and expense (i.e., "non-owner changes in equity") in the statement of changes in equity, requiring non-owner changes in equity to be presented separately from owner changes in equity in a statement of comprehensive income. As a result of the revised standard, the Group presents in the consolidated statement of changes in equity all owner changes in equity, whereas all non-owner changes in equity are presented in the consolidated statement of comprehensive loss. Comparative information has been re-presented so that it also is in conformity with the revised standard.
- c) IFRS 2 (amendment), "Share-based payment," effective January 1, 2009. This amendment deals with vesting conditions and cancellations. It clarifies that vesting conditions are service conditions and performance conditions only. Other features of a share-based payment are not vesting conditions. Such features would need to be included in the grant date fair value for transactions with employees and others providing similar services; they would not impact the number of awards expected to vest or valuation thereof subsequent to grant date. All cancellations, whether by the entity or by other parties, should receive the same accounting treatment in the financial statements. The Group adopted IFRS 2 (amendment) effective January 1, 2009. The amendment did not have a material impact on the Group's financial statements for the periods reported herein.
- d) IAS 38 (amendment), "Intangible Assets," effective January 1, 2009. The amendment is part of the IASB's annual improvements project published in May 2008. The amendment stipulates that a prepayment may only be recognized in the event that payment has been made in advance of obtaining the right of access to goods or receipt of services.
- e) IAS 20 (amendment), "Accounting for Government Grants and Disclosure of Government Assistance," effective January 1, 2009. This amendment requires that the benefit of a below-market-rate government loan be measured as the difference between the carrying amount of the loan upon initial recognition in accordance with IAS 39, "Financial Instruments: Recognition and Measurement," and the proceeds received with the benefit accounted for in accordance with IAS 20.

# NOTES TO THE FINANCIAL STATEMENTS

## NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)

2) Standards, amendments and interpretations to existing standards that are not yet effective and have not been early adopted by the Group

The following standards and amendments to existing standards have been published and are mandatory for the Group's accounting periods beginning on or after January 1, 2010 or later periods, but the Group has not early adopted them:

- a) IFRS 3 (revised), "Business combinations," effective July 1, 2009. The revised standard continues to apply the acquisition method to business combinations, with some significant changes. For example, all payments to purchase a business are to be recorded at fair value at the acquisition date, with contingent payments classified as debt subsequently re-measured through the income statement. There is a choice on an acquisition-by-acquisition basis to measure the non-controlling interest in the acquiree at fair value or at the non-controlling interest's proportionate share of the acquiree's net assets. All acquisition-related costs are to be expensed. The Group intends to apply IFRS 3 (revised) prospectively to all business combinations from January 1, 2010, and it is currently assessing the possible effects of applying the revised standard on its financial statements in future periods.
- b) IAS 27 (revised), "Consolidated and separate financial statements," effective July 1, 2009. The revised standard requires the effects of all transactions with non-controlling interests to be recorded in equity if there is no change in control and these transactions will no longer result in goodwill or gains and losses. The standard also specifies the accounting when control is lost. Any remaining interest in the entity is remeasured to fair value, and a gain or loss is recognized in profit or loss. The Group intends to apply IAS 27 (revised) prospectively to transactions with non-controlling interests from January 1, 2010.
- c) IAS 32 (amendment), "Classification of rights issues," effective October 2009. For rights issues offered for a fixed amount of foreign currency, current practice appears to require such issues to be accounted for as derivative liabilities. The amendment states that if such rights are issued pro rata to all existing shareholders of an entity in the same class for a fixed amount of currency, they should be classified as equity regardless of the currency in which the exercise price is denominated. The amendment will be effective for annual periods beginning on or after February 1, 2010, with early application permissible. The Group intends to apply this amendment in its financial statements beginning on January 1, 2011.
- d) IFRIC 17 (amendment), "Distribution of non-cash assets to owners," effective July 1, 2009. This interpretation provides guidance on accounting for arrangements whereby an entity distributes non-cash assets to shareholders either as a distribution of reserves or as dividends. IFRS 5 has also been amended to require that assets are classified as held for distribution only when they are available for distribution in their present condition and the distribution is highly probable. The Group intends to apply IFRIC 17 from January 1, 2010.
- e) IFRS 5 (amendment), "Disclosures required in respect of non-current assets (or disposal groups) classified as held for sale or discontinued operations," effective January 1, 2010. The amendment provides clarification that IFRS 5 specifies the disclosures required in respect of non-current assets (or disposal groups) classified as held for sale or discontinued operations. It also clarifies that the general requirements of IAS 1 still apply, particularly paragraph 15 (to achieve a fair presentation) and paragraph 125 (sources of estimation uncertainty). The Group intends to apply IFRS 5 (amendment) from January 1, 2010.



## NOTES TO THE FINANCIAL STATEMENTS

# NOTE 3 - FINANCIAL RISK MANAGEMENT

According to estimates by the Group's management, the Group's exposure to credit risks as of December 31, 2009 is immaterial (see Note 3b). The activities of the Group expose it to market risks, particularly as a result of currency risks.

The Company's finance department is responsible for carrying out risk management activities in accordance with policies approved by its Board of Directors. In this regard, the finance department identifies, defines and assesses financial risks in close cooperation with other Company departments. The Board of Directors provides written guidelines for overall risk management, as well as written policies dealing with specific areas, such as exchange rate risk, interest rate risk, credit risk, use of financial instruments, and investment of excess cash.

## a. Market risks

1) Concentration of currency risks

The Group's activities are partly denominated in foreign currency, which exposes the Group to risks resulting from changes in exchange rates (primarily the dollar).

The effect of fluctuations in various exchange rates on the Group's income and equity is as follows:

	December 31, 2009					
	Income (loss) 10% 5% increase increase		Value on	Incom	e (loss)	
Sensitive instrument			balance sheet	5% decrease	10% decrease	
			NIS in thousands	5		
Dollar-linked balances:						
Cash and cash equivalents	3,367	1,684	33,674	(1,684)	(3,367)	
Restricted deposits*	60	30	604	(30)	(60)	
Trade receivables	3,775	1,888	37,750	(1,888)	(3,775)	
Trade payables	(299)	(149)	(2,987)	149	299	
Payable to licensors	(1,057)	(528)	(10,570)	528	1,057	
Total dollar-linked balances	5,846	2,925	58,471	(2,925)	(5,846)	
Euro-linked balances:						
Cash and cash equivalents	155	77	1,550	(77)	(155)	
Trade payables	(219)	(110)	(2,196)	110	219	
	(64)	(33)	(646)	33	64	
Cash and cash equivalents linked to pound	40	20	399	(20)	(40)	
sterling						
Total	5,822	2,912	58,224	(2,912)	(5,822)	

\* See also Note 11b(1).

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 3 — FINANCIAL RISK MANAGEMENT – (continued)

# The Company believes that the likelihood of a fluctuation in exchange rates of up to 10% in the coming period is reasonable.

	December 31, 2008					
	Income (loss)		Value on	Incom	ie (loss)	
Sensitive instrument	10% increase	5% increase	balance sheet	5% decrease	10% decrease	
			NIS in thousands	5		
Dollar-linked balances:						
Cash and cash equivalents	4,381	2,191	43,812	(2,191)	(4,381)	
Restricted deposits*	60	30	604	(30)	(60)	
Trade payables	(1,125)	(563)	(11,254)	563	1,125	
Total dollar-linked balances	3,316	1,658	33,162	(1,658)	(3,316)	
Euro-linked balances:						
Cash and cash equivalents	498	249	4,982	(249)	(498)	
Trade payables	(100)	(50)	(997)	50	100	
	398	199	3,985	(199)	(398)	
Trade payables linked to pound sterling	(64)	(32)	(647)	32	64	
Total	3,650	1,825	36,500	(1,825)	(3,650)	

\* See also Note 11b(1).

Set forth below is data regarding exchange rates and the CPI:

	Exchange rate of USD 1	Exchange rate of € 1	Exchange rate of £ 1	Israeli CPI*
	NIS	NIS	NIS	Points
As of December 31:				
2008	3.802	5.298	5.548	117.95
2009	3.775	5.442	6.111	122.57
Percentage increase (decrease) in:				
2008	(1.7)%	(6.4)%	(28.0)%	3.8%
2009	(0.7)%	2.7%	10.2%	3.9%
2008 2009 Percentage increase (decrease) in: 2008	3.775 (1.7)%	5.442 (6.4)%	6.111 (28.0)%	122.57 3.8%

\* Based on the index for the month ending on each balance sheet date, on the basis of 2000 average = 100.

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 3 — FINANCIAL RISK MANAGEMENT – (continued)

Information on the linkage of monetary items:

	De	cember 31, 20	08	E	December 31, 2009		
	Dollar	Other <u>currencies</u>	NIS	Dollar	Other <u>currencies</u>	NIS	
			NIS in	thousands			
Assets:							
Current assets:							
Cash and cash equivalents	43,812	4,982	11,585	33,674	1,949	70,267	
Financial assets at fair value through profit or loss	_	—	30,749	—	—	_	
Financial assets at fair value through profit or loss – restricted	—	—	139	—	—	—	
Trade receivables	—		—	37,750	—		
Other receivables	—	—	5,709		—	2,313	
Non-current assets:							
Restricted deposits	604		—	604		3,100	
Financial assets at fair value through profit or loss – restricted	—	—	3,618	—	—	—	
Total assets	44,416	4,982	51,800	72,028	1,949	75,680	
Liabilities:							
Current liabilities:							
Accounts payable and accruals:							
Trade	11,254	1,644	18,447	2,987	2,221	1,244	
OCS			—			14,005	
Licensors		—	—	10,570		—	
Other		_	5,983	_		10,203	
Total liabilities	11,254	1,644	24,430	13,557	2,221	25,452	
Net asset value	33,162	3,338	27,370	58,471	(272)	50,228	

#### 2) Fair value of financial instruments

As of December 31, 2009, the financial instruments of the Group consist of non-derivative assets and liabilities (primarily working capital items and restricted deposits).

In view of their nature, the fair value of the financial instruments included in working capital is generally close or identical to their carrying amount. The fair value of the restricted cash in long-term deposits also approximates the carrying amount, as these financial instruments bear interest at a rate similar to the prevailing interest rate.

3) Exposure to market risks and the management thereof

The trade receivable balance as of December 31, 2009 relates to the transaction with Ikaria, in respect of which, as described in Note 11a(7), there is a high probability of collection. The Company has also invested in deposits and short-term government bonds. Accordingly, in the opinion of the Company's management, the market risks to which the Company is exposed are primarily related to the exposure to currency risks, as mentioned above. Additionally, the Company's management does not consider the interest rate risk mentioned in paragraph 4 below to be material.

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 3 — FINANCIAL RISK MANAGEMENT - (continued)

#### 4) Interest rate risks

The Company's management does not consider interest rate risk to be material as the Company holds deposits and short-term government bonds whose fair value and/or cash flows are not materially affected by changes in the interest rate.

If market interest rates had been 50 basis points higher (lower) at December 31, 2008, the Company's net loss would have been NIS 36,000 lower (higher).

### b. Credit risks

Credit risks are managed at the Group level. These risks relate to cash and cash equivalents, bank deposits and trade receivables.

The Group's cash and cash equivalents at December 31, 2008 and 2009 were mainly deposited with major Israeli banks. In the Company's opinion, the credit risk in respect of these balances is remote. In addition, as of December 31, 2008, all financial assets that were classified as financial assets at fair value through profit or loss were held in short-term government bonds.

The Group considers its maximum exposure to credit risk to be as follows:

	Decem	ber 31,	
	2008	2009	
	NIS in th	iousands	
Assets:			
Cash and cash equivalents	60,739	105,890	
Financial assets at fair value through profit or loss	30,749		
Trade accounts receivable	—	37,750	
Other receivables	5,709	2,313	
Financial assets at fair value through profit or loss – restricted	3,757	_	
Restricted deposits	604	3,704	
Total	101,558	149,657	

#### c. Liquidity risks

The Company's management monitors rolling forecasts of the Group's liquidity reserves on the basis of anticipated cash flows and maintains the liquidity balances at a level that is sufficient to meet its needs.

As mentioned in Note 1, the Company has not yet generated profits from its activities and cannot determine with reasonable certainty if and when the Company will become profitable. The Company's management believes that the Company's current cash balances will enable it to execute its operating plans until the second half of 2011. Accordingly, in the event that the Company does not continue to generate cash from its operating activities, the Company's long-term operations in their current form are contingent on its raising additional capital during 2011.

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 3 — FINANCIAL RISK MANAGEMENT – (continued)

## d. Financial instruments

As of December 31, 2009, the Group's financial instruments consisted solely of loans and receivables.

As of December 31, 2008, the composition of financial instruments was as follows:

#### December 31, 2008

Assets:	Loans and receivables	Assets at fair value through profit or loss NIS in thousands	Total
A55C15.			
Cash and cash equivalents	60,739	—	60,739
Financial assets at fair value through profit or loss		30,749	30,749
Other receivables	5,748		5,748
Financial assets at fair value through profit or loss – restricted		3,757	3,757
Restricted deposits	604		604
Total	67,091	34,506	101,597

## NOTE 4 — CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

As part of the financial reporting process, the Company's management is required to make certain assumptions and estimates that may affect the value of the assets, liabilities, income, expenses and some of the disclosures included in the Company's consolidated financial statements. By their very nature, such estimates are subjective and complex and consequently may differ from actual results.

The accounting estimates and assumptions that are used in the preparation of the financial statements are continually evaluated and are based on historical experience and other factors, including expectation of future events that are believed to be reasonable under the circumstances.

Described below are the critical accounting estimates that are used in the preparation of the financial statements, the formulation of which required the Company's management to make assumptions as to circumstances and events that involve significant uncertainty. In using its judgment to determine the accounting estimates, the Company takes into consideration, as appropriate, the relevant facts, past experience, the effect of external factors and reasonable assumptions under the circumstances.

#### a. Development expenses

Development expenses are capitalized in accordance with the accounting policy described in Note 2o. The capitalization of costs is based on management's judgment of technological and economic feasibility, which is usually achieved when a product development project reaches a predefined milestone, or when the Company enters into a transaction to sell the know-how that resulted from the development process. In determining the amount to be capitalized, management makes assumptions as to the future anticipated cash inflows from the assets, the discount rate and the anticipated period of future benefits. The Company's management has concluded that, as of December 31, 2009, the foregoing conditions have not been met and therefore development expenses have not been capitalized for any project.

If management had assessed that the aforementioned conditions had been met, the capitalization of development costs would have reduced the Group's loss.

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 4 — CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS – (continued)

## b. Grants/loans from the OCS

In accordance with the accounting treatment prescribed in Note 2p, the Company's management is required to evaluate whether there is reasonable assurance that the grant/loan received will be paid or repaid. Additionally, whenever the grant/loan is initially recognized as income, management is required to evaluate whether the payment of royalties/repayment of loans to the OCS is considered more likely than not.

See Notes 11a(1) and 11a(2) with regard to the expected amount repayable to the OCS as of December 31, 2009.

#### c. Revenue recognition

In accordance with the accounting treatment prescribed in Note 2n, the Company's management is required to evaluate whether it is probable that the economic benefits related to the out-licensing agreement with Ikaria will flow to the Group and whether it is possible to reliably measure the amount of the revenues relating to the transaction.

In the opinion of management, as of December 31, 2009, receipt of payment in respect of the second milestone under the agreement (as described in Note 14) was considered probable, whereas receipt of additional economic benefits associated with the transaction was not considered probable. Accordingly, no revenues with respect to additional milestone payments were recorded in the 2009 financial statements.

# NOTE 5 — CASH AND CASH EQUIVALENTS

	Decen	ıber 31,
	2008	2009
	NIS in t	housands
Cash on hand and in bank	262	700
Short-term bank deposits	60,117	105,190
	60,739	105,890

Most of the Company's available cash is held in short-term bank deposits.

The carrying amount of cash and cash equivalents is close or identical to their fair value, since they bear interest at rates similar to the prevailing market interest rates.

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 6 — PROPERTY AND EQUIPMENT:

a. The composition of property and equipment and the accumulated depreciation thereon, grouped by major classifications, and changes therein in 2008 and 2009 are as follows:

U	Cost				A	Accumulated	depreciatio	Net book value December 31,		
	Balance at beginning of year	Additions during year	Deletions during year	Balance at end of year	Balance at beginning of year	Additions during year	Deletions during year	Balance at end of year	2008	2007
		NIS in th	iousands			NIS in th	nousands		NIS in th	nousands
Composition in 2008										
Office furniture and equipment	446	250	_	696	76	35	_	111	585	370
Computers and communications equipment	1,137	314	—	1,451	705	292	—	997	454	432
Laboratory equipment, net*	1,654	1,346	_	3,000	459	374	_	833	2,167	1,195
Leasehold improvements	2,830	1,317	—	4,147	1,097	772	—	1,869	2,278	1,733
	6,067	3,227		9,294	2,337	1,473		3,810	5,484	3,730
<ul> <li>Item is net of OCS grants received – see b. below</li> </ul>	(2,222)	(28)		(2,250)	(478)	(334)		(812)	(1,438)	(1,744)
		Co	ost		A	Accumulated	depreciatio	n	Net boo Decem	ok value ber 31,
	Balance at beginning of year	Additions during year	Deletions during year	Balance at end of year	A Balance at beginning of year	Additions during year	Deletions during year	n Balance at end of year	Decem 2009	ber 31, 2008
	beginning	Additions during	Deletions during year	end of	Balance at beginning	Additions during	Deletions during year	Balance at end of	Decem 2009	ber 31,
Composition in 2009	beginning of year	Additions during year	Deletions during year	end of year	Balance at beginning of year	Additions during year NIS in th	Deletions during year	Balance at end of year	Decem 2009 NIS in th	ber 31, 2008
Office furniture and equipment	beginning of year 696	Additions during year NIS in th	Deletions during year ousands	end of year 696	Balance at beginning of year 111	Additions during year NIS in th 58	Deletions during year ousands	Balance at end of year 169	Decem 2009 NIS in th 527	ber 31, 2008
	beginning of year	Additions during year	Deletions during year	end of year	Balance at beginning of year	Additions during year NIS in th	Deletions during year	Balance at end of year	Decem 2009 NIS in th	ber 31, 2008
Office furniture and equipment Computers and	beginning of year 696	Additions during year NIS in th	Deletions during year ousands	end of year 696	Balance at beginning of year 111	Additions during year NIS in th 58	Deletions during year ousands	Balance at end of year 169	Decem 2009 NIS in th 527	ber 31, 2008
Office furniture and equipment Computers and communications equipment	beginning of year 696 1,451	Additions during year NIS in th  106	Deletions during year iousands 8	end of year 696 1,549	Balance at beginning of year 111 997	Additions during year NIS in th 58 258	Deletions during year nousands – 4	Balance at end of year 169 1,251	Decem 2009 NIS in th 527 298	ber 31, 2008 housands 585 454
Office furniture and equipment Computers and communications equipment Laboratory equipment, net*	beginning of year 696 1,451 3,000	Additions during year NIS in th  106	Deletions during year iousands 8	end of year 696 1,549 3,136	Balance at beginning of year 111 997 833	Additions during year NIS in th 58 258 467	Deletions during year nousands – 4	Balance at end of year           169           1,251           1,300	Decem 2009 NIS in th 527 298 1,836	ber 31, 2008 housands 585 454 2,167

**b.** As to the participation of the OCS in laboratory setup costs, see Note 11a(1)d.

# NOTE 7 — INTANGIBLE ASSETS

	Decem	ber 31,
	2008	2009
	NIS in th	nousands
Computer software:		
Cost	721	760
Accumulated amortization	(337)	(544)
Net book value	384	216
Intellectual property:		
Cost	3,424	3,577
Accumulated impairment	(603)	(751)
Net book value	2,821	2,826
Total net book value	3,205	3,042

During 2009, intellectual property dispositions with a total cost of NIS 436,000 were recorded to cost of revenues in respect of the BL-1040 project (see Note 14).

# NOTES TO THE FINANCIAL STATEMENTS

## NOTE 8 — EQUITY

#### a. Share capital

As of December 31, 2008 and 2009, share capital is composed of Ordinary Shares, as follows:

	Number of Ordinary Shares			
	Decem	December 31,		
	2008	2009		
Authorized share capital	250,000,000	250,000,000		
Issued share capital	62,504,883	123,497,029		
Paid-up share capital	62,504,883	123,497,029		
	In	NIS		
		NIS nber 31,		
		-		
Authorized share capital	Decer	nber 31,		
Authorized share capital Issued share capital	Decer 2008	nber 31, 2009		

#### b. Rights related to shares

- 1) The Ordinary Shares confer upon their holders voting and dividend rights and the right to receive assets of the Company upon its liquidation.
- 2) See Note 8c(4) for details regarding the conversion of the preferred A-1 shares and the preferred A shares into ordinary shares, and their classification in equity.
- 3) All of the abovementioned classes of shares had conferred upon their holders the right to one vote per share at the general meeting of shareholders, based on their conversion ratio into Ordinary Shares. As of December 31, 2008 and 2009, all outstanding shares of the Company are Ordinary Shares and no preferred A shares or preferred A-1 shares are outstanding.

#### c. Changes in the Company's equity

1) In December 2003, the Company entered into an agreement with its CEO pursuant to which the CEO received 956,522 restricted Ordinary Shares. In accordance with the agreement, the restricted shares were placed in trust and allotted to the CEO in tranches over a period of four years commencing in May 2003. The fair value these restricted shares on the date of grant amounted to approximately NIS 4,168,000.

In 2007, the vesting period ended for all of the abovementioned restricted shares and the CEO paid the par value of the vested shares (approximately NIS 10,000) which were then held in trust in his name.

2) In December 2005, the Company entered into an agreement with its CEO pursuant to which the CEO received an additional 773,978 restricted Ordinary Shares. In accordance with the agreement, the restricted shares were placed in trust and allotted to the CEO in tranches over a period of four years commencing in May 2003. The fair value of the restricted shares on the date of grant amounted to approximately NIS 3,554,000, of which NIS 72,000 was recorded as an expense in 2007.

In December 2007, the vesting period ended for all of the abovementioned restricted shares, and the CEO paid the par value of the vested shares (approximately NIS 7,000), which were then held in trust in his name.

# NOTES TO THE FINANCIAL STATEMENTS

## NOTE 8 — EQUITY – (continued)

In January 2007, the Company entered into an agreement with its CEO pursuant to which the CEO received an additional 1,543,717 restricted Ordinary Shares. The shares were placed in trust and are being allotted to the CEO over a four-year period commencing in January 2007.

In July 2007, the Company entered into an agreement with the Company's CEO pursuant to which the CEO received an additional 570,300 restricted Ordinary Shares, subject to the Company's achievement of certain research and development related milestones. As of December 31, 2007, the milestones were achieved and the shares had been placed in trust and are being allotted to the CEO over a period of four years commencing in July 2007.

The fair value of the grants made in 2007 amounted to approximately NIS 12,597,000 of which NIS 6,527,000, NIS 3,651,000 and NIS 1,773,000 were recorded as an expense in 2007, 2008 and 2009, respectively.

- 3) In January 2007, the Company entered into an agreement (the "Convertible Loan Agreement") with Pan Atlantic Investment Limited ("Pan Atlantic"), an unrelated third-party investor, pursuant to which Pan Atlantic provided to the Company a USD 9,000,000 loan that was convertible into shares of the Company. In accordance with the agreement, and in connection with the Company's initial public offering in Israel, the loan was converted into 6,716,418 Ordinary Shares and classified as an equity investment in the Company.
- 4) In January 2007, the authorized share capital of the Company was increased to 100,000,000 shares of NIS 0.01 par value each, as follows: 66,350,000 Ordinary Shares, 13,650,000 preferred A shares, 10,000,000 preferred A-1 shares and 10,000,000 preferred B shares. In connection with the Company's initial public offering in Israel (see (5) below), all outstanding preferred shares were converted into Ordinary Shares. Since that time, the authorized and issued share capital of the Company has been composed solely of Ordinary Shares.
- 5) In February 2007, the Company conducted an initial public offering on the TASE of 28,690,000 Ordinary Shares and 14,345,000 Series 1 warrants. The net proceeds to the Company from the issuance amounted to approximately NIS 198,000,000.

Each Series 1 warrant was exercisable into one Ordinary Share at an exercise price of NIS 8.50 which, in accordance with the original terms of such warrants, was linked to the CPI (subject to adjustments). The warrants were exercisable over a period of two years from the date of their listing for trading. The consideration allocated to the warrants was approximately NIS 32,100,000, computed under the Black-Scholes model, which reflected their fair value as of the issuance date. Issuance costs related to the warrants of approximately NIS 2,100,000 were recorded as an expense. As of December 31, 2007, the warrants were marked to market on the Company's balance sheet (at the market price on the TASE), with the change in fair value of the warrants recorded to income (see also Note 2k).

In July 2008, the exercise price of the warrants ceased to be linked to the CPI and, accordingly, the market value of the warrants at that time, amounting to NIS 947,000, was reclassified from current liabilities to equity.

In February 2009, 380 warrants were exercised for total consideration of NIS 3,000, and the remaining 14,344,620 warrants expired.

6) In November 2007, the Company's shareholders approved an increase in the Company's authorized share capital to 250,000,000 shares, NIS 0.01 par value each.

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 8 — EQUITY – (continued)

- 7) In July 2009, the Company issued 46,667,719 Ordinary Shares in a public rights offering. The total net proceeds from the offering amounted to NIS 51,800,000, after deducting NIS 900,000 of issuance costs. The rights offering included an embedded benefit of 25% to the Company's shareholders (such embedded benefit being essentially a stock dividend for financial statement purposes).
- 8) In December 2009, the Company issued 11,293,419 Ordinary shares and 7,528,946 Series 2 warrants in a public offering. Each warrant is exercisable into one Ordinary Share at an exercise price of NIS 6.08 (not linked). The warrants are exercisable for a period of two years from the date that they were registered for trading.

The total net proceeds from the offering amounted to NIS 45,700,000, after deducting NIS 1,400,000 in issuance costs. The issuance costs have been allocated between share premium and the warrants based on the relative market value (as indicated on the TASE) of the shares and warrants on the date of the offering.

#### d. Share-based payments

 In 2003, the Company's Board of Directors approved a stock option plan for employees and consultants pursuant to which 1,328,500 Ordinary Shares were reserved for issuance upon the exercise of options. In 2005, the Company's Board of Directors approved an expansion of the stock-option plan for employees and consultants, to allow the allotment of an additional up to 2,136,022 options exercisable into Ordinary Shares. In 2007, the Company's Board of Directors approved a stock option plan for employees and consultants, pursuant to which up to 9,996,556 shares and options exercisable into Ordinary Shares were allotted to employees and consultants.

See Note 14 regarding a new option allocation to employees and consultants approved by the Company's Board of Directors at the beginning of 2010.

#### 2) Employee stock options

As of December 31, 2009, the Company had granted its employees 6,610,478 options exercisable into Ordinary Shares. This amount includes 1,099,871 options that were forfeited and 3,461,581 options that were exercised. The weighted average exercise price of options granted prior to December 31, 2006 was USD 0.01. In 2007, the Company changed the exercise price of all options previously granted with an exercise price of USD 0.01, as well as some of the options granted in 2007 with an exercise price of USD 0.01, to an exercise price of NIS 0.039, based on the exchange rate of the dollar at the date of the change. Accordingly, this change in exercise price did not affect the fair value of the options on the date of such change. In 2008 and 2009, additional options were granted at exercise prices of 90% or 100% of the market price of the shares at the date of grant. The weighted average exercise price of the options granted in 2009 was NIS 2.31. The options vest over four years.

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 8 — EQUITY – (continued)

The following table contains additional information concerning options granted to employees under the existing stockoption plans:

	Year ended December 31,							
	2007 2008			08	20	2009		
	Number of options	Weighted average exercise price (in NIS)	Number of options	Weighted average exercise price (in NIS)	Number of options	Weighted average exercise price (in NIS)		
Outstanding at beginning of	2,611,500	0.04	5,071,486	1.02	5,509,986	1.16		
year								
Granted	3,124,748	1.58	491,500	2.98	198,330	2.31		
Forfeited	(234,434)	0.46	(53,000)	4.25	(658,137)	2.61		
Exercised*	(430,328)	0.04	_		(2,996,628)	0.04		
Outstanding at end of year	5,071,486	1.02	5,509,986	1.16	2,053,551	2.44		
Exercisable at end of year	1,914,106	0.21	2,972,124	0.67	689,946	2.92		

<sup>\*</sup> The total consideration received from these exercises was NIS 16,000 and NIS 120,000 for 2007 and 2009, respectively. The weighted average exercise price was NIS 4.88 and NIS 2.42 for 2007 and 2009, respectively.

Set forth below is data regarding the range of exercise prices and weighted-average remaining contractual life (in years) for the options outstanding at the end of each of the years indicated.

As of December 31,	Number of options outstanding	Range of exercise prices (in NIS)	Weighted average remaining contractual life (in years)
2007	5,071,486	0.04 - 5.04	8.47
2008	5,509,986	0.04 - 5.04	7.45
2009	2,053,551	0.04 - 5.04	6.56

The Ordinary Shares allotted under these plans will confer the same rights as all other Ordinary Shares in the Company.

Employees of the Group have been granted options under Section 102 of the Israeli Income Tax Ordinance (the "Ordinance"). Non-employees of the Group (service providers, consultants, etc.), as well as controlling shareholders in the Company (as this term is defined in Section 32(9) of the Ordinance), have been granted options under Section 3(i) of the Ordinance.

The fair value of all options granted to employees prior to December 31, 2009 has been determined using the Black-Scholes option-pricing model. These values are based on the following assumptions as of the applicable grant dates:

	2007	2008	2009
Expected dividend yield	0%	0%	0%
Expected volatility*	67%	70%	64%
Risk-free interest rate	5%	5%	5%
Expected life of options (in years)	10	7	7

<sup>\*</sup> For 2007, the expected volatility was computed on the basis of similar companies operating in the same industry; whereas, in 2008 and 2009, the expected volatility was computed on the basis of specific Company market data, as well as the data of similar companies operating in the same industry.

# NOTES TO THE FINANCIAL STATEMENTS

## NOTE 8 — EQUITY – (continued)

#### 3) Stock options to consultants

From inception through December 31, 2006, the Company issued to consultants options for the purchase of 220,990 Ordinary Shares at an average exercise price of USD 0.01 per share. In 2007, the Company changed the exercise price to NIS 0.039 per share (see Note 8d(2) above). The options vest over four years.

In 2007, the Group issued options to consultants for the purchase of 144,242 Ordinary Shares at an average exercise price of NIS 0.73 per share. The options vest over four years.

The above options may be exercised for a period of 10 years.

The Company's management estimates the fair value of the options granted to consultants based on the value of services received over the vesting period of the applicable options. The value of such services (primarily in respect of clinical advisory services) is estimated based on the additional cash compensation the Company would need to pay if such options were not granted. The value of services recorded in 2008 and 2009 amounted to NIS 437,000 and NIS 640,000, respectively.

#### NOTE 9 — TAXES ON INCOME

# a. Measurement of results for tax purposes in accordance with the Income Tax (Inflationary Adjustments) Law, 1985 (the "Inflationary Adjustments Law")

Pursuant to the Inflationary Adjustments Law, through the end of the 2007 tax year, results for tax purposes were measured in real terms, taking into account changes in the CPI. The Company and the Subsidiary had been taxed under this law.

According to the Income Tax (Inflationary Adjustments) Law (Amendment No. 20), 2008 (the "Amendment"), enacted in February 2008, the provisions of the Inflationary Adjustments Law no longer applied to the Company for the 2008 tax year and thereafter. The Amendment prescribes transitional provisions for the discontinued application of the Inflationary Adjustments Law, which applied to the Company until the end of the 2008 tax year.

The Partnership is not subject to tax under Israeli tax law; rather, each of the partners thereof (the Company and the Subsidiary) is liable for the tax applicable to the operations of the Partnership in proportion to their respective share in the Partnership's results.

#### b. Tax rates

The income of the Company and the Subsidiary is taxed at the standard Israeli corporate tax rate. Israeli corporate tax rates for 2007 and thereafter are as follows: 2007 - 29%, 2008 - 27%, 2009 - 26%, 2010 - 25%, 2011 - 24%, 2012 - 23%, 2013 - 22%, 2014 - 21%, 2015 20%, and 2016 and thereafter - 18%.

Capital gains (except "real" capital gains on the sale of marketable securities, which are taxed at the standard corporate tax rates) are taxed as follows: capital gains derived after January 1, 2003 are subject to a reduced tax rate of 25%, while capital gains derived until that date are taxed at the standard corporate tax rate.

#### c. Tax loss carryforwards

As of December 31, 2009, the tax loss carryforwards of the Company and the Subsidiary are approximately NIS 291,000,000 and NIS 1,000,000, respectively. These tax loss carryforwards have no expiration dates.

The Company has not created deferred tax assets in respect of these tax loss carryforwards. See Note 2m.

# d. Tax assessments

The Company and its subsidiaries have not been assessed for tax purposes since their respective incorporation or formation.



# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 9 — TAXES ON INCOME – (continued)

# e. Theoretical taxes

As described in Note 2m, the Company has not recognized any deferred tax assets in the financial statements, since the Company does not expect to generate taxable income in the foreseeable future. The tax on the Group's profit before tax differs from the theoretical amount that would arise using the weighted average tax rate applicable to profits of the consolidated entities as follows:

	Year ended December 31,					
		2007		2008		2009
		NIS in thousands		NIS in thousands		NIS in thousands
Loss before taxes	29%	(59,419)	27%	(114,849)	26%	(61,518)
Theoretical tax expense (tax benefit)		(17,232)		(31,009)		(15,995)
Disallowed deductions (tax exempt income):						
Gain on adjusting warrants to fair value		(7,992)		(988)		
Share-based compensation		4,558		2,439		852
Other		88		52		51
Difference between the measurement basis of income reported for tax purposes and the measurement basis of income for financial reporting purposes (see Note 9a)		(584)		(2,491)		(10)
Increase in taxes for tax losses and timing differences incurred in the reporting year for which deferred taxes were not created		21,162		31,997		15,102
Taxes on income for the reported year						

# f. Deductible temporary differences

The amount of cumulative deductible temporary differences, other than unused tax loss carryforwards (as mentioned in c. above), for which deferred tax assets have not been recognized in the statement of financial position as of December 31, 2008 and 2009, were NIS 14,704,000 and NIS 12,958,000, respectively. These temporary differences have no expiration dates.

# NOTE 10 — LOSS PER SHARE

**a.** The following table contains the data used in the computation of the basic loss per share:

	Year ended December 31,		
	2007	2008	2009
		NIS in thousands	
Loss as reported in financial statements	(59,419)	(114,849)	(61,518)
Allocated to preferred A shares (see Note 8b)	(494)	—	
Allocated to preferred A-1 shares (see Note 8b)	(257)	—	—
Loss attributed to ordinary shares	(60,170)	(114,849)	(61,518)
Number of shares used in calculation (in thousands)	69,301	78,131	96,693
		NIS	
Basic loss per ordinary share*	(0.88)	(1.44)	(0.63)



# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 10 - LOSS PER SHARE - (continued)

\* The loss per share and the number of shares for the years 2007 and 2008 have been retroactively adjusted in order to give retroactive effect to the benefit embedded in the rights offering, as detailed in Note 8c(7). The embedded benefit, which is the equivalent of a stock dividend, in such rights offering was 25%.

Diluted loss per share data is not presented in the financial statements, due to the antidilutive effect of the inclusion of potentially dilutive shares.

**b.** The following table contains pro forma loss per share data reflecting the loss per share that would have resulted had the preferred shares been converted into Ordinary Shares at a conversion rate of one preferred share per one Ordinary Share upon their issuance. The pro forma data is designed to enable comparability between the periods in which the preferred shares were outstanding and the periods following their automatic conversion into Ordinary Shares:

	Year ended December 31,		
	2007	2008	2009
		NIS in thousands	
Loss reported in financial statements	(59,419)	(114,849)	(61,518)
	Number of shares in thousands		
Number of Ordinary Shares	69,301	78,131	96,693
Number of preferred A shares	1,774	—	
Number of preferred A-1 shares	926		
Number of shares used in calculation	72,001	78,131	96,693
		NIS	
Pro forma basic loss per Ordinary Share*	(0.82)	(1.44)	(0.63)

\* The loss per share and the number of shares for the years 2007 and 2008 have been retroactively adjusted in order to give retroactive effect to the benefit embedded in the rights offering, as detailed in Note 8c(7). The embedded benefit in such rights offering was 25%.

# NOTE 11 — COMMITMENTS AND CONTINGENT LIABILITIES

#### a. Commitments

1) Agreement with the State of Israel for the operation of a biotechnology incubator

As part of the Incubator agreement between the Partnership and the State of Israel, represented by the OCS (see principal provisions below), the State of Israel has agreed to grant loans to the Partnership to partially finance projects approved by the OCS.

The loans bear interest in accordance with the Interest and Linkage Law, 1961 (as of December 31, 2008 and 2009 - 3.94% and 1.70%, respectively), and are repayable at the discretion of the Partnership (but subject to the conditions described below concerning the sale of project assets or the realization of income from the project), as follows:

- In the three years of a project's incubator stage, the loan is repayable, plus accrued interest.
- In the subsequent two years, the loan is repayable under the same terms, provided that the Incubator undertakes to maintain the advancement of the project at a rate similar to that of the preceding years.



# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 11 — COMMITMENTS AND CONTINGENT LIABILITIES – (continued)

In the three following years, the loan is repayable with the addition of a double interest charge, provided that the Incubator undertakes to continue advancing the project at a rate similar to that of the preceding years.

If the Incubator sells assets or generates income from a project (including any intellectual property related thereto), at least 25% of the income from such sale must be used to repay the project loan, up to the original amount of the loan with the addition of interest as described herein. The Partnership is required to repay the loan in full upon the sale of a project's intellectual property or the grant of an exclusive license to use the project's intellectual property. The total payments to the State of Israel from such income will not exceed the original amount of the applicable loan with the addition of interest and linkage to the CPI. In certain circumstances, if the intellectual property or manufacturing rights are transferred outside of Israel, the repayment amounts may be greater.

Pursuant to the Incubator agreement, the Incubator has undertaken to register a first-ranking pledge in favor of the OCS to cover the loans made to the Incubator. In accordance with the agreement, each pledge is specific to a loan for a specific project and includes a restriction on the transfer of, and/or licensing rights in, technologies that originate from the project, and on any equipment purchased for the use of the project. As of the date of these financial statements, the Group has signed and submitted the pledge registration documents to the OCS, but they have not yet been signed by the OCS, and thus the pledge has not yet been registered.

The proceeds from the sale or use of a project-related intellectual property serve as the exclusive source for repayment of OCS loans financing such projects, and the sole collateral for the repayment of project loans are pledges on project-related intellectual property and assets purchased with loan proceeds.

In 2007, 2008 and 2009, the Group received NIS 13,934,000, NIS 9,192,000 and NIS 6,453,000 from the OCS, of which NIS 631,000, NIS 2,210,000 and NIS 2,949,000, respectively, were related to discontinued projects. The Company has agreed with the OCS on a procedure for the discontinuation of projects by the Incubator and the action that should be taken to forgive or repay loans received in respect of such discontinued projects.

The biotechnological incubators program is an initiative of the OCS that is designed to strengthen and promote the Israeli biotechnology industry, as well as biotechnology projects. This program was launched in late 2001, following publication of Directive No. 8.4 of the Director-General of Israel's Ministry of Industry, Trade and Labor ("Directive 8.4"). This directive implements the recommendations of the "Monitor" report, which reviewed ways to promote the Israeli biotechnology industry and recommended the establishment of for-profit incubators to support commercially viable projects by providing physical, organizational, professional, marketing and business infrastructure to promote research and development by early-stage biotechnology enterprises.

Directive 8.4 was amended in May 2004, to prescribe two tracks for operating biotech incubators (see (e) below). Immediately after the amendment of Directive 8.4, the OCS issued a call for proposals to establish and operate incubators. The Company, whose proposal was accepted by the OCS, entered into an agreement with the OCS, through the Partnership, for the operation of a designated biotechnology incubator. The principal provisions of the incubator agreement are as follows:

## (a) Period of the agreement

The incubator agreement has a six-year period. At the end of four years after the effectiveness of the Incubator agreement, the Group may request an extension for an additional three-year period (i.e., nine years in total).

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 11 — COMMITMENTS AND CONTINGENT LIABILITIES – (continued)

#### (b) Scope of Incubator operations

The Incubator is designed for the simultaneous operation of at least eight OCS-approved projects. The Group may operate additional projects within the Incubator's facilities that are not funded by the State or under the incubator program, provided that the operation of such additional projects does not interfere with OCS-approved projects.

### (c) Summary of the Group's obligations

Within the framework of the incubator agreement, the Group has agreed to operate a biotechnology-designated incubator, to identify projects suitable for OCS approval, to make adequate premises and physical infrastructure available for at least eight projects and to provide administrative, organizational, professional and business support to the projects in order to facilitate research and development of commercially viable biotechnology projects. Among other things, some minimum requirements have been set for Incubator staff in terms of skills and employment levels. In addition, the Group has agreed to maintain a central laboratory for the use of all projects, equip the laboratory in accordance with the specifications provided in Directive 8.4 and in the Group's incubator proposal, and operate the Incubator using capable personnel. The Group is also required to make consulting and auditing services (accounting, legal, patent consulting, quality assurance, information science services, regulatory consulting and clinical trials) available to the projects at an acceptable scope and quality, from service providers approved by the OCS. The Group has undertaken to invest at least NIS 2,700,000 per year in the operation of the Incubator.

### (d) Summary of OCS obligations

The OCS has undertaken to finance 50% of the cost of the equipment required for setting up the central laboratory and to make available State loans to each of the projects approved by the OCS at the rates of 85%, 80% and 75% of the project's approved budget in its first three years of operation, respectively, which are to be repaid to the State as described above. Each Incubator project is limited to a period of three years and a maximum budget of NIS 8,100,000, in respect of which the Group is responsible for obtaining the complementary financing (15% to 25%) for all three years, as described above.

In exchange for the services from the Incubator, the Group is entitled to receive participation by the OCS in operating expenses of up to 20% of the personnel costs associated with each project's approved budget, and may not collect additional payments in respect of the basket of services required by the OCS. The participation limit also applies to the operating expenses of the central laboratory, but does not apply to the costs of consumable materials.

### (e) The different tracks

Directive 8.4 offers two tracks for the operation of an incubator. Under the first track, each project is incorporated as a separate and independent company in which the incubator receives shares (the separate companies will allocate at least 30% of their share capital to the holder of the license/knowhow, up to 5% of the share capital for incubator services, and the remaining shares will be allotted to the incubator and other investors in proportion to their investments in the independent company, including the incubator's investments derived from State loans).

Under the second track, the projects are directly run within the incubator by the concessioner, with the holder of the license/know-how being entitled to a fixed amount for the use of his know-how as well as to royalties upon the sale of the knowhow and in respect of the sales of a final product developed under the project. An incubator operating under the second track is allowed to operate additional specific projects under the guidelines of the first track, subject to fulfillment of the provisions in the guidelines. The Group has elected to operate the Incubator under the second track.

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 11 — COMMITMENTS AND CONTINGENT LIABILITIES - (continued)

#### (f) Primary restrictions imposed on the Group and the Incubator

The agreement stipulates certain restrictions regarding operation of the Incubator and the projects, including, among others: maximum ownership of 15% in the Incubator by university research institutions; a limitation of subcontracting to no more than 40% of the approved budget; ownership by the Group (or the project company under the first track) of the intellectual property created in the project; a prohibition on duplicate grants and participation or duplicity of projects; compliance with guidelines on investment of funds; restrictions on the terms of the licensing agreements with the holders of the know-how, which mainly involves securing the rights of the OCS; compliance with the Israel R&D Law (the Encouragement of Research and Development in Industry Law) in terms of keeping in Israel the intellectual property and manufacturing rights relating to OCS-funded projects.

#### (g) Repayment of loans

Repayment of State loans is restricted to a project's own resources out of the proceeds received from the sale or licensing of a project (at least 25% of the proceeds). The sale or licensing of the technology is subject to payment of the aforementioned royalties, up to the amount of the loans received from the State for such project.

The State is entitled to foreclose on the collateral related to a given project to secure repayment of the related loan at the end of eight years from the date of project approval, or even earlier, in the event of a breach of the incubator agreement by the Group, liquidation, and other events as set forth in the agreement.

# (h) Security

The Group has provided a bank guarantee to the OCS in the amount of NIS 8,100,000 (linked to the consumer price index (CPI)) to secure its liabilities under the incubator agreement. After two years from the initial date of the incubator agreement, the amount of the guarantee is reduced every year by half the amount of the Incubator's reported approved expenses, subject to a minimum guarantee of NIS 1,500,000 (see Note 11b). Additionally, the rights in the various projects are pledged to the State to secure repayment of the loan out of project proceeds. With respect to incubators operating under the second track, a floating charge is placed on all intellectual property and all equipment purchased in connection with a project, including a restriction on the transfer or licensing of the technology created in the project. The collateral discussed in this paragraph may be forfeited even after the repayment period or upon breach of the incubator agreement.

(i) To the best knowledge of the Company's management, as of the date of approval of these financial statements, the Group is in compliance with its material obligations to the OCS under the incubator agreement.

With respect to the accounting treatment of State loans, see Note 2p.

2) Obligation to pay royalties to the Government of Israel

The Company is required to pay royalties to the Government of Israel, computed on the basis of proceeds from the sale or license of products whose development was supported by Government grants.

This obligation relates solely to the Government's financial participation in the development of products by the Company outside the framework of the Incubator operated by the Partnership.

In accordance with the terms of the financial participation, the Government is entitled to royalties on the sale or license of any product whose development was supported with Government participation. These royalties are 3% in the first three years from initial repayment, 4% of sales in the three subsequent years and 5% of sales in the seventh year until repayment of 100% of the grants (linked to the USD) received by the

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 11 — COMMITMENTS AND CONTINGENT LIABILITIES – (continued)

Company plus annual interest at the LIBOR rate. As of December 31, 2009, the maximum amount of royalties payable by the Company is NIS 18,800,000.

The Group's aggregate contingent liability to the OCS, both in respect of loans received in the framework of the biotechnology incubator (see paragraph (1) above), as well as the grants described herein, amounted to NIS 34,634,000 as of December 31, 2009.

3) Licensing agreements

From time to time, the Group enters into in-licensing agreements with academic institutions, research institutions and companies in connection with development of certain technologies (the "licensors").

The objective of each engagement with a licensor is to obtain rights for one or more drugs in the preliminary stages of development by the licensors, to continue joint development of the drugs by the Group and the licensors until advanced stages of development and, consequently, to manufacture, distribute and market the drugs or to out-license the development, manufacture and commercialization rights to third parties. Such post-development activities are carried out by either the Group and/or by companies or institutions to which the Group has entered into an out-license agreement, subject to certain restrictions stipulated in the various agreements.

The licenses that have been granted to the Group are broad and comprehensive, and generally include various provisions and usage rights, as follows: (i) territorial scope of the license (global); (ii) term of the license (unrestricted but not shorter than the life of the patent); and (iii) development of the therapeutic compound (allowing the Group to perform all development activities on its own, or by outsourcing under Group supervision, as well as out-licensing development under the license to other companies, subject to the provisions of the licensing agreements).

According to the provisions of the licensing agreements, the intellectual property rights in the development of any licensed technology remain with the licensor until the date the applicable license agreement is effective, while the rights in products and/or other deliverables developed by the Group after the license is granted belong to the Group. In cases where the licensor has a claim to an invention that was jointly developed with the Group, the licensor also co-owns the related intellectual property. In any event, the scope of the license also covers these rights.

In addition, the Group has generally undertaken in the licensing agreements to protect registered patents resulting from developments under the various licenses, to promote the registration of developments in cooperation with the licensor, and to bear responsibility for all related costs. Pursuant to the various agreements, the Group will work to register the various patents worldwide, and if the Group decides not to initiate or continue a patent registration proceeding in a given country, the Group is required to notify the applicable licensor to this effect and the licensor will be entitled to take action for registration of the patent in such country.

The consideration paid pursuant to the licensing agreements includes several components that are payable over the license period and that relate, inter alia, to the progress made in research and development activities, as well as commercial success, as follows: (a) one-time payment of up to USD 200,000 and/or periodic payments of up to USD 30,000 per year; (b) royalties on amounts the Group receives from an out-licensing transaction that range from 20% to 29.5% of net consideration; (c) payments through the early stages of development ( i.e. through the end of phase 2) of up to USD 150,000; (d) payments of up to USD 2,000,000 upon the achievement of milestones necessary for advancing to phase 3; (e) payments of up to USD 5,000,000 from the end of a successful phase 3 trial through approval of the therapeutic compound; and f) royalties on sales of the final product resulting from development under the license or including any component thereof, ranging between 3%-5% of the Group's net sales of the product.

### NOTES TO THE FINANCIAL STATEMENTS

# NOTE 11 — COMMITMENTS AND CONTINGENT LIABILITIES – (continued)

The license agreement may be cancelled, generally upon the occurrence of one of the following events: (a) the Group's failure to meet certain milestones stipulated in the applicable license agreement and appended timetables; (b) default, insolvency, receivership, liquidation, etc. of the Group that is not imposed and/or lifted within the timeframe stipulated in the license agreement; and (c) fundamental breach of the license agreement that is not corrected within the stipulated timeframe. In addition, some of the agreements may be cancelled with prior notice of 30 to 90 days, due to unsuccessful development or any other cause.

The Group has undertaken to indemnify the various licensors, their employees, officers, representatives or anyone acting on their behalf for any damage and/or expense that they may incur in connection with the Group's use of a license granted to it, all in accordance with the terms stipulated in the applicable license agreements.

Some of the license agreements are accompanied by consulting, support and cooperation agreements, pursuant to which the Group is committed to pay the various licensers a fixed monthly amount, over the period stipulated in the agreement, for their assistance in the continued research and development under the license.

### 4) Lease agreements

a) The Company has entered into an operating lease agreement with one of its shareholders, which was a related party of the Company on the date the agreement was signed, in connection with the lease of its premises. The agreement expires on December 15, 2010. The Group has an option to extend the lease agreement for three additional periods of 24 months each. The annual lease fees are linked to the dollar and amount to approximately NIS 800,000. As to bank deposits pledged to secure the Company's liability under the lease agreement, see Note 11b(1).

b) The Company has entered into operating lease agreements in connection with a number of vehicles. The lease periods are generally for three years. The annual lease fees, linked to the dollar, are approximately NIS 1,820,000. To secure the terms of the lease agreements, the Group has made certain prepayments to the leasing company, representing approximately two months of lease payments. These amounts were recorded as prepaid expenses. See also Note 13b.

5) Agreement for the performance of clinical trials

The Company has entered into an agreement with a related party for the use of that party's facilities to conduct clinical trials for one of its projects. The usage fees are up to USD 50,000, conditioned on the achievement of milestones, as stipulated in the agreement.

6) Early Development Program ("EDP") agreement

On the signature date of the convertible loan agreement with Pan Atlantic, as described in Note 8c(3), the Company also entered into an agreement with Pan Atlantic for the funding of an early development program (the "EDP Agreement"). According to the EDP Agreement, Pan Atlantic undertook to provide grants for the promotion of drug-development projects in the preliminary stages of research in an aggregate amount of up to USD 5,000,000, in semi-annual "calls" of up to USD 625,000 each, through April 2011. In parallel, for every dollar of EDP project funding provided by Pan Atlantic, the Company committed to provide twenty cents of funding (i.e., a funding ratio of 5:1). Pan Atlantic undertakings under the EDP agreement are not subject to Pan Atlantic being a lender to, or a shareholder of, the Company.

In consideration for the EDP funding commitment, the Company granted to Pan Atlantic the right to participate in a future initial public offering of the Company outside of Israel, at the public offering price, in an amount of up to USD 5,000,000.

### NOTES TO THE FINANCIAL STATEMENTS

## NOTE 11 — COMMITMENTS AND CONTINGENT LIABILITIES – (continued)

During 2007, 2008 and 2009, Pan Atlantic provided funding to the Group of NIS 1,273,000, NIS 2,876,000 and NIS 4,881,000, respectively, under the EDP Agreement. The amounts recognized as a reduction of research and development expenses in 2007, 2008 and 2009 were NIS 298,000, NIS 2,525,000 and NIS 3,297,000, respectively.

### b. Contingent liabilities

1) Guarantees and liens

a) As part of the Group's obligations under the Incubator agreement and to secure the Group's liabilities to the OCS, the Company has provided a NIS 8,100,000 bank guarantee (linked to the CPI) in favor of Israel's Ministry of Finance.

The guarantee is valid through March 2011. According to the Incubator agreement, after the two year anniversary of the initial date of the Incubator agreement, the amount of the guarantee will be reduced every year by half of the amount of the Incubator's reported approved expenses. In October 2007 and May 2009, the OCS permitted the Group to reduce the amount of the guarantee to approximately NIS 3,400,000 and NIS 2,700,000, respectively. In no event will the amount of the guarantee fall below NIS 1,500,000 (linked to the CPI).

To secure the above guarantee, the Company has pledged to a bank a short-term deposit in the amount of NIS 3,100,000, which is presented under non-current assets.

b) To secure the Company's liability to the lessor of its premises, the Company has pledged several dollar-denominated bank deposits in the amount of USD 159,000 (NIS 604,000), which are presented under non-current assets.

#### 2) Legal proceeding

The Company was one of several respondents in a lawsuit filed against a third party that had purchased from the Company the shares of an associated company. The third party has raised various contentions in the lawsuit with respect to the transaction.

Subsequent to the balance sheet date, this lawsuit was rejected by the Israeli Supreme Court.

# NOTE 12 - TRANSACTIONS AND BALANCES WITH RELATED PARTIES

#### a. Transactions with related parties

Expenses (income):

	Yea	r ended December	r 31,
	2007	2008	2009
		NIS in thousands	
Participation in EDP project funding <sup>(1)</sup>	(298)	(2,525)	(3,297)
Benefits to related parties:			
Wages and related expenses to CEO	1,735	1,138	1,136
Benefit component in shares granted to CEO <sup>(2)</sup>	6,628	3,651	
Compensation to directors and officers, including benefit	17,792	11,635	7,623
component of option grants			
Conducting of clinical trials <sup>(3)</sup>	106	111	39
Professional fees <sup>(4)</sup>	172	21	12

1) This amount relates to a grant received from a related party of the Company, in accordance with the EDP Agreement, as detailed in Note 11a(6).

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 12 — TRANSACTIONS AND BALANCES WITH RELATED PARTIES – (continued)

2) As to shares granted to the CEO, see Notes 8c(1) and 8c(2).

3) As to the agreement signed with a related party to conduct clinical trials, see Note 11a(5).

4) Represents fees paid in connection with membership in the Company's Scientific Advisory Board.

### b. Balances with related parties

	December 31,	
	2008	2009
	NIS in the	ousands
Presented in accounts payable and accruals:		
Grants on account of project development financing not yet recognized in income	1,326	2,896
Accounts payable and accruals – other <sup>(1)</sup>	8	

1) As to an engagement with a related party to conduct clinical trials, see Note 11a(5).

# NOTE 13 — SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

# a. Other receivables

	Decemb	December 31,	
	2008	2009	
	NIS in th	ousands	
Institutions	959	1,991	
Grants receivable from the OCS	4,750	322	
Other	39		
	5,748	2,313	

### b. Long-term prepaid expenses

The prepaid expenses relate to operating lease agreements in respect of the vehicles used by the Group, as well as materials utilized by the Company to produce the BL-1040 compound.

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 13 — SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION – (continued)

### c. Accounts payable and accruals

	December 31,	
	2008	2009
	NIS in the	ousands
1) Trade:		
Accounts payable:		
In Israel	1,434	1,224
Overseas	12,898	5,208
Checks payable	17,013	20
	31,345	6,452
2) Other:		
Payroll and related expenses	1,522	1,318
Accrual for vacation and recreation pay	1,263	881
Accrued expenses	1,847	4,924
Grants on account of EDP project development financing not yet recognized in	1,326	2,896
income		
Other	25	184
	5,983	10,203

The carrying amount of accounts payable and accruals is close or identical to their fair value, as the effect of discounting is not material.

# d. Cost of revenues

Yea	Year ended December 31,		
2007	2007 2008		
	NIS in thousands		
_		17,817	
	—	4,369	
—	—	436	
		22,622	
	-	2007 2008	

\* See Note 14

# NOTES TO THE FINANCIAL STATEMENTS

# NOTE 13 — SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION – (continued)

# e. Research and development expenses — net

	Year ended December 31,		
	2007	2008	2009
		NIS in thousands	
Payroll and related expenses, including vehicles	22,951	21,161	16,384
Depreciation and amortization	1,012	2,180	1,781
Patent related expenses	2,595	3,841	2,907
Research and development services	56,403	95,665	66,534
Professional fees	1,192	594	1,113
Materials	1,786	1,693	247
Overseas travel	1,272	2,231	471
Office supplies and telephone	2,248	2,699	2,661
Payments to the OCS (see Note 11a(7))	—		8,739
Other	849	1,691	187
	90,308	131,755	101,025
Less – OCS participations in research and development costs – see also Notes 11a(1) and (2)	(14,147)	(23,074)	(7,426)
Less – participations in research and development costs by a related party – see Note 12a	(298)	(2,525)	(3,297)
	75,863	106,156	90,302

# f. Sales and marketing expenses

	Ye	Year ended December 31,		
	2007	2008	2009	
		NIS in thousands		
Payroll and related expenses	—	—	1,396	
Marketing	_	—	1,400	
Overseas travel		—	289	
			3.085	

# g. General and administrative expenses

	Year ended December 31,		
	2007	2008	2009
		NIS in thousands	
Payroll and related expenses, including vehicles	8,500	7,863	6,792
Professional fees	4,289	3,707	2,499
Office supplies and telephone	114	170	121
Office maintenance	50	100	117
Depreciation	64	99	121
Other	594	1,144	1,532
	13,611	13,083	11,182

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## NOTES TO THE FINANCIAL STATEMENTS

## NOTE 13 — SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION - (continued)

### h. Finance income

	Year ended December 31,		
	2007	2008	2009
		NIS in thousands	
Gain on change in fair value of financial assets at fair value through profit or loss	—	273	98
Income from interest and exchange differences on deposits	7,875	12,728	3,830
	7,875	13,001	3,928

#### i. Finance expenses

	Year ended December 31,		
	2007	2008	2009
		NIS in thousands	
Warrant issuance expenses	2,067	—	—
Exchange differences	3,184	12,172	2,064
Bank commissions	126	97	100
	5,377	12,269	2,164

# NOTE 14 — IKARIA AGREEMENT

During the third quarter of 2009, the Company entered into an out-licensing agreement with Ikaria, pursuant to which the Company granted Ikaria an exclusive, worldwide license to develop, manufacture and commercialize BL-1040 — a compound for the treatment of patients that have suffered an acute myocardial infarction ("AMI"). The agreement was signed in July 2009 and the transaction closed in September 2009, following receipt by the Company of OCS approval for the transaction, and transfer by the Company to Ikaria of all deliverables as stipulated under the agreement.

In accordance with the agreement, Ikaria is obligated to use commercially reasonable efforts to complete clinical development of and to commercialize BL-1040, and will bear all subsequent costs involved in the continued development of the product, the conduct and funding of its commercialization, and the prosecution and maintenance of patents.

Prior to execution of the agreement, the Company commenced a pilot phase 1/2 study designed to assess the safety and preliminary efficacy of BL-1040, and completed recruitment and treatment of the patients under the study. See Note 14 with regard to the final results of the study, which were received subsequent to the balance sheet date. According to the agreement, the Company is required to bear the costs related to completion of the present stage of the phase 1/2 study. The Company does not deem these costs, related to follow up and documentation of results, as material.

Total payments to the Company under the agreement (not including royalties) are up to USD 282,500,000, subject to the achievement of certain milestones. Upon the closing of the agreement, the Company became entitled to the first payment in the amount of USD 7,000,000, which was received in October 2009. As of December 31, 2009, the Company's management believed that receipt of the next milestone payment of USD 10,000,000 was probable. This assessment was made because, as of that date, all 27 patients participating in the phase 1/2 clinical trial had been treated. In addition, to complete the trial endpoint, all patients had to experience a six-month period post-treatment with no adverse safety event (such as a heart attack or death). As of December 31, 2009, 25 out of the 27 patients had completed the full six-month post-treatment period with no adverse event and the two remaining patients had only two weeks left in their post-treatment period. The likelihood at December 31, 2009 of a severe adverse event in respect of the

### NOTES TO THE FINANCIAL STATEMENTS

## NOTE 14 — IKARIA AGREEMENT – (continued)

last patients was considered extremely remote. Based on the foregoing, the results of the clinical trial were known as of December 31, 2009 and the Company therefore determined that the payment was probable.

Approximately 50% of the remaining payments are subject to certain development and regulatory milestones and the rest are subject to commercialization milestones. The first two milestone payments were recognized as revenues in 2009, and future milestone payments will be recognized as revenues if and when their receipt will become probable and their amount can be reliably measured. In connection with the first milestone payment made under the agreement, the Company undertook to indemnify Ikaria for any obligations it may have had to withhold taxes on such payment.

The Company is also entitled to royalties on the net sales of any product developed under the agreement, ranging from 11% to 15%, depending on annual net sales levels.

The Company has the option to manufacture at least 20% of BL-1040 products, pursuant to the terms of a supply agreement to be negotiated in good faith between the parties.

The out-licensing agreement with Ikaria terminates on the date that the last patent rights in respect of BL-1040 are still valid (through at least 2024).

The Group is required to pay to the licensors of the BL-1040 compound 28% of all consideration received under the agreement. This expense is recorded in the statement of comprehensive loss as cost of revenues. Additionally, the Group is obligated to repay the grants and loans received from the OCS regarding the BL-1040 project, in accordance with the Israeli R&D Law and as agreed with the OCS. This expense, up to the amount of funding received from the OCS, has been recorded in the statement of comprehensive loss in research and development expenses, with the balance recorded in cost of revenues. Although the Group has made its best estimate of the total liability to the OCS in respect of the BL-1040 project, the exact amount and timing of payments due to the OCS have not been finally determined and the amount accrued may therefore be subject to change. Once the OCS and the Group have reached agreement regarding final amount payable (including loans/grants received, interest and amounts due for transferring the research and development outside of Israel), the Company will no longer have any repayment obligation to the OCS associated with BL-1040.

As of December 31, 2009, the liabilities to the licensor and the OCS in connection with BL-1040 are presented on the balance sheet in current liabilities, and the intangible asset related to the project was written off and is reflected in cost of revenues for 2009.

# NOTE 15 — EVENTS SUBSEQUENT TO THE BALANCE SHEET DATE

a. In January 2010, the Company granted a total of 752,100 options to certain employees, exercisable into Ordinary Shares at exercise prices of NIS 4.83 and NIS 5.02 per share. The options vest over a four-year period and are exercisable for a period of seven years from the date of grant.

b. In February and March 2010, the Company granted a total of 4,020,300 options to all Company employees (other than the Company's CEO) and to members of the Company's Scientific Advisory Board, exercisable into Ordinary Shares at an exercise price of NIS 4.034 per share. The options vest over a four-year period and are exercisable for a period of five years from the date of grant.

c. In March 2010, the Company's Board of Directors approved the allocation of 400,000 options to the Company's two external directors, exercisable into Ordinary Shares at an exercise price of NIS 4.348 per share. The allocation is subject to approval by shareholders. The options vest over a three-year period and are exercisable for a period of five years from the date of grant.

### NOTES TO THE FINANCIAL STATEMENTS

# NOTE 15 — EVENTS SUBSEQUENT TO THE BALANCE SHEET DATE – (continued)

d. In February 2010, the final assessment of the Independent Safety Monitoring Board ("ISMB") was received in respect of the BL-1040 pilot phase 1/2 study (designed to assess the safety and preliminary efficacy of BL-1040). The ISMB's conclusions, relating to the 27 patients who participated in the study and completed a six-month follow-up period, indicated that the treatment is safe and that it would be appropriate to continue clinical development of the device. These positive conclusions of the ISMB constitute successful fulfillment of the second milestone under the Company's out-licensing agreement with Ikaria, thus triggering the payment of USD 10,000,000 as set forth in the agreement. The payment is expected to be received in April 2010. The Company is obligated to pay approximately USD 2,800,000 of the amount received to the original licensors of the compound.

# NOTE 16 — INFORMATION REGARDING INVESTMENTS IN CONSOLIDATED ENTITIES

Set forth below are details regarding the consolidated entities of the Group:

	Decemb	oer 31, 2009		
Name of consolidated entity and country of registration	Company's rights in the consolidated entity	Total investment in consolidated entity	Stock exchange information	Dividends received or receivable
BioLine Innovations	1) Equity rights: 99%	NIS 14,115,000	Private	No dividends have
Jerusalem Limited	2) Voting rights: 99%			been declared
Partnership; registered in Israel	3) Loans to entity: outstanding loan balance of NIS 11,892,000 as of December 31, 2009, with annual interest at 4%, not linked to the CPI			since inception
BioLine Innovations Jerusalem Ltd.; registered in Israel	<ol> <li>Equity rights: 100%</li> <li>Voting rights: 100%</li> </ol>	—	Private	No dividends have been declared since inception
BioLineRx USA, Inc.; registered in the United States	<ol> <li>Equity rights: 100%</li> <li>Voting rights: 100%</li> </ol>	—	Private	No dividends have been declared since inception



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### PART II INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 6. Indemnification of Directors, Officers and Employees

An Israeli company may indemnify an office holder in respect of certain liabilities either in advance of an event or following an event provided that a provision authorizing such indemnification is inserted in its articles of association. Our Articles of Association contain such a provision. An undertaking provided in advance by an Israeli company to indemnify an office holder with respect to a financial liability imposed on him or her in favor of another person pursuant to a judgment, settlement or arbitrator's award approved by a court must be limited to events which in the opinion of the Board of Directors can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or a criteria determined by the Board of Directors as reasonable under the circumstances, and such undertaking must detail the abovementioned events and amount or criteria.

In addition, a company may indemnify an office holder against the following liabilities incurred for acts performed as an office holder:

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder as a result of an investigation or
  proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided
  that (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) no
  financial liability, such as a criminal penalty, was imposed upon him or her as a substitute for the criminal proceeding as a
  result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an
  offense that does not require proof of criminal intent; and
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf or by a third party or in connection with criminal proceedings in which the office holder was acquitted or as a result of a conviction for a crime that does not require proof of criminal intent.

An Israeli company may insure a director or officer against the following liabilities incurred for acts performed as a director or officer:

- a breach of duty of care to the company or to a third party, including a breach arising out of the negligent conduct of an office holder;
- a breach of duty of loyalty to the company, provided the director or officer acted in good faith and had a reasonable basis to believe that the act would not prejudice the interests of the company; and
- financial liabilities imposed on the office holder for the benefit of a third party.

An Israeli company may not indemnify or insure an office holder against any of the following:

- a breach of duty of loyalty, except to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach of duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine levied against the office holder.

Under the Israeli Companies Law, indemnification and insurance of office holders must be approved by our audit committee and our Board of Directors and, in respect of our directors, by our shareholders. Our directors and officers are currently covered by a directors and officers' liability insurance policy with respect to specified claims. To date, no claims for liability have been filed under this policy. In addition, we have entered into indemnification agreements with each of our directors and officers and the directors and officers of our subsidiaries providing them with indemnification for liabilities or expenses incurred as a result of acts performed by them in their capacity as our, or our subsidiaries', directors and officers. This indemnification is

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limited both in terms of amount and coverage. In the opinion of the SEC, however, indemnification of directors and office holders for liabilities arising under the Securities Act is against public policy and therefore unenforceable.

#### Item 7. Recent Sales of Unregistered Securities

### Ordinary Shares

During the second half of 2007, we issued an aggregate of 252,118 ordinary shares pursuant to the exercise by our employees and consultants of outstanding options to purchase ordinary shares. The total aggregate consideration for such issuances was approximately NIS 10,200, or \$2,483 (based on an exchange rate of \$1.00 to NIS 4.1081, the average rate reported by the Bank of Israel for 2007).

During 2009, we issued an aggregate of 3,032,008 ordinary shares in connection with the exercise of warrants and stock options. Total aggregate consideration received in consideration for these issuances was approximately NIS 123,000, or \$31,277 (based on an exchange rate of \$1.00 to NIS 3.9326, the average rate reported by the Bank of Israel for 2009).

During 2010 through the date of this prospectus, we issued an aggregate of 20,141 ordinary shares in connection with the exercise of stock options. Total aggregate consideration received in consideration for these issuances was approximately NIS 864, or \$223 (based on the exchange rate reported by the Bank of Israel for June 30, 2010).

No underwriters were involved in the foregoing sales of ordinary shares. All of the securities referred to above were sold pursuant to an exemption from registration under Regulation S of the Securities Act relative to sales of securities outside of the United States and/or under Section 4(2) of the Securities Act as not involving a public offering, to the extent an exemption from such registration was required.

#### Public Offering of Ordinary Shares in Israel

#### Shelf registration

On May 3, 2009, we filed a shelf prospectus with the TASE and Israeli Securities Authority. The shelf prospectus allows us, for a period of two years, the possibility to issue the securities described in the prospectus to the public in Israel by means of shelf offering reports, without being required to publish a full prospectus. Following their issuance, such securities will be registered for trade on the TASE with no lock-up period. As permitted under applicable Israeli law, our shelf prospectus registered different classes of securities, including ordinary shares, up to three series of ordinary debentures, up to three series of debentures convertible into ordinary shares, up to three series of warrants exercisable into shares and up to three series of warrants exercisable into debentures.

### Rights offering

On July 2, 2009, we issued 46,666,719 shares in a rights offering to our shareholders by means of a shelf offering report, published on June 10, 2009, under the shelf prospectus of May 3, 2009. The per share price at the issuance was NIS 1.13 per share, or approximately \$0.29 (based on the exchange rate reported by the Bank of Israel for that date). The issuance was not underwritten, although Clal Finance Underwriting Ltd. provided marketing and distribution services in connection with the offering. The offering received a 99% response rate. The aggregate gross proceeds raised in the rights offering was approximately NIS 52.7 million, or approximately \$13.7 million (based on the exchange rate reported by the Bank of Israel for that date). The marketing and distribution services paid to Clal Finance Underwriting Ltd. in connection with this offering were approximately \$140,000 (NIS 570,000) (based on the exchange rate reported by the Bank of Israel for that date).

### Follow-On Offering in Israel

On December 29, 2009, we issued 11,293,419 of our ordinary shares, and Series 2 Warrants exercisable for 7,528,946 of our ordinary shares, in a follow-on public offering in Israel, or the Israeli Follow-On Offering, on the TASE. The per share offering price of the Israeli Follow-On Offering was NIS 4.167, or approximately \$1.10 (based on the exchange rate reported by the Bank of Israel for that date), and the



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ordinary shares were offered in units consisting of three ordinary shares and two Series 2 Warrants, which were offered for no further consideration. The ordinary shares and the Series 2 Warrants are both listed for trading on the TASE and the Series 2 Warrants trade separately from the ordinary shares. The exercise price of the Series 2 Warrants is NIS 6.08, or approximately \$1.60 (based on the exchange rate reported by the Bank of Israel for that date), per share and the warrants are exercisable until December 29, 2011. The offering was not underwritten. Clal Finance Underwriting Ltd. provided marketing and distribution services in connection with the offering as our agent. The offering received a 207% response rate. The aggregate gross proceeds raised were approximately NIS 47.1 million, or approximately \$12.4 million (based on the exchange rate reported by the Bank of Israel for that date). The fee paid to Clal Finance Underwriting Ltd., or Clal, for its marketing and distribution services was approximately NIS 1.2 million, or \$310,000 (based on the exchange rate reported by the Bank of Israel reported by the Bank of Israel for that date). In addition, Clal is entitled to a commission equal to 1% of the total consideration we receive from exercises of Series 2 Warrants payable on a quarterly basis.

# Item 8. Exhibits and Financial Statement Schedules

### (a) Financial Statement Schedules

All schedules have been omitted because either they are not required, are not applicable or the information is otherwise set forth in the consolidated financial statements and related notes thereto.

# Item 9. Undertakings

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the provisions described in Item 6 hereof, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes:

- (1) To provide the underwriters at the closing specified in the Underwriting Agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.
- (2) That for purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4), or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (3) That for the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and this offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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### SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Jerusalem, State of Israel on this 24th day of September, 2010. BIOLINERX, LTD.

By: /s/ Kinneret Savitsky

Kinneret Savitsky, Ph.D. Chief Executive Officer

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### **POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTED, that each director and officer of BIOLINERX, LTD. whose signature appears below hereby appoints Kinneret Savitsky, Ph.D. and Philip Serlin, and each of them severally, acting alone and without the other, his/her true and lawful attorney-in-fact with full power of substitution or re-substitution, for such person and in such person's name, place and stead, in any and all capacities, to sign on such person's behalf, individually and in each capacity stated below, any and all amendments, including post-effective amendments to this Registration Statement, and to sign any and all additional registration statements relating to the same offering of securities of the Registration Statement that are filed pursuant to Rule 462(b) of the Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed below by the following persons in the capacities and on the dates indicated: 

Name	Title	Date
/s/ Kinneret Savitsky	Chief Executive Officer, Director	September 24, 2010
Kinneret Savitsky, Ph.D.	(principal executive officer)	
/s/ Philip Serlin	Chief Financial Officer and Chief Operating Officer	September 24, 2010
Philip Serlin	(principal financial officer and principal accounting	
-	officer)	
/s/ Aharon Schwartz	Chairman of the Board	September 24, 2010
Aharon Schwartz, Ph.D.	-	
/s/ Raphael Hofstein	Director	September 24, 2010
Raphael Hofstein, Ph.D.	-	
/s/ Yakov Friedman	Director	September 24, 2010
Yakov Friedman	-	
/s/ Avraham Molcho	Director	September 24, 2010
Avraham Molcho, M.D.	-	
/s/ Nurit Benjamini	Director	September 24, 2010
Nurit Benjamini	-	
/s/ Michael J. Anghel	Director	September 24, 2010
Michael J. Anghel, Ph.D.	-	
/s/ Nir Gamliel	Authorized United States Representative	September 24, 2010
Nir Gamliel	-	

### EXHIBIT INDEX

- 1.1 Form of Underwriting Agreement.\*
- 3.1 Articles of Association of the Registrant.
- 4.1 Specimen ordinary share certificate.\*
- 4.2 Registration Rights Agreement by and among Star Group, Yehuda Zisapel, Jerusalem Development Authority, the Company, Teva Pharmaceutical Industries Ltd., the Pitango Group, the Giza Group, and Hadasit Medical Research Services and Development Ltd. dated January 25, 2007.
- 5.1 Opinion of Yigal Arnon and Co., Israeli counsel to the Registrant, as to the validity of the ordinary shares (including consent).\*
- 10.1 Employment Agreement with Morris C. Laster, M.D., dated May 1, 2003.
- 10.2 Employment Agreement with Moshe Phillip, M.D., dated January 28, 2004.
- 10.3 Employment Agreement with Kinneret Savitsky, Ph.D., dated October 13, 2004.
- 10.4 Employment Agreement with Nir Gamliel, dated January 2, 2007.
- 10.5 Employment Agreement with Philip Serlin, dated May 24, 2009.
- 10.6<sup>†</sup> License Agreement entered into as of January 10, 2005, by and between BioLine Innovations Jerusalem L.P. and B.G. Negev Technologies and Applications Ltd.
- 10.7 Assignment Agreement dated as of January 1, 2009 entered into by and between BioLine Innovations Jerusalem L.P. and BioLineRx Ltd.
- 10.8†Research and License Agreement entered into as of April 15, 2004 by and among BioLineRx<br/>Ltd., Bar Ilan Research and Development Company Ltd., and Ramot and Tel Aviv University.
- First Amendment, dated as of June 2004, of Research and License Agreement, dated April 15,
   2004, by and among the Registrant, Ramot at Tel Aviv University Ltd. and Bar Ilan Research and
   Development Company Ltd.
- 10.10 Amendment Agreement dated as of December 20, 2005 entered into by and between the Registrant, Bar Ilan Research and Development Company Ltd. and Ramot at Tel Aviv University Ltd.
- 10.11 Amendment Agreement dated as of March 7, 2006, entered into by and between the Registrant, Bar Ilan Research and Development Company Ltd. and Ramot at Tel Aviv University Ltd.
- 10.12<sup>†</sup> Assignment Agreement dated as of July 2, 2006 entered into by and between BioLineRx Ltd., Bar Ilan Research and Development Company Ltd., and Ramot and Tel Aviv University.
- 10.13 Incubator agreement with the Office of the Chief Scientist, January 2005.
- 10.14 Bridge Loan Agreement with Pan Atlantic Investments Limited dated January 10, 2007.
- 10.15 Early Development Program Agreement with Pan Atlantic Investments Limited, dated January 10, 2007.
- 10.16<sup>†</sup> License Agreement between Innovative Pharmaceutical Concepts, Inc. and BioLineRx Ltd. dated November 25, 2007.
- 10.17<sup>†</sup> Amended and Restated License and Commercialization Agreement by and among Ikaria Development Subsidiary One LLC and BioLineRx Ltd. and BioLine Innovations Jerusalem L.P. dated August 26, 2009.
- 10.18 BioLineRx Ltd. 2003 Share Option Plan.
- 10.19 Lease Agreement between Kaps-Pharma Ltd. and BioLine Innovations Jerusalem L.P., dated July 10, 2005.
- 10.20 Extension to lease Agreement between Kaps-Pharma Ltd. and BioLine Innovations Jerusalem L.P., dated December 4, 2008.
- 10.21 Amendment to Employment Agreement with Kinneret Savitsky, Ph.D., dated January 2, 2010.

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10.22 Employment Agreement with Leah Klapper, Ph.D., dated January 27, 2005.

- 10.23<sup>+</sup> Amended and Restated License Agreement entered into on June 20, 2010 between Cypress Bioscience, Inc. and BioLineRx Ltd.\*
- 10.24<sup>†</sup> Payment Date Extension Amendment by and among Ikaria Development Subsidiary One LLC and BioLineRx Ltd. and BioLine Innovations Jerusalem L.P., dated April 21, 2010.
- 10.25 Amendment to the Amended and Restated license and Commercialization Agreement by and among Ikaria Development Subsidiary One LLC and BioLineRx Ltd. and BioLine Innovations Jerusalem L.P., dated April 21, 2010.
- 21.1 List of subsidiaries of the Registrant.
- 23.1 Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Registrant.
- 23.2 Consent of Opinion of Yigal Arnon and Co., Israeli counsel to the Registrant (included in Exhibit 5.1).\*
- 24.1 Powers of Attorney (included in signature page to Registration Statement).

<sup>†</sup> Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

<sup>\*</sup> To be filed by amendment.

TRANSLATION FROM HEBREW

BioLineRX Ltd.

Articles of Association of a Public Company

In accordance with

The Companies Law, 5759-1999

BioLineRX Ltd.

# 1. Name of Company

The name of the Company is BioLineRX Ltd.

## 2. Goals of the Company

The goal of the Company is to engage in any lawful business.

### 3. Interpretation

- 3.1 Any statement in the singular shall also include the plural and vice versa; any statement in the masculine shall also include the feminine and vice versa.
- 3.2 Except insofar as these Articles include special definitions of certain terms, any word and expression in these Articles shall have the meaning attributed thereto in the Companies Law, 5759-1999 (in these Articles "the Companies Law,") unless this contradicts the written matter or the content thereof.
- 3.3 To prevent doubt it is clarified that regarding matters regulated in the Companies Law in such manner that the arrangements in these matters may be conditioned in the Articles, and in cases in which these Articles do not include different provisions from those in the Companies Law, the provisions of the Companies Law shall apply.
- 3.4 It is hereby clarified that the provisions of the Articles of Association of the Company as detailed below are subject to the provisions of the Companies Law, the Securities Law, and any law.

### 4. The Share Capital of the Company and the Rights Attached to Shares

4.1 The registered capital of the Company is NIS 2,500,000, divided into 250,000,000 ordinary shares with a nominal value of NIS 0.01 each.

## 4.2 The ordinary shares shall entitle their owners to –

4.2.1 An equal right to participate in and vote at the general meetings of the Company, whether ordinary meetings or extraordinary meetings. Each of the shares in the Company shall entitle its owner present at the meeting and participating in the vote in person, by proxy, or by means of a letter of voting, to one vote;

- 4.2.2 An equal right to participate in the distribution of dividends, whether in cash or in benefit shares, in the distribution of assets, or in any other distribution, according to the proportionate nominal value of the shares held thereby;
- 4.2.3 An equal right to participate in the distribution of the surplus assets of the Company in the event of its liquidation in accordance with the proportionate nominal value of the shares held thereby.
- 4.3 The Board of Directors is entitled to issue shares and other convertible securities or securities that may be realized as shares up to the limit of the Company's registered capital. For the purpose of calculating the limit of the registered capital, convertible securities or securities that may be realized as shares shall be considered to have been converted or realized as of their date of issue.

# 5. Limited Liability

The liability of the shareholders for the Company's debts shall be limited to the full amount (nominal value with the addition of premium) they shall be required to pay the Company for the shares and which they have not yet paid.

# 6. Joint Shares and Share Certificates

6.1 The owner of a share registered in the registry of shareholders is entitled to receive from the Company, without payment and within a period of three months following the allocation or the registration of transfer, one share certificate stamped with the Company's stamp regarding all the shares registered in his name, which certificate shall detail the number of shares. In the event of a jointly owned share, the Company shall issue one share certificate for all the joint owners of the share, and the delivery of such a certificate to one of the partners shall be considered delivery to them all.

Each share certificate shall bear the signature of at least one director, together with the Company stamp or its printed name.

6.2 A share certificate that has been defaced, destroyed, or lost may be renewed on the basis of such proof and guarantees as shall be required by the Company from time to time.

# 7. <u>The Company's Reliefs relating to Shares that Have Not Been Fully Paid</u>

7.1 If any or all of the remuneration the shareholder undertook to pay the Company in return for his shares has not been paid by such date and on such conditions as established in the conditions for the allocation of his shares and/or in the payment request as stated in section 7.2 below, the Company is entitled, by way of a decision of the Board of Directors, to forfeit the shares whose remuneration has not been fully paid. The forfeiture of shares shall take place provided that the Company has sent the shareholder written warning of its intention to forfeit the shares after at least 7 days from the date of receipt of the warning, insofar as payment shall not be made during the period determined in the letter of warning.

The Board of Directors is entitled, at any time prior to the date on which the forfeited share is sold, reallocated, or otherwise transferred, to nullify the forfeiture on such conditions as it shall see fit.

The forfeited shares shall be held by the Company as retired shares or shall be sold to another.

7.2 If, in accordance with the conditions of allocation of the shares, there is no fixed date for the payment of any part of the price to be paid on account thereof, the Board of Directors is entitled, from time to time, to present payment requests to the shareholders on account of monies not yet removed for the shares they hold, and each shareholder shall be obliged to pay the Company the amount requested on the date determined as stated, provided that he shall receive prior notice of 14 days of the date and place of payment (hereinafter – "**the Payment Request**.") The notification shall specify that non-payment by or before the determined date and in the specified place may lead to the forfeiture of the shares regarding which payment is requested. A Payment Request may be nullified or postponed to another date, all as shall be decided by the Board of Directors.

- 7.3 Unless otherwise determined in the conditions of allocations of the shares, a shareholder shall not be entitled to receive a dividend or to exercise any right as a shareholder on account of shares that have not yet been fully paid.
- 7.4 Persons who are the joint owners of a share shall be liable jointly and severally for payment of the amounts due to the Company on account of the share.
- 7.5 The content of this section shall not derogate from any other relief of the Company vis-à-vis a shareholder who fails to pay his debt to the Company on account of his shares.

# 8. Transfer of Shares

- 8.1 The Company's shares are transferable.
- 8.2 The transfer of shares must be made in writing, and it shall be recorded only if
  - 8.2.1 A proper certificate for the transfer of shares, together with the certificates of the share intended for transfer, if such were issued, is delivered to the Company at its registered office. The certificate of transfer shall be signed by the transferor and by a witness confirming the signature of the transferor. In the event of the transfer of shares that are not fully paid as of the date of transfer, the certificate of transfer shall also be signed by the recipient of the share and by a witness testifying to the signature of the recipient; or
  - 8.2.2 A court order for the amendment of the registration shall be delivered to the Company; or
  - 8.2.3 It shall be proved to the Company that lawful conditions pertain for the transfer of the right to the share.

- 8.3 The transfer of shares that have not been fully paid requires the authorization of the Board of Directors, which is entitled to refuse to grant its authorization at its absolute discretion and without stating grounds therefore.
- 8.4 The recipient of the transfer shall be considered the shareholder regarding the transferred shares from the moment of the registration of his name in the registry of shareholders.

### 9. <u>Changes in Capital</u>

- 9.1 The general meeting is entitled to increase the Company's registered share capital by creating new shares of an existing type or a new type, all as shall be determined in the decision of the general meeting.
- 9.2 The general meeting is entitled to nullify registered share capital that has not yet been allocated, provided that there is no commitment, including a conditioned commitment, by the Company to allocate the shares.
- 9.3 The general meeting shall be entitled, subject to the provisions of any law:
  - 9.3.1 To unify and redivide its share capital, or any part thereof, into shares of a nominal value greater than the nominal value of the existing shares.
  - 9.3.2 To divide, by way of the redivision of any or all of the existing shares, its share capital into shares of a nominal value smaller than the nominal value of the existing shares.
  - 9.3.3 To reduce its share capital and any reserved fund for the repayment of capital in such manner and on such conditions and with the receipt of such authorization as shall be required by the Companies Law.

# 10. Changes in the Rights of Share Types

- 10.1 Unless otherwise stated in the conditions of issue of the shares, and subject to the provisions of any law, the rights of any share type may be changed following a decision of the Company's Board of Directors, and with the authorization of the general meeting of shareholders of that type, or with the written consent of all the shareholders of that type. The provisions of the Company's Articles of Association regarding general meetings shall apply, *mutatis mutandis*, to a general meeting of type shareholders.
- 10.2 The rights granted to the holders of shares of a specific type issued with special rights shall not be considered to have been changed by virtue of the creation or issue of additional shares of equal grade, unless otherwise conditioned in the conditions of issue of the said shares.

# 11. General Meetings

- 11.1 Company decisions on the following matters shall be taken at the general meeting
  - 11.1.1 Changes to the Articles;
  - 11.1.2 Exercising the authorities of the Board of Directors in the event that the Board of Directors is unable to perform its function;
  - 11.1.3 Appointment of the auditing accountant of the Company and the cessation of employment thereof;
  - 11.1.4 Appointment of directors, including external directors;
  - 11.1.5 Authorization of actions and transactions requiring the authorization of the general meeting in accordance with the provisions of the Companies Law and any other law;
  - 11.1.6 Increasing and decreasing the registered share capital;
  - 11.1.7 Merger as defined in the Companies Law.
- 11.2 Subject to the provisions of the law, the general meeting is entitled to assume authorities granted to another organ in the Company, including the Board of Directors, for a particular matter or for a given period of time.

If the general meeting has assumed authorities granted to the Board of Directors in accordance with the Companies Law, the shareholders shall bear the same rights, obligations, and liability as apply to the Board of Directors regarding the exercising of those same authorities, as detailed in Article 50 of the Companies Law, as this shall be amended from time to time.

# 12. Convening of General Meetings

- 12.1 General meetings shall be convened at least once a year at such a venue and on such a date as shall be determined by the Board of Directors, and subject to the provisions of the law, but not later than 15 months after the previous general meeting. These general meetings shall be called "annual meetings." The remaining meetings of the Company shall be called "extraordinary meetings."
- 12.2 The agenda at the annual meeting shall include discussion of the report of the Board of Directors and financial statements as required by law. The annual meeting shall appoint an auditing accountant; shall appoint the directors in accordance with these Articles; and shall discuss all other matters to be discussed at the annual meeting of the Company in accordance with these Articles or in accordance with the Companies Law, as well as any other matter as shall be determined by the Board of Directors.
- 12.3 The Board of Directors is entitled to convene an extraordinary meeting in accordance with its decision, and must convene a general meeting if a written request is received from any of the following (hereinafter "**Request to Convene:**")
  - 12.3.1 Two directors or one-fourth of the incumbent directors; and/or
  - 12.3.2 One or more shareholders holding at least five percent of the issued capital and at least one percent of the voting rights in the Company; and/or
  - 12.3.3 One or more shareholders holding at least five percent of the voting rights in the Company.

- 12.4 Any Request to Convene must specify the goals for whose purpose the meeting is to be convened, and shall be signed by those requesting the convening and delivered at the Company's registered office. The request may consist of a number of documents of identical format, each signed by one or more individuals making the request.
- 12.5 A Board of Directors required to convene an extraordinary meeting shall convene such meeting within twenty-one days from the date on which the Request to Convene was submitted thereto, for a date determined in an invitation in accordance with section 12.6 below and subject to any law.
- 12.6 Notification of the members of the Company regarding the convening of a general meeting shall be published or delivered to all the shareholders registered in the registry of shareholders in the Company in accordance with the requirements of the law. The notification shall include the agenda, the proposed decisions, and arrangements regarding voting in writing.

# 13. Discussion at General Meetings

- 13.1 The discussion at the general meeting shall be opened only if a legal quorum is present at the time the discussion begins. A legal quorum is the presence of at least two shareholders holding at least 25 percent of the voting rights (including presence by means of proxy or through a letter of voting) within one half-hour from the time specified for the opening of the meeting.
- 13.2 If, at the end of one half-hour from the time specified for the opening of the meeting, no legal quorum is present, the meeting shall be postponed by one week, to the same day, the same hour, and the same venue, or to a later date, if specified on the invitation to the meeting or in the notification of the meeting (hereinafter "**the Postponed Meeting**.") Notification and invitation regarding a Postponed Meeting postponed for a period of not more than 21 days shall be made not later than seventy-two hours prior to the Postponed Meeting. Notification of a Postponed Meeting shall be made as stated in section 12.6, *mutatis mutandis*.

- 13.3 The legal quorum for commencing a Postponed Meeting shall be any number of participants.
- 13.4 The chairperson of the Board of Directors shall serve as the chairperson of the general meeting. If the chairperson of the Board of Directors is absent from the meeting after 15 minutes from the time specified for the meeting, or if he refuses to serve as the chairperson of the meeting, the chairperson shall be elected by the general meeting.
- 13.5 A general meeting with a legal quorum is entitled to decide on the postponement of the meeting to another date and to such venue as shall be determined and, in this case, notifications and invitations to the Postponed Meeting shall be made as stated in section 13.2 above.

### 14. Voting at a General Meeting

- 14.1 A shareholder in the Company shall be entitled to vote at general meetings in person or by means of a proxy or a letter of voting. Shareholders entitled to participate in and vote at the general meeting are the shareholders as of such date as shall be determined by the Board of Directors in the decision to convene the general meeting, and subject to any law.
- 14.2 In any vote, each shareholder shall have a number of votes equivalent to the number of shares in their possession entitling the holder to a vote.
- 14.3 A decision at the general meeting shall be taken by an ordinary majority unless another majority is determined in the Companies Law or in these Articles.
- 14.4 The declaration by the chairperson of the meeting that a decision has been adopted unanimously or by a given majority, or rejected or not adopted by a given majority, shall constitute prima facie evidence of the content thereof.

- 14.5 If the votes at the meeting are equally divided, the chairperson of the meeting shall not have an additional or casting opinion and the decision presented for voting shall be rejected.
- 14.6 Subject to any law, the shareholders in the Company are entitled to vote in any matter on the agenda of a general meeting (including type meetings) by means of a letter of voting, provided that the Board of Directors, subject to any law, has not negated in its decision to convene the general meeting the possibility of voting by means of a letter of voting on that matter. If the Board of Directors has prohibited voting by means of a letter of voting, the fact of the negation of the possibility of voting by means of a letter of voting on the meeting in accordance with section 12.6 above.
- 14.7 A shareholder is entitled to state the manner of his vote in the letter of voting and to deliver this to the Company up to 48 hours prior to the time of commencement of the meeting. A letter of voting stating the manner of voting of the shareholder reaching the Company at least 48 hours prior to the time of commencement of the meeting shall be considered tantamount to presence at the meeting, including for the matter of the presence of the legal quorum as stated in section 13.1 above.
- 14.8 Appointment of a proxy shall be in writing, signed by the appointer (hereinafter "**Power of Attorney**.") A corporation shall vote by means of its representatives, who shall be appointed in a document signed properly by the corporation (hereinafter "**Letter of Appointment**.")
- 14.9 A vote in accordance with the conditions of a Power of Attorney shall be lawful even if the appointer dies before the voting, or becomes legally incompetent, is liquidated, becomes bankrupt, nullifies the Letter of Appointment, or transfers the share regarding which it was given, unless written notification is received at the Company's office prior to the meeting that the shareholder has died, become legally incompetent, been liquidated, become bankrupt, or has nullified the Letter of Appointment or transferred the shares as stated.

- 14.10 The Letter of Appointment and the Power of Attorney, or a copy authorized by an attorney, shall be deposited at the Company's registered offices at least forty eight (48) hours prior to the time determined for the meeting or for the Postponed Meeting at which the person mentioned in the document intends to vote in accordance therewith.
- 14.11 A shareholder in the Company shall be entitled to vote at the Company's meetings by means of several proxies appointed thereby, provided that each proxy shall be appointed on account of different sections of the shares held by the said shareholder. There shall be no impediment to each proxy as stated voting in a different manner in the Company's meetings.
- 14.12 If a shareholder is legally incompetent, he is entitled to vote by means of his trustees, the recipient of his assets, his natural guardian or other legal guardian, and these are entitled to vote in person or by proxy or a Letter of Voting.
- 14.13 When two or more persons are the joint owners of a share, in a vote on any matter the vote of the person whose name is registered first in the registry of shareholders as the owner of that share shall be accepted, whether in person or by proxy, and he is entitled to deliver Letters of Voting to the Company.

# 15. The Board of Directors

The Board of Directors shall set the Company's policy, supervise the execution of the functions and actions of the general director, and, within this, shall act and shall enjoy all the authorities detailed in Article 92 of the Companies Law. In addition, any authority not granted in the Companies Law or in these Articles to another organ may be exercised by the Board of Directors, in addition to the authorities and functions of the Board of Directors in accordance with the content of any law.

# 16. Appointment of the Board of Directors and Cessation of Office Thereof

- 16.1 The number of directors in the Company shall be determined from time to time by the annual general meeting, provided that this shall not be fewer than 5 and not more than 10 directors, including external directors. The number of external directors in the Company shall not be less than the number determined in the Companies Law.
- 16.2 The directors in the Company shall be elected at an annual meeting and/or an extraordinary meeting, and shall serve in their office for so long as they have not been replaced by the shareholders of the Company at an annual meeting and/or at an extraordinary meeting, or until they cease to serve in their office in accordance with the provisions of the Articles or any law, whichever is the earlier.
- 16.3 In addition to the content of section 16.2 above, the Board of Directors is entitled to appoint a director in place of a director whose position has become vacant and/or by way of an addition to the Board of Directors, subject to the maximum number of directors on the Board of Directors as stated in section 16.1 above. The appointment of a director by the Board of Directors shall remain valid through the next annual meeting or until the director shall cease to serve in their office in accordance with the provisions of these Articles or of any law, whichever is the earlier.
- 16.4 A director whose period of office has expired may be reelected, with the exception of an external director, who may be reelected for an additional period of office subject to the provisions of the law.
- 16.5 The office of a director shall commence on the date of their appointment by the annual meeting and/or the extraordinary meeting and/or the Board of Directors, or on a later date if this date is determined in the decision of appointment of the annual meeting and/or the extraordinary meeting and/or the Board of Directors.

- 16.6 The Board of Directors shall elect one of its members as the chairperson of the Board of Directors. The elected chairperson shall run the meetings of the Board of Directors and shall sign the minutes of the discussion. If no chairperson is elected, or if the chairperson of the Board of Directors is not present after 15 minutes from the time set for the meeting, the directors present shall choose one of their number to serve as the chairperson at that meeting, and the chosen member shall run the meeting and sign the minutes of the discussion. The chairperson of the Board of Directors shall not be the general director of the Company unless the conditions stipulated in Article 121(C) of the Companies Law apply.
- 16.7 The general meeting is entitled to transfer any director from their office prior to the end of the period of their office, inter alia whether the director was appointed thereby in accordance with section 16.2 above or was appointed by the Board of Directors in accordance with section 16.3 above, provided that the director shall be given a reasonable opportunity to state their case before the general meeting.
- 16.8 Any director is entitled, with the agreement of the Board of Directors, to appoint a substitute for themselves (hereinafter "a Substitute Director,") provided that a person who is not competent shall not be appointed to serve as a Substitute Director, nor a person who has been appointed as a Substitute Director for another director and/or a person who is already serving as a director in the Company. The appointment or cessation of office of a Substitute Director shall be made in a written document signed by the director who appointed him; in any case, however, the office of a Substitute Director shall be terminated if one of the cases stipulated in the paragraphs in section 16.9 below shall apply, or if the office of the member of the Board of Directors for whom he serves as a substitute shall become vacant for any reason.

A Substitute Director is considered tantamount to a director and all the legal provisions and the provisions of these Articles shall apply, with the exception of the provisions regarding the appointment and/or dismissal of a director as established in these Articles.

- 16.9 The office of a director shall become vacant in any of the following cases:
  - 16.9.1 He resigns from his office by means of a letter signed in his hand, submitted to the Company and detailing the reasons for his resignation;
  - 16.9.2 He is removed from his office by the general meeting;
  - 16.9.3 He is convicted of an offense as stated in Article 232 of the Companies Law;
  - 16.9.4 In accordance with a court decision as stated in Article 233 of the Companies Law;
  - 16.9.5 He is declared legally incompetent;
  - 16.9.6 He is declared bankrupt and, if the director is a corporation it opted for voluntary liquidation or a liquidation order was issued against it.
- 16.10 In the event that the position of a director becomes vacant, the remaining directors shall be entitled to continue to act, provided the number of directors remaining shall not be less than the minimum number of directors as stated above in section 16.1 above. If the number of directors falls below the above-mentioned minimum number, the remaining directors shall be entitled to act solely in order to fill the place of the director that has become vacant as stated in section 16.3 above, or in order to convene a general meeting of the Company, and pending the convening of the general meeting of the Company as stated they may act to manage the Company's affairs solely in matters that cannot be delayed.
- 16.11 The conditions of office of the members of the Board of Directors shall be authorized in accordance with the provisions of the Companies Law.

# 17. <u>Meetings of the Board of Directors</u>

17.1 The Board of Directors shall convene for a meeting in accordance with the needs of the Company, and at least once every three months.

- 17.2 The chairperson of the Board of Directors is entitled to convene the Board at any time. In addition, the Board of Directors shall hold a meeting on such subject as shall be specified in the following cases:
  - 17.2.1 In accordance with the request of two directors; however, if at the time the Board of Directors comprises five directors or less in accordance with the request of one director;
  - 17.2.2 In accordance with the request of one director if, in his request to convene the Board, he states that he has learned of a matter in the Company ostensibly entailing a violation of the law or infringement of proper business practice;
  - 17.2.3 If a general director has been appointed in the Company or if a notification or report by the general director require an action on the part of the Board of Directors;
  - 17.2.4 If the auditing accountant has informed the chairperson of the Board of Directors or, in the event that no chairperson was appointed for the Board of Directors, has informed the Board of Directors of substantial defects in the accounting control of the Company.
- 17.3 Notification of the meeting of the Board of Directors shall be delivered to all members of the Board at least three days prior to the date of convening of the Board, or with shorter prior notice insofar as the chairperson of the Board decided that, in the circumstances of the matter, it is vital and reasonable to convene the Board of Directors with notice shorter than three days. Notification shall be delivered to the address of the director as forwarded to the Company in advance, and shall stipulate the time of the meeting and the venue at which it shall convene, as well as reasonable detail of all subjects on the agenda.

Notwithstanding the above, the Board of Directors is entitled to convene a meeting without notification, with the consent of all the directors.

17.4 The agenda of the meetings of the Board of Directors shall be determined by the chairperson of the Board and shall include: Subjects determined by the chairperson of the Board; subjects deriving from the report of the general director and/or the auditing accountant; any subject a director of the general director have requested of the chairperson of the Board to include on the agenda, at least two days prior to the convening of the meeting of the Board.

If no chairperson has been appointed for the Board of Directors, the agenda for the meetings of the Board shall be determined by the directors in such manner that each director shall send to the Company, at least two days before the convening of the meeting of the Board, the subjects that, in his opinion, should be included in the meeting of the Board. The agenda for the meetings of the Board shall also include subjects deriving from the report of the general director and/or the auditing accountant.

- 17.5 The details of the subjects on the agenda as stated in section 17.4 above do not prevent discussion of a subject or subjects not mentioned in the notification of the meeting of the Board of Directors (hereinafter: "**a New Subject**.") If a New Subject is discussed at the meeting of the Board of Directors, a director not present at the meeting of the Board of Directors at which the New Subject was discussed may express in writing his opposition to the decision and/or request that the subject be discussed again, within three days from the date on which he received a copy of the decision. If a further discussion is requested as stated, this shall be held by the Board of Directors on such date as shall determined by the chairperson of the Board of Directors or, in his absence, by the Board of Directors, and not later than seven days after the receipt of the request. However, the objection of the director to the decision on the New Subject shall not impair the validity of actions regarding third parties undertaken on the basis thereof.
- 17.6 The legal quorum for the commencement of a meeting of the Board of Directors shall be a majority of the members of the Board of Directors. If, at the end of one half-hour from the time set for the commencement of the meeting, no quorum is present, the meeting shall be postponed to another date as decided by the chairperson of the Board, or, in his absence, by the directors present at the convened meeting, provided that prior notification of three days shall be given to all directors regarding the date of the Postponed Meeting. The legal quorum for the opening of a Postponed Meeting shall be any number of participants.

- 17.7 The Board of Directors is entitled to hold meetings by use of any means of communication, providing that all the participating directors can hear each other simultaneously.
- 17.8 The Board of Directors is entitled to take decisions without actually convening, provided that all the directors entitled to participate in the discussion and to vote on the subject brought for decision agree thereto. If decisions are made as stated in this section, the chairperson of the Board of Directors shall record minutes of the decisions stating the manner of voting of each director on the subjects brought for decision, as well as the fact that all the directors agreed to take the decision without convening.

# 18. Voting on the Board of Directors

- 18.1 Each director shall have one vote when voting on the Board of Directors.
- 18.2 Decisions of the Board of Directors shall be taken by a majority vote. The chairperson of the Board of Directors shall not have any additional or casting opinion, and in the event of a tie vote, the decision brought for voting shall be rejected.

# 19. Committees of the Board of Directors

19.1 The Board of Directors is entitled to establish committees and to appoint members thereto (hereinafter – "**the Committees of the Board of Directors**.") If Committees of the Board of Directors are established, the Board of Directors shall determine, in the conditions of empowerment thereof, whether specific authorities of the Board of Directors shall be delegated to the Committees of the Board of Directors, in such manner that the decision of the Committee of the Board of Directors shall be considered tantamount to a decision of the Board of Directors, or whether the decision of the Committee of the Board of Directors shall merely constitute a recommendation, subject to the authorization of the Board of Directors; provided that authorities to make decisions in the matters stated in Article 112 of the Companies Law shall not be delegated to a committee.

- 19.2 A person who is not a director shall not serve in a Committee of the Board of Directors to which the Board of Directors has delegated authorities. Persons who are not members of the Board of Directors may serve in a Committee of the Board of Director whose function is merely to advise or submit recommendations to the Board of Directors.
- 19.3 The provisions included in these Articles relating to the meetings of the Board of Directors and voting therein shall apply, *mutatis mutandis* and subject to the decisions of the Board of Directors regarding the procedures for the meetings of the committee (if any), to any Committee of the Board of Directors comprising two or more members.

## 20. Audit Committee

- 20.1 The Board of Directors of the Company shall appoint an audit committee from among its members. The number of members of the audit committee shall be not less than three, and any external director may be a member thereof. The chairperson of the Board of Directors or any director employed by the Company, or providing it with services on a regular basis, or a controlling shareholder in the Company, or a relative thereof shall not be appointed to the committee.
- 20.2 The functions of the audit committee shall be
  - 20.2.1 To identify defects in the business management of the Company, inter alia through consultation with the internal auditor of the Company or the auditing accountant, and to propose methods to the Board of Directors for correcting these;

20.2.2 To decide whether to authorize actions and transactions requiring the authorization of the audit committee in accordance with the Companies Law.

# 21. General Director

The Board of Directors of the Company shall appoint a general director, and is entitled to appoint more than one general director. The general director shall be responsible for the routine management of the Company's affairs within the framework of the policy set by the Board of Directors and subject to its guidelines.

# 22. Exemption, Insurance, and Indemnification

- 22.1 The Company is entitled to exempt an office holder therein in advance from any or all liability on account of damages deriving from the violation of the duty of care thereto in accordance with the provisions of the Companies Law, as this shall be amended from time to time and as it shall be valid on the date on which the exemption shall be granted.
- 22.2 The Company is entitled to indemnify an office holder therein retroactively, and to undertake in advance to indemnify an office bearer on account of all liabilities, expenses, and matters regarding which the Company is entitled to indemnify office holders, in accordance with the provisions of the Companies Law, as this shall be amended from time to time and as it shall be valid on the date on which the indemnification shall be required.
- 22.3 The Company is entitled to associate in a contract for the insurance of the liability of an office holder therein on account of all liabilities, expenses, and matters regarding which the Company is entitled to insure office holders, in accordance with the provisions of the Companies Law, as this shall be amended from time to time and as it shall be valid on the date on which the insurance contact shall be signed.

22.4 Decisions regarding exemption, insurance, indemnification, or the granting of an undertaking to indemnify a director and/or an office holder other than a director shall be taken subject to any law.

## 23. Internal Auditor

- 23.1 The Board of Directors of the Company shall appoint an internal auditor in accordance with the proposal of the audit committee. A person who is an interested party in the Company, an office holder therein, or the relative or either of the above, as well as the auditing accountant or any person on his behalf, shall not serve as an internal auditor in the Company.
- 23.2 The Board of Directors shall determine which office holder shall be organizationally accountable for the internal auditor and, in the absence of such determination, this shall be the chairperson of the Board of Directors.
- 23.3 The internal audit plan prepared by the auditor shall be submitted to the audit committee for authorization; however, the Board of Directors is permitted to determine that the plan shall be submitted to the Board of Directors for authorization.

## 24. Auditing Accountant

- 24.1 The general meeting shall appoint an auditing accountant for the Company. The auditing accountant shall service in his office through the end of the following annual meeting, or for a longer period as determined by the annual meeting, provided that the period of office shall not be extended beyond the end of the third annual meeting following that at which he was appointed.
- 24.2 The fee of the auditing accountant for the auditing operations shall be determined by the Board of Directors. The Board of Directors shall report to the annual meeting on the fee of the auditing accountant.

# 25. Signing in the Company's Name

25.1 The rights to sign in the Company's name shall be determined from time to time by the Board of Directors of the Company.

25.2 The Company's authorized signatory shall do so together with the Company's stamp, or alongside its printed name.

### 26. Dividend and Benefit Shares

26.1 The decision by the Company to allocate a dividend and/or to allocate benefit shares shall be taken by the Company's Board of Directors.

- 26.2 Unless determined otherwise by the Board of Directors, it shall be permitted to pay any dividend by way of check or payment order to be sent by mail in accordance with the registered address of the shareholder or the personal eligible thereto or, in the case of joint registered owners of the same share, to that shareholder whose name is mentioned first in the registry of shareholders with regard to the joint ownership. Any such check shall be made out to order of the person to whom it is sent. A receipt from a person whose name, as of the date of declaration of the dividend, is registered in the registry of shareholders as the owner of any share or, in the case of joint owners, of one of the joint owners, shall serve as authorization regarding all payments made in connection with that share and regarding which the receipt was received.
- 26.3 For the purpose of executing any decision in accordance with the provisions of this section, the Board of Directors is entitled to resolve as it sees fit any difficulty that emerges regarding distribution of the dividend and/or the benefit shares, including determining the value for the purpose of the said division of certain assets, and to determine that payments in cash shall be made to members on the basis of the value so determined; to determine provisions regarding fractions of shares; or to determine that sums of less than NIS 50 shall not be paid to a shareholder.

# 27. <u>Redeemable Securities</u>

The Company is entitled, subject to any law, to issue redeemable securities on such conditions as shall be determined by the Board of Directors, provided that the general meeting shall approve the recommendation of the Board of Directors and the conditions established thereby.

# 28. Donations

The Company is entitled to donate a reasonable sum of money for a fit purpose. The Board of Directors of the Company is entitled to determine, at its discretion, rules for the making of donations by the Company.

## 29. <u>Accounts</u>

- 29.1 The Company shall maintain accounts and shall prepare financial statements in accordance with the Securities Law and in accordance with any law.
- 29.2 The account ledgers shall be held at the Company's registered offices or in any other place as the directors shall see fit, and shall always be open for inspection by the directors.

## 30. Notifications

30.1 Subject to any law, a notification or any other document that shall be delivered by the Company, and which it is entitled or required to issue in accordance with the provisions of the Articles and/or the Companies Law, the Securities Law, or any law, shall be delivered by the Company to any person in one of the following manners as decided by the Company in each individual case: (A) By dispatch by registered mail in a letter addressed in accordance with the registered address of that shareholder in the registry of shareholders, or in accordance with such address as stated by the shareholder in a letter to the Company as the letter for the delivery of notifications or other documents; or (B) By dispatch by facsimile in accordance with the number stated by the shareholder as the number for the delivery of facsimile notifications; or (C) By way of publication in two daily newspapers appearing in Israel; or (D) By way of publication in the distribution site of the Securities Authority and the Tel Aviv Stock Exchange Ltd.

- 30.2 Any notification to be made to shareholders shall be made, regarding jointly owned shares, to that person whose name is mentioned first in the registry of shareholders as the holder of that share, and any notification made in this manner shall be sufficient notification for the holders of that share.
- 30.3 Any notification or other document sent in accordance with the provisions of section 30.1 above shall be considered to have reached its destination: (A) Within 3 business days if sent by registered mail in Israel; or (B) On the first business day after its dispatch, if delivered by hand or sent by facsimile; or (C) On the date of publication, if published in a newspaper or on the distribution site of the Securities Authority and the Tel Aviv Stock Exchange Ltd. In proving delivery, it shall be sufficient to prove that the letter sent by mail included the notification and that the document was addressed properly and was delivered to the post office as a letter bearing stamps, or as a registered letter bearing stamps, and, regarding a facsimile, it
- 30.4 Any record made in an ordinary manner in the company's registry shall be considered prima facie evidence of dispatch as recorded in that registry.
- 30.5 When it is necessary to provide prior notification of a certain number of days, or when notification is valid for a certain period, the date of delivery shall be included in reckoning the number of days or the period.

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shall be sufficient to produce a dispatch confirmation sheet from the dispatching facsimile machine.

[The Articles were adopted on November 29, 2007]

### **REGISTRATION RIGHTS AGREEMENT**

This Registration Rights Agreement (the "**Agreement**") made as of the \_\_\_ day of January, 2007 by and among BioLine Rx Ltd., with a business address at 19 Hartum St., P.O. Box 45158, Jerusalem 91450, Israel (the "**Company**") and shareholders of the Company listed on Schedule 1 hereto (the "**Holders**");

### WITNESSETH

**WHEREAS** the Board of Directors of the Company has determined that it is in the best interest of the Company that the Company shall grant the Holders certain rights as set forth herein; and

**NOW THEREFORE**, the parties, intending to be legally bound, hereby agree as follows:

1. <u>Registration</u>. The following provisions govern the registration of the Company's securities:

1.1 <u>Definitions</u>. As used herein, the following terms have the following meanings:

(a) "Form S-3" means Form S-3 or Form F-3 under the United States Securities Act of 1933, as amended (the "Securities Act"), as in effect on the date hereof or any registration form under the Securities Act subsequently adopted by the Securities and Exchange Commission ("SEC") which permits inclusion or incorporation of substantial information by reference to other documents filed by the Company with the SEC;

(b)

"**IPO**" shall mean the first registration statement for a public offering of securities of the Company, other than a registration statement relating to the sale of securities to employees of the Company pursuant to a stock option, stock purchase or similar plan;

(c) "Registrable Securities" means (1) Ordinary Shares now owned or hereafter acquired by the Holders, including all Ordinary Shares issuable with respect to Preferred Shares of the Company, and (2) any Ordinary Shares issued in respect of the shares described in clause (1) above (as a result of share splits, share dividends, reclassifications, recapitalizations or similar); provided, however, that Ordinary Shares that are Registrable Securities shall cease to be Registrable Securities upon (i) any sale thereof pursuant to a Registration Statement or Rule 144 under the Securities Act or (ii) any sale thereof in any manner to a person or entity which is not entitled to the rights provided by this Agreement;

(d) "**Register**", "**registered**" and "**registration**" refer to a registration effected by filing a registration statement in compliance with the Securities Act and the declaration or ordering by the SEC of effectiveness of such registration statement, or the equivalent actions under the laws of any other jurisdiction;

### 1.2 Incidental Registration.

(a) If the Company at any time proposes to register any of its securities (other than in its IPO, a demand registration under Section 1.3, a registration relating to stock option plan(s) of the Company, or a registration on Form F-4/S-4 in connection with a merger, acquisition or other business combination, but including the first public offering of the Company's shares in a U.S. market following an IPO), it shall give prompt written notice to all Holders of such intention, together with a list of jurisdictions in which the Company intends to attempt to qualify such securities under applicable state securities laws. Upon the written request of any such Holder given within twenty (20) days after receipt of any such notice, the Company shall include in such registration all of the Registrable Securities indicated in such request, so as to permit the disposition of the shares so registered. The said "piggyback" or incidental right of the Holders under this Section, may be exercised an unlimited number of times.

(b) Notwithstanding any other provision of this Section 1.2, if the managing underwriter, if any, advises the Company in writing that marketing factors require a limitation of the number of shares to be underwritten (an "**Underwriters' Cutback**"), then, there shall be excluded from such registration and underwriting, to the extent necessary to satisfy such limitation, *first*, securities of the Company not held by the Holders, to the extent necessary, and *second*, Registrable Securities, to the extent necessary (on a pro rata basis according to the respective holdings of the Holders of Registrable Securities at the time of such registration); <u>provided however</u>, that if the number of Registrable Securities to be registered by the Holders is limited by the underwriter, the securities to be sold for the account of the Company shall have priority over those of the Holders in each such registration and the number of Registrable Securities, if any, that may be included in the registration shall be in accordance with the above order and preference; further provided, however, that without the written consent of the Holders holding a majority of the Registrable Securities requested to be included in such registrable Securities, held by the Holders shall not be reduced to less than twenty-five percent (25%) of the aggregate shares to be registered in such underwriting.

## 1.3 <u>Demand Registration</u>.

(a) If the Company receives, at any time beginning six (6) months after the effective date of the IPO, from the Holders of a majority in interest of the Registrable Securities (calculated on an as converted basis) then outstanding, a request in writing that all or part of the Registrable Securities held by them having an aggregate value of at least \$5,000,000 shall be registered for trading under the Securities Act, then, within seven (7) days after receipt of any such request, the Company shall give written notice of such request to the other Holders, and shall include in such registration all Registrable Securities held by all such Holders who wish to participate in such demand registration and provide the Company with written requests for inclusion therein within fifteen (15) days after the receipt of the Company's notice. Thereupon, the Company shall use its best efforts to effect the registration of all Registrable Securities, as to which it has received requests for registration under the Securities Act.

(b) Notwithstanding any other provision of Section 1.3(a), if the managing underwriter, if any, advises the Company in writing that marketing factors require an Underwriters Cutback, then there shall be excluded from such registration and underwriting, to the extent necessary to satisfy such limitation, *first*, securities of the Company not held by the Holders, to the extent necessary, and *second*, Registrable Securities, to the extent necessary (on a pro rata basis according to the respective holdings of the Holders of Registrable Securities at the time of such registration); provided however, that in any event all Registrable Securities must be included in such registration prior to any other shares of the Company. The Holders shall not be entitled to request a registration under Section 1.3(a) if the Company it would be seriously detrimental to the Company or its shareholders for such registration statement to be effected at such time, in which event the Company shall have the right to defer the filing of the registration statement for a period of no more than ninety (90) days after the receipt of the request of the Holders under Section 1.3(a); provided, however, the Company may not make more than one (1) such deferral in any twelve (12) month period.

Section 1.3(a):

(c)

In addition, the Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to

if such request does not cover shares representing a market value at the time of such request equal to a minimum of

if such request does not cover shares representing a market value at the time of such request equal to a minimum of

(i) after the Company has effected two (2) registrations pursuant to Section 1.3(a);

(ii) during the period ending (A) six (6) months after the effective date of a registration subject to Section 1.3(a) hereof or (B) six (6) months after the effective date of any other registration statement pertaining to Ordinary Shares of the Company, or such shorter periods if such shorter periods are acceptable to the underwriters of such offering;

(iii) in any jurisdiction in which the Company would be required to execute a general consent to service of process in effecting such registration, qualification or compliance, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act or applicable rules or regulations thereunder; or

\$5,000,000.

1.4

Form S-3 Registration.

(iv)

(iv)

(a) In the event the Company receives from any Holder a written request that the Company effect a registration on Form S-3, and any related qualification or compliance, the Company will within seven (7) days from receipt of any such request give written notice of the proposed registration, and any related qualification or compliance, to all other Holders, and include in such registration all Registrable Securities held by all such Holders, who wish to participate in such registration and provide the Company with written requests for inclusion therein within fifteen (15) days after the receipt of the Company's notice. Thereupon, the Company shall use its best efforts to effect such registration of the Registrable Securities held by the Holders, and all such qualifications and compliances as may be so requested and as would permit or facilitate the sale and distribution of all or such portion of such Registrable Securities as are specified in such request.

(b) In addition, the Company shall not be obligated to effect, or to take any action to effect, any registration qualification or compliance pursuant to Section 1.4(a):

(i) if the Company has, within the twelve (12) month period preceding the date of such request, already effected two registrations on Form S-3 for the Holders pursuant to this Section 1.4;

(ii) in any particular jurisdiction in which the Company would be required to qualify to do business or to execute a general consent to service of process in effecting such registration, qualification or compliance;

(iii) during the period ending 90 days after the effective date of any registration statement pertaining to Ordinary Shares of the Company (or such shorter period if such shorter period is acceptable to the underwriters of such offering);

\$1,000,000; or

## (v) if Form S-3 is not available for such offering by the Holders.

## 1.5 <u>Designation of Underwriter</u>.

(a) In the case of any underwritten registration effected pursuant to Section 1.3, a majority in interest of the Holders of the Registrable Shares (calculated on an as converted basis) that submitted the request for registration shall appoint an underwriter reasonably acceptable to the Company.

(b) In the case of any registration initiated by the Company, the Company shall have the right to designate the managing underwriter in any underwritten offering.

1.6 <u>Expenses</u>. All expenses incurred in connection with any registration or sale of shares under Section 1.2, Section 1.3 or Section 1.4 shall be borne by the Company (including fees up to \$200,000 of one counsel for the selling shareholders); <u>provided</u>, however, that each of the Holders participating in such registration or sale shall pay its pro rata portion of the customary and standard discounts or commissions payable to any underwriter.

1.7 <u>Indemnities</u>. In the event of any registered offering of Ordinary Shares pursuant to this Section 1:

1.7.1 The Company will indemnify and hold harmless, to the fullest extent permitted by law, any Holder (including its officers, directors, partners and legal counsel) and any underwriter for such Holder, and each person, if any, who controls the Holder or such underwriter, from and against any and all losses, damages, claims, liabilities, joint or several, costs and expenses (including any amounts paid in any settlement effected with the Company's consent) to which the Holder or any such underwriter or controlling person may become subject under applicable law or otherwise, insofar as such losses, damages, claims, liabilities (or actions or proceedings in respect thereof), costs or expenses arise out of or are based upon (i) any untrue statement or alleged untrue statement of any material fact contained in the registration statement or included in the prospectus, as amended or supplemented including any free writing prospectus, or (ii) the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances in which they are made, not misleading, (iii) any violation or alleged violation by the Company of the Securities Act, the Securities Exchange Act of 1934, as amended, any state securities law; or any rule or regulation promulgated under the Securities Act, Securities Exchange Act or any state security law; and the Company will reimburse the Holder, such underwriter and each such controlling person of the Holder or the underwriter, promptly upon demand, for any legal or any other expenses reasonably incurred by them in connection with investigating, preparing to defend or defending against or appearing as a third-party witness in connection with such loss, claim, damage, liability, action or proceeding; provided, however, that the Company will not be liable in any such case to the extent that any such loss, damage, liability, cost or expense arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission so made in conformity with information furnished in writing by a Holder, such underwriter or such controlling persons in writing specifically for inclusion therein; provided, further, that the indemnity agreement contained in this subsection 1.7.1 shall not apply to amounts paid in settlement of any such claim, loss, damage, liability or action if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld. Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of the selling shareholder, the underwriter or any controlling person of the selling shareholder or the underwriter, and regardless of any sale in connection with such offering by the selling shareholder. Such indemnity shall survive the transfer of securities by a selling shareholder.

172 Each Holder participating in a registration hereunder will indemnify and hold harmless the Company, any underwriter for the Company, and each person, if any, who controls the Company or such underwriter, from and against any and all losses, damages, claims, liabilities, costs or expenses (including any amounts paid in any settlement effected with the selling shareholder's consent) to which the Company or any such controlling person and/or any such underwriter may become subject under applicable law or otherwise, insofar as such losses, damages, claims, liabilities (or actions or proceedings in respect thereof), costs or expenses arise out of or are based on (i) any untrue or alleged untrue statement of any material fact contained in the registration statement or included in the prospectus, as amended or supplemented, including any free writing prospectus or (ii) the omission or the alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances in which they were made, not misleading, and each such Holder will reimburse the Company, any underwriter and each such controlling person of the Company or any underwriter, promptly upon demand, for any reasonable legal or other expenses incurred by them in connection with investigating, preparing to defend or defending against or appearing as a third-party witness in connection with such loss, claim, damage, liability, action or proceeding; in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was so made in strict conformity with written information furnished by such Holder specifically for inclusion therein. The foregoing indemnity agreement is subject to the condition that, insofar as it relates to any such untrue statement (or alleged untrue statement) or omission (or alleged omission) made in the preliminary prospectus but eliminated or remedied in the amended prospectus at the time the registration statement becomes effective or in the Final Prospectus, such indemnity agreement shall not inure to the benefit of (i) the Company and (ii) any underwriter, if a copy of the Final Prospectus was not furnished to the person or entity asserting the loss, liability, claim or damage at or prior to the time such furnishing is required by the Securities Act; provided, further, that this indemnity shall not be deemed to relieve any underwriter of any of its due diligence obligations; provided, further, that the indemnity agreement contained in this subsection 1.7.2 shall not apply to amounts paid in settlement of any such claim, loss, damage, liability or action if such settlement is effected without the consent of the Holders, as the case may be, which consent shall not be unreasonably withheld. In no event shall the liability of a Holder exceed the net proceeds from the offering received by such Holder.

1.7.3 Promptly after receipt by an indemnified party pursuant to the provisions of Sections 1.7.1 or 1.7.2 of notice of the commencement of any action involving the subject matter of the foregoing indemnity provisions, such indemnified party will, if a claim thereof is to be made against the indemnifying party pursuant to the provisions of said Section 1.7.1 or 1.7.2, promptly notify the indemnifying party of the commencement thereof; but the omission to notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party otherwise than hereunder. In case such action is brought against any indemnified party and it notifies the indemnifying party of the commencement thereof, the indemnifying party shall have the right to participate in, and, to the extent that it may wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; provided, however, that if the defendants in any action include both the indemnified party and the indemnifying party and there is a conflict of interests which would prevent counsel for the indemnifying party from also representing the indemnified party, the indemnified party or parties shall have the right to select one separate counsel to participate in the defense of such action on behalf of such indemnified party or parties. After notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof, the indemnifying party will not be liable to such indemnified party pursuant to the provisions of said Sections 1.7.1 or 1.7.2 for any legal or other expense subsequently incurred by such indemnified party in connection with the defense thereof, unless (i) the indemnified party shall have employed counsel in accordance with the provision of the preceding sentence, (ii) the indemnifying party shall not have employed counsel reasonably satisfactory to the indemnified party to represent the indemnified party within a reasonable time after the notice of the commencement of the action and within fifteen (15) days after written notice of the indemnified party's intention to employ separate counsel pursuant to the previous sentence, or (iii) the indemnifying party has authorized the employment of counsel for the indemnified party at the expense of the indemnifying party. No indemnifying party will consent to entry of any judgment or enter into any settlement which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect to such claim or litigation.

1.7.4 If recovery is not available under the foregoing indemnification provisions, for any reason other than as specified therein, the parties entitled to indemnification by the terms thereof shall be entitled to contribution to liabilities and expenses as more fully set forth in an underwriting agreement to be executed in connection with such registration. In determining the amount of contribution to which the respective parties are entitled, there shall be considered the parties' relative knowledge and access to information concerning the matter with respect to which the claim was asserted, the opportunity to correct and prevent any statement or omission, and any other equitable considerations appropriate under the circumstances. In no event shall the contribution obligation of a Holder exceed the net proceeds from the offering received by such Holder.

1.8 <u>Obligations of the Company</u>. Whenever required under this Section 1 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as possible:

1.8.1 Prepare and file with the SEC a registration statement with respect to such Registrable Securities and use its best efforts to cause such registration statement to become effective, and, upon the request of the holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for a period of up to nine months or, if sooner, until the distribution contemplated in the Registration Statement has been completed;

1.8.2 Prepare and file with the SEC such amendments and supplements to such registration statement and the prospectus used in connection with such registration statement as may be necessary to comply with the provisions of the Securities Act with respect to the disposition of all Registrable Securities covered by such registration statement;

1.8.3 Furnish to the Holders such numbers of copies of a prospectus, including a preliminary prospectus, in conformity with the requirements of the Securities Act, and such other documents, including any free writing prospectus as they may reasonably request in order to facilitate the disposition of Registrable Securities owned by them;

1.8.4 In the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the managing underwriter of such offering. Each Holder participating in such underwriting shall also enter into and perform its obligations under such an agreement;

1.8.5 Notify each holder of Registrable Securities covered by such registration statement at any time when a prospectus relating thereto is required to be delivered under the Securities Act of the happening of any event as a result of which the prospectus included in such registration statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing;

1.8.6 Cause all Registrable Securities registered pursuant hereunder to be listed on each securities exchange on which similar securities issued by the Company are then listed;

1.8.7 Provide a transfer agent and registrar for all Registrable Securities registered pursuant hereunder and a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

1.8.8 Furnish, at the request of any Holder requesting registration of Registrable Securities pursuant to this Section 1, on the date that such Registrable Securities are delivered to the underwriters for sale in connection with a registration pursuant to this Section 1, if such securities are being sold through underwriters, or, if such securities are not being sold through underwriters, on the date that the registration statement with respect to such securities becomes effective, (i) an opinion, dated such date, of the counsel representing the Company for the purposes of such registration, in form and substance as is customarily given to underwriters in an underwritten public offering, addressed to the underwriters, if any, and to the Holders requesting registration of Registrable Securities, and (ii) a letter dated such date, from the independent certified public accountants of the Company, in form and substance as is customarily given by independent certified public accountants to underwritters in an underwritters, if any, and to the Holders requesting registration of Registrable Securities, and to the Holders requesting registration of Registrable Securities;

1.9 <u>Assignment of Registration Rights</u>. Any of the Holders may assign its rights to cause the Company to register Shares pursuant to this Section 1 to any transferee of its Registrable Securities; provided, however, that within thirty (30) days subsequent to such transfer, such transferor shall furnish the Company with written notice of the name and address of such transferee and the securities with respect to which such registration rights are being assigned, and the transferee's written agreement to be bound by this Section 1.

1.10 Lock-Up and Other Requests by the Underwriter. Each Holder hereby agrees that such Holder shall not sell or otherwise transfer or dispose of any Registrable Securities of the Company held by such Holder (other than those included in the registration) for a period specified by the representative of the underwriters of Ordinary Shares (or other securities) of the Company not to exceed one hundred eighty (180) days following the effective date of the IPO, and provided that each of the senior officers of the Company (i.e. CEO and CFO) and holders of at least one percent (1%) of the Company's issued and outstanding shares enters in an identical undertaking. Each Holder agrees to execute and deliver such other agreements as may be reasonably requested by the Company or the underwriter which are consistent with the foregoing or which are necessary to give further effect thereto. The Company may impose stop-transfer instructions with respect to the shares of Ordinary Shares (or other securities) subject to the foregoing restriction until the end of said one hundred eighty (180) day period;

1.11 <u>Rule 144 Reporting</u>. With a view to making available to the Holders the benefits of certain rules and regulations of the SEC which may permit the sale of the Registrable Securities to the public without registration, the Company agrees to use its best efforts to:

(a) make and keep public information available, as those terms are understood and defined in SEC Rule 144 or any similar or analogous rule promulgated under the Securities Act, at all times after the effective date of the first registration filed by the Company for an offering of its securities to the general public;

(b) file with the SEC, in a timely manner, all reports and other documents required of the Company under the Exchange Act; and

(c) so long as a Holder owns any Registrable Securities, furnish to such Holder forthwith upon request: a written statement by the Company as to its compliance with the reporting requirements of said Rule 144 of the Securities Act, and of the Exchange Act (at any time after it has become subject to such reporting requirements); a copy of the most recent annual or quarterly report of the Company; and such other reports and documents as a Holder may reasonably request in availing itself of any rule or regulation of the SEC allowing it to sell any such securities without registration;

1.12 <u>Termination of Registration Rights</u>. All registration rights granted under this Section 1, shall terminate and be of no further force and effect five (5) years after the date of the IPO. In addition, a Holder's registration rights shall expire if all Registrable Securities held by and issuable to such Holder may be sold under Rule 144(k) during any ninety (90) day period.

1.13 <u>Additional Rights to Third Parties</u>. The Company shall not grant shareholder registration rights to any party that is not a party to this Agreement having preference over, or in parity with, the registration rights of the Holders hereunder, without the written consent of a majority of interest of the holders of the Registrable Securities.

# 2. <u>Miscellaneous</u>.

2.1 <u>Further Assurances</u>. Each of the parties hereto shall perform such further acts and execute such further documents as may reasonably be necessary to carry out and give full effect to the provisions of this Agreement and the intentions of the parties as reflected thereby.

2.2 <u>Governing Law</u>. This Agreement shall be governed by and construed according to the laws of New York, without regard to the conflict of laws provisions thereof.

2.3 <u>Successors and Assigns</u>. Except as otherwise expressly limited herein, the provisions hereof shall inure to the benefit of, and be binding upon, the successors, assigns, heirs, executors, and administrators of the parties hereto.

# 2.4 Entire Agreement; Amendment and Waiver.

(a) This Agreement constitutes the full and entire understanding and agreement between the parties, and supersedes any agreement and understanding between any of the parties, with regard to the subject matters hereof. (b)Any term of this Agreement (as amended) may be amended and the observance of any term hereof may be waived (either prospectively or retroactively and either generally or in a particular instance) only with the written consent of: (i) the Company, and (ii) a majority of interest of the holders of Registrable Securities (calculated on an as converted basis); provided that (x) should such waiver or amendment adversely affect the rights or privileges granted hereunder to the particular Holder or group of Holders, in a manner which discriminates such Holder/s against other Holders (a "Discriminated Class"), such waiver or amendment shall be subject to the written approval of the Holder/s who are the owners of record of a majority of the outstanding shares of such Discriminated Class, and (y) any right or limitation provided for the express benefit of a specifically named party may not be amended or waived without the consent of such party. Any amendment or waiver effected in accordance with this Section 2.4 shall be binding upon the Company, the Holders, and each of their respective successors and assigns.

### 2.5 <u>Notices, etc.</u>

2.5.1 All notices and other communications made pursuant to this Agreement shall be in writing and shall be conclusively deemed to have been duly given: (i) in the case of hand delivery to the address shown below, on the next Business Day after delivery; (ii) in the case of delivery by an internationally recognized overnight courier to the address set forth below, freight prepaid, on the next Business Day after delivery; (iii) in the case of a notice sent by facsimile transmission or email to the number, and addressed as, set forth below, on the next Business Day after delivery; if facsimile transmission or email is confirmed; (iv) in the case of a notice sent by email to any of the email addresses set forth in Schedule 1 hereto, on the date of written acknowledgment of receipt of such email by the receiving party. A "Business Day" means a day on which the banks are open for business in the country of receipt of any notice.

2.5.2 In the event that notices are given pursuant to one of the methods listed in subsections 2.5.1 (i) to (iii) above, a copy of the notice shall also be sent by email to such address set forth in Schedule 1.

2.5.3 A party may change or supplement the contact details for service of any notice pursuant to this Agreement, or designate additional addresses, facsimile numbers and email addresses for the purposes of this Section 2.5 by giving the other party written notice of the new contact details in the manner set forth above.

if to the Holders:	to the addresses set forth in <u>Schedule 1</u> ;
If to the Company:	To the address set forth in the Preamble
With a copy to:	Yigal Arnon & Co. 22 Rivlin Street Jerusalem, Israel 91000 Attn.: Adv. Barry P. Levenfeld Tel: 972-2-623-9200 Fax: 972-2-623-9236

2.6 <u>Delays or Omissions</u>. No delay or omission to exercise any right, power, or remedy accruing to any party upon any breach or default under this Agreement, shall be deemed a waiver of any other breach or default therefore or thereafter. Any waiver, permit, consent, or approval of any kind or character on the part of any party of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies, either under this Agreement or by law or otherwise afforded to any of the parties, shall be cumulative and not alternative.

2.7 <u>Severability</u>. If any provision of this Agreement is held by a court of competent jurisdiction to be unenforceable under applicable law, then such provision shall be excluded from this Agreement and the remainder of this Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms; provided, however, that in such event this Agreement shall be interpreted so as to give effect, to the greatest extent consistent with and permitted by applicable law, to the meaning and intention of the excluded provision as determined by such court of competent jurisdiction.

2.8 <u>Counterparts</u>. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and enforceable against the parties actually executing such counterpart, and all of which together shall constitute one and the same instrument.

2.9 <u>No Third Party Beneficiaries</u>. Except as expressly provided in this Agreement, this Agreement (including the documents and instruments referred to herein) is not intended to confer on any person other than the parties hereto any rights, remedies, obligations or liabilities hereunder.

**IN WITNESS WHEREOF,** the parties have signed this Investors Rights Agreement as of the date first hereinabove set forth.

BIOLINE RX LTD.	SHAREHOLDERS – SEE SEPARATE SIGNATURE PAGE
by: /s/ Yuri Shoshan name:Yuri Shoshan title: Vice President, Finance and Corporate Development	

IN WITNESS WHEREOF, by executing this Signature Page, the undersigned has read, understood and acknowledged the representations and covenants in the Registration Rights Agreement (the "RRA") by and between BioLine Rx Ltd. (the "Company") and its shareholders. Upon receipt by the Company of this Signature Page and execution by the Company of its counterpart signature page, the undersigned shall become a party to the RRA, and hereby authorizes this signature page to be attached to a counterpart of the RRA executed by the Company.

<u>Jerusalem Development Authority</u>	/s/ Ezriel M. Levi		
Print or Type Name of Shareholder	Signature		
	C.E.O. (Title, if applicable)		
Typed or printed name and address of Shareholder:	Fax Number: <u>972-2-6250875</u>		
	Telephone: <u>972-2-6297629</u>		
	Email: <u>ezri@jda.gov.il</u>		

IN WITNESS WHEREOF, by executing this Signature Page, the undersigned has read, understood and acknowledged the representations and covenants in the Registration Rights Agreement (the "RRA") by and between BioLine Rx Ltd. (the "Company") and its shareholders. Upon receipt by the Company of this Signature Page and execution by the Company of its counterpart signature page, the undersigned shall become a party to the RRA, and hereby authorizes this signature page to be attached to a counterpart of the RRA executed by the Company.

Typed or printed name and address of Shareholder:

### /s/ RUTH ALON

Pitango Venture Capital Fund III (Israeli Sub), L.P. Pitango Venture Capital Fund III (Israeli Sub) Non-Q L.P. Pitango Venture Capital Fund III (Israeli Investors), L.P. Pitango Principals Fund III (Israel), L.P. Pitango Venture Capital Fund III Trusts 2000 Ltd.

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<u>Hadasit</u> Print or Type Name of Shareholder

Typed or printed name and address of Shareholder:

/s/ RAFI HOFSTEIN Signature C.E.O. (Title, if applicable) Fax Number: Telephone: Email:

IN WITNESS WHEREOF, by executing this Signature Page, the undersigned has read, understood and acknowledged the representations and covenants in the Registration Rights Agreement (the "RRA") by and between BioLine Rx Ltd. (the "Company") and its shareholders. Upon receipt by the Company of this Signature Page and execution by the Company of its counterpart signature page, the undersigned shall become a party to the RRA, and hereby authorizes this signature page to be attached to a counterpart of the RRA executed by the Company.

Giza GE Venture Fund III, LLC Giza Alpinvest Venture Fund III, LLC Giza Venture Fund III Limited Partnership Giza Gmulot Venture Fund III Limited Partnership Giza Executive Venture Fund III, LLC Giza Venture Fund IV, LP Giza Venture Fund IV (TW) L.P. Giza Venture Fund IV (Jersey) LP Giza Venture Fund IV (Israel) Limited Partnership

Print or Type Name of Shareholder

/s/ Ezer Soref, Managing Director

/s/ Zvi Schechter, Managing Director

Signature

IN WITNESS WHEREOF, by executing this Signature Page, the undersigned has read, understood and acknowledged the representations and covenants in the Registration Rights Agreement (the "RRA") by and between BioLine Rx Ltd. (the "Company") and its shareholders. Upon receipt by the Company of this Signature Page and execution by the Company of its counterpart signature page, the undersigned shall become a party to the RRA, and hereby authorizes this signature page to be attached to a counterpart of the RRA executed by the Company.

SVE Star Ventures Enterprises GmbH & Co. No. IX KG SVM Star Ventures Managementgesellschaft mbH Nr. 3 & Co. Beteiligungs KG Nr. 4

By: SVM Star Ventures Managementgesellschaft mbH Nr. 3 Title: Managing Partner /s/ Meir Barel By: Dr. Meir Barel Title: Managing Director

Star Management of Investments No II (2000), L.P. By: SVM STAR Venture Capital Management Ltd. Title: Managing Partner /s/ Meir Barel By: Dr. Meir Barel Title: Director

IN WITNESS WHEREOF, by executing this Signature Page, the undersigned has read, understood and acknowledged the representations and covenants in the Registration Rights Agreement (the "RRA") by and between BioLine Rx Ltd. (the "Company") and its shareholders. Upon receipt by the Company of this Signature Page and execution by the Company of its counterpart signature page, the undersigned shall become a party to the RRA, and hereby authorizes this signature page to be attached to a counterpart of the RRA executed by the Company.

<u>Yehuda Zisapel</u>	/s/ Yehuda Zisapel		
Print or Type Name of Shareholder	Signature		
(Title, i		le, if applicable)	
Typed or printed name and address of Shareholder:	Fax Number:	972-3-6498520	
Yehuda Zisapel c/o RAD Group	Telephone:	972-3-6455522	
24 Raoul Wallenberg Street, Tel Aviv 69719, Israel	Email:	yehuda_z@rad.com	

IN WITNESS WHEREOF, by executing this Signature Page, the undersigned has read, understood and acknowledged the representations and covenants in the Registration Rights Agreement (the "RRA") by and between BioLine Rx Ltd. (the "Company") and its shareholders. Upon receipt by the Company of this Signature Page and execution by the Company of its counterpart signature page, the undersigned shall become a party to the RRA, and hereby authorizes this signature page to be attached to a counterpart of the RRA executed by the Company.

Pan Atlantic Investments Limited	/s/ Robert J. Bourque		
	Robert J. Bourque		
	Managing Director		
Musson Building, 2nd Floor Hincks Street	Fax Number:	(246) 228-1158	
Bridgetown Barbados West Indies 11000	Telephone:	(246) 436-9756	
	Email:	rjbourque@pabt.bb	

May 1, 2003

Dr. Morris Laster 11 Reuven Shari Street Jerusalem 97246

Dear Morris,

### Re: Engagement Offer

Further to our discussions, we are pleased to offer you employment with BioLine Therapeutics Ltd., in accordance with the terms and conditions set forth in this letter. By signing this letter you indicate your acceptance to the offer and thus turning this letter into a binding employment contract between you and us (this "**Agreement**"). For purposes of convenience, BioLine Therapeutics Ltd. will be called in this letter the "Company" or "we", and you will be called the "Employee" or "you".

## <u>General</u>

1. <u>Position</u>. You shall serve as the Chief Executive Officer of the Company. In such position you shall report regularly to, and be subject to the direction of the Company's Board of Directors. You shall perform your duties diligently, conscientiously and in furtherance of the Company's best interests. You agree and undertake to inform the Company, immediately after you become aware of any matter that may in any way raise a conflict of interest between yourself and the Company. You shall not receive during your employment by the Company any payment, compensation or benefit from any third party in connection, directly or indirectly, with the execution of your position in the Company (except from Spin Off's as set forth herein).

2. <u>Full Time Employment</u>. You will be employed on a full time basis. You shall devote your entire business time and attention to the business of the Company and you shall engage in other business or professional activities, in your business time, whether or not such activities are pursued for gain, profit or other pecuniary advantage, only with the prior written consent of the Company's Board of Directors. You confirm and declare that your position is one that requires a special measure of personal trust and loyalty; accordingly, the provisions of the Hours of Work and Rest Law-1951 shall not apply to you, and you shall not be entitled to any compensation for working more than the maximum number of hours per week set forth in said law or any other applicable law in addition to the compensation set forth in this Agreement.

3. <u>Location</u>. You shall perform your duties hereunder at the Company's facilities in Israel, but you understand and agree that your position may involve significant domestic and international travel.

4. <u>Employee's Representations and Warranties</u>. You represent and warrant that the execution and delivery of this Agreement and the fulfillment of all its terms: (i) will not constitute a default under or conflict with any agreement or other instrument to which you are a party to or by which you are bound; and (ii) do not require the consent of any person or entity. Further, with respect to any past engagement you may have had with third parties and with respect to any allowed engagement you may have with any third party during the term of your engagement with the Company (for purposes hereof, such third parties shall be referred to as ("**Other Employers**"), you represent, warrant and undertake that: (a) your engagement with the Company is and/or will not be in breach of his undertakings towards Other Employers, and (b) you will not disclose to the Company, or use, in provision of any services to the Company, any proprietary or confidential information belonging to any Other Employers.

### Term of Employment

5. <u>Term</u>. Your employment by the Company shall be deemed to have commenced on the date of May 1, 2003 (the "**Commencement Date**"), and shall continue until it is terminated pursuant to the terms set forth herein.

6. <u>Termination at Will</u>. Either party may terminate the employment relationship hereunder at any time by giving the other party a prior written notice of at least 4 (four) months (the "**Notice Period**"). However, the Company, at its own discretion, may terminate this Agreement and the employment relationship at any time immediately upon a written notice and pay you a one time amount equal to the Salary, and other benefits hereunder, that would have been paid to you during the Notice Period in lieu of the prior notice. Notwithstanding the aforesaid, in such case, you will still be entitled to make use of the Car (as such term is defined in Section 16) and the Phone (as such term is defined in Section 17), and the Vesting Period (as such term is defined in Section 2.4.1 of Exhibit A) shall be deemed to continue until the end of such 4-month period.

7. <u>Termination for Cause</u>. The Company may immediately terminate the employment relationship for Cause, and such termination shall be effective as of the time of notice of the same. "**Cause**" means (a) a serious breach of trust including but not limited to theft, embezzlement, self-dealing, prohibited disclosure to unauthorized persons or entities of confidential or proprietary information of or relating to the Company or its affiliates and the engaging by yourself in any prohibited business competitive to the business of the Company; or (b) any repetitive willful failure to perform or to perform competently any of your fundamental functions or duties hereunder, to the extent such failure was not remedied after appropriate notice was given by the Company; or (c) a material breach of the any material provision of this Agreement, to the extent such breach (if it can be remedied) was not remedied after appropriate notice was given by the Company.

8. <u>Notice Period; End of Relations</u>. During the period following notice of termination by either party, the employment relationship hereunder shall remain in full force and effect and there shall be no change in your position with the Company, in your Salary and other benefits hereunder, or in any other obligations of either party hereunder, and you shall cooperate with the Company and assist the Company with the integration into the Company of the person who will assume your responsibilities.

## **Covenants**

9. <u>Proprietary Information; Assignment of Inventions and Non-Competition</u>. By executing this letter you confirm and agree to the provisions of the Company's Proprietary Information, Assignment of Inventions, Confidentiality and Non-Competition Agreement attached as <u>Exhibit B</u>.

## Salary and Additional Compensation; Insurance; Advanced Study Fund

10. <u>Salary</u>. The Company shall pay to you as compensation for the employment services an aggregate monthly compensation in the amount of US\$16,100 (sixteen thousand one hundred U.S. Dollars) (the "**Salary**"). Notwithstanding the aforesaid, it is agreed that in the event that by the end of July 2003 the income ceiling for contributions for national insurance and health insurance which was cancelled as of July 1, 2002, shall not be reinstated, then, and so long as a ceiling is not reinstated, (i) the Company shall further pay to you an additional monthly gross amount of US\$1,000 (one thousand U.S. Dollars); and (ii) the Company shall further pay to you an additional monthly gross amount of the income tax payments borne by you with respect to provision of the Car under Section 16. Such additional compensations shall not be deemed as part of the Salary but rather as a separate additional compensation.

Except as specifically set forth herein, the Salary includes any and all payments to which you are entitled from the Company hereunder and under any applicable law, regulation or agreement. The Salary is to be paid to you no later then the 7<sup>th</sup> day of each calendar month after the month for which the Salary is paid, after deduction of applicable taxes and other mutually agreed upon payments.

### 11. <u>Insurance and Social Benefits</u>.

The Company will insure you under a "Manager's Insurance Scheme" to be mutually agreed upon (the "**Insurance Scheme**") as follows: (i) the Company will pay, at its expense, an amount equal to 13 1/3% (thirteen percent and one third of a percent) of the Salary towards a fund for life insurance and pension, which includes an amount equal to 8 1/3% (eight percent and one third of a percent) of the Salary towards a fund for severance compensation and 5% (five percent) for pension (Gemel), and shall also deduct an amount equal to 5% (five percent) of the Salary and pay such amount towards the Insurance Scheme for your benefit; (ii) the Company will pay, at its expense, an amount of up to 2.5% (two percent and one half of a percent) of the Salary towards an insurance for the event of loss of working ability ("Ovdan Kosher Avoda"). Further, the Company will also open and maintain an advanced study fund ("Keren Hishtalmut") on your behalf such that the Company shall contribute, at its expense, an amount equal to 7.5% (seven percent and one half of a percent) of the Salary and pay such amount towards the Keren Hishtalmut for your benefit. All of your aforementioned contributions (i.e., not those which at the Company's expense) shall be transferred to the above referred to plans and funds by the Company by deducting such amounts from each monthly Salary payment.

All amounts paid by the Company in accordance with this Section will be unconditionally transferred to you or the policies and funds will be transferred in your name, as applicable, upon the termination of your employment under any circumstances and for any reason whatsoever without limitation, provided that the same shall constitute the full and only compensation to be paid by the Company to you in such circumstances, as severance compensation or any other amounts you may be entitled to upon or due termination of your employment in accordance with any applicable law, rule or regulation, or any collective agreement or the like, except that the above shall not be deemed as derogating from remedies available for breach of contract and other unlawful acts or omissions, to the extent applicable.

### **Additional Benefits**

12. <u>Expenses</u>. In addition, the Company will reimburse you for business expenses borne by you, in accordance with the Company's policies as determined by the Company from time to time, and provided that substantial or extraordinary expenses are approved in advance by the Company. As a condition to reimbursement, you shall be required to provide the Company with all invoices, receipts and other evidence of expenditure as may be reasonably required by the Company from time to time.

13. <u>Bonuses</u>. In addition, at the beginning of each one-year period of engagement under this Agreement, the Company's Board of Directors may consider the grant of a yearly bonus based upon the achievement of certain goals and milestones to be set and determined by the Company's Board of Directors. For the avoidance of doubt, any bonus grant, its amount, and the goals and milestone criteria shall be at the sole and absolute discretion of the Company's Board of Directors.

14. <u>Vacation</u>. You shall be entitled to 21 (twenty one) vacation days per year, the use of which will be coordinated with the Company. In the event that the demands of your activities shall preclude or limit your ability to actually use such vacation days in any specific year, you shall be entitled to the balance of the unused vacation days only in the next succeeding year or, if unable to take the balance in that next succeeding year, to receive an amount equal to the rate of Salary then applicable to the vacation days not taken during such year.

15. <u>Sick Leave; Recreation Pay</u>. You shall be entitled to paid sick leave and to Recreation Pay ("Dmei Havra'a") pursuant to applicable law.

16. <u>Company Car</u>. In addition, for purposes of performance of your duties and tasks, the Company will provide you with a car of a "management class" level (such as Mazda 6, Peugeot 406, etc.) to be agreed upon in accordance with market standards (the "**Car**"). The Car will remain in the Company's ownership, and will be returned to the Company by you immediately after the later of the actual termination of your employment by the Company, or at the end of the Notice Period. The Company shall bear and pay, at its expense, any and all costs of maintenance and repairs, fuel, and any insurance deductibles for the Car. You shall be liable for paying for any parking and/or traffic fines received in connection with the Car, and for indemnification of the Company in case of unlawful use of the Car.

17. <u>Company Telephone</u>. For purposes of performance of your duties and tasks, the Company will provide you with a mobile phone (the "**Phone**"). The Phone will remain in the Company's ownership, and will be returned to the Company by you immediately after the later of the actual termination of your employment by the Company, or at the end of the Notice Period. The Company shall bear and pay, at its expense, any and all costs of maintenance, insurance and repairs for the Phone.

18. <u>Stock Incentive</u>. In additional consideration for your employment with the Company, you shall be entitled to a stock incentive, in accordance with the terms and conditions set forth in <u>Exhibit A</u>.

## **Miscellaneous**

19. The laws of the State of Israel shall apply to this Agreement and the sole and exclusive place of jurisdiction in any matter arising out of or in connection with this Agreement shall be the Tel-Aviv Regional Labor Court. The provisions of this Agreement are in lieu of the provisions of any collective bargaining agreement, and therefore, no collective bargaining agreement shall apply with respect to the relationship between the parties hereto (subject to the applicable provisions of law). No failure, delay of forbearance of either party in exercising any power or right hereunder shall in any way restrict or diminish such party's rights and powers under this Agreement, or operate as a waiver of any breach or nonperformance by either party of any terms of conditions hereof. In the event it shall be determined under any applicable law that a certain provision set forth in this Agreement is invalid or unenforceable, such determination shall not affect the remaining provisions of this Agreement unless the business purpose of this Agreement is substantially frustrated thereby. This Agreement constitutes the entire understanding and agreement between the parties hereto, supersedes any and all prior discussions, agreements and correspondence with regard to the subject matter hereof, and may not be amended, modified or supplemented in any respect, except by a subsequent writing executed by both parties hereto. Both parties acknowledge and confirm that all terms of your employment are personal and confidential, and undertake to keep such term in confidence and refrain from disclosing such terms to any third party; the aforesaid shall not be interpreted as limiting the Company from any disclosure which may be required under applicable law or as part of its business activities. You shall be covered by a Directors and Officers insurance policy to the same extent as such insurance policy shall cover the members of Company's Board of Directors appointed by the Founders.

Please indicate your acceptance to the terms of this letter by signing and dating them and returning a counterpart hereof to us.

Sincerely yours, Aharon Schwartz /s/ Aharon Schwartz BioLine Therapeutics Ltd.

Allon Reiter /s/ Allon Reiter

I agree to all terms of this letter.

Name: Dr. Morris Laster Date: May 1, 2003 /s/ Morris Laster

## Exhibit A to the Employment Agreement between BioLine Therapeutics and Dr. Morris Laster

### Stock Incentive Scheme

This Stock Incentive Scheme is attached as <u>Exhibit A</u> to that certain Employment Agreement by and between BioLine Therapeutics Ltd. (the "**Company**") and Dr. Morris Laster ("**Employee**") (the "**Employment Agreement**").

In additional consideration for Employee's employment with the Company, Employee shall be entitled to grant of securities in accordance with the terms and conditions set forth herein below:

## **Definitions**

- 1. All the capitalized terms herein shall have the meanings ascribed to them in the Employment Agreement. Additionally, the following capitalized terms shall have the meaning ascribed next to them:
  - 1.1. "Adjustment Actions" Any of the following actions which may be taken by a Corporation with respect to securities issued by such Corporation: (i) forfeiture by the Corporation, (ii) redemption by the Corporation for the securities' par value (or for less than that amount, if allowed under applicable law), (iii) purchase by the Corporation or by any other person or entity designated by the Corporation, for the securities' par value (or for less than that amount, if allowed under applicable law), (iii) purchase by the Corporation or by any other person or entity designated by the Corporation, for the securities' par value (or for less than that amount, if allowed under applicable law); (iv) conversion into deferred shares entitling their holder only to their par value upon liquidation of the Corporation, or (v) any other action which may be required in order to achieve similar results all as shall be determined by the Corporation, at its sole and absolute discretion.
  - 1.2. "**Applicable Percent**" The percentage of Financing Securities to which Employee may be entitled under this Exhibit from time to time. Initially, the Applicable Percent shall be 8% (eight percent), but it may be adjusted downwards in accordance with the provisions of Section 2.4 of this Exhibit.
  - 1.3. "**Corporation**" Either of the Company or a Spin-Off.
  - 1.4. "Equity Investors" Holders of Financing Securities.
  - 1.5. "Financing Securities" - Any Corporation shares issued to a person or other legal entity making an equity investment in the Corporation, the principal purpose of which issuance is the raising of capital by the Corporation through the sale of securities of the Corporation. Without derogating from the aforesaid definition, the following securities are specifically excluded from the above definition of "Financing Securities": (a) loans, debentures convertible notes, and the like so long as they have not yet been actually exercised, exchanged, or converted into shares of the Corporation ("Loans"); notwithstanding the aforesaid, it is agreed that any convertible notes which may be issued to Teva under the Founders Agreement shall not be deemed as a Loan for purpose of this provision, but rather shall be deemed Financing Securities (for the avoidance of doubt, shares which may be issued upon conversion of such Convertible Notes of Teva shall not be deemed as additional Financing Securities); (b) securities issued pursuant to or under various incentive arrangements (e.g., employees and service providers stock incentive plans, stock grants to directors and officers, etc.); (c) securities issued in consideration for goods or services provided and the like issuances (such as and specifically including issuances to banks and the like financial institutions granting loans or credit lines or the like facilities, issuances to equipment lessors, acquisition of other corporations, etc.); (d) securities issued upon exercise or conversion of shares, options, warrants, convertible notes and the like securities the issuance of which already entitled Employee to an Update Issuance or was exempted from Employee's right to an Update Issuance (except for securities which may be issued upon exercise or conversion of Loans, which securities shall be deemed as Financing Securities upon such exercise or conversion of a Loan); (e) securities issued to all shareholders of the Corporation in connection with any stock combination or subdivision or split, issue of bonus shares or stock dividends, or any other similar recapitalization of the share capital of the Corporation; (f) securities issued in an M&A Transaction; or (g) securities issued to the public.

- 1.6. "Founders" Teva Pharmaceutical Industries Ltd. ("Teva"), Hadasit Medical Research Services and Development Ltd. ("Hadasit"), Pitango Venture Capital Fund III (Israeli Sub), L.P. and related entities (collectively, "Pitango"), Giza GE Venture Fund III, LLC and related entities (collectively, "Giza"), and other persons and entities which may be added from time to time at the discretion of the Company.
- 1.7. **"Founders Agreement**" That certain Founders Agreement, dated as of March 31, 2003, by and between the Company and the Founders, a copy of which was provided to Employee and his legal counsel.
- 1.8. "Incentive Shares" Ordinary A Shares par value NIS 0.01 each of the Company
- 1.9. "**M&A Transaction**" A merger of the Company with or into any other corporation, or the sale of all or substantially all of the outstanding shares of the Company or the sale of all or substantially all of the assets of the Company.
- 1.10. "**Spin-Off**" Any subsidiary or division of the Company spun-off, so that it shall be held, in whole or in part, by the Company's Equity Investors.
- 1.11. "**Update Issuance**" An issuance as defined in Section 4.1.

## 2. Equity in the Company

2.1. <u>General</u>. Employee shall be entitled to and issued Incentive Shares in accordance with the following provisions of this Section 2 and the other provisions of this Exhibit. The Incentive Shares shall be granted and issued in accordance with the provisions of Section 102 of the Tax Ordinance ("**Section 102**"), pursuant to the "Capital Gains" track thereof, and subject to and in accordance with the general terms and conditions of a stock incentive plan to be adopted by the Board of Directors of the Company (the "**Plan**") and to be approved by the Israeli Tax Authorities, and a particular Stock Incentive Grant Agreement to be signed by and between the Company and Employee (the "**Stock Incentive Grant Agreement**") pursuant to the terms and conditions hereof. In the event of any discrepancy between the provisions of this Exhibit and either of the Plan or the Stock Incentive Grant Agreement, then the provisions hereof shall apply.

The Company shall complete such Plan, and file the Plan with the Israeli Tax Authorities within 45 (forty five) days from the date hereof.

2.2. <u>Initial Grant of Incentive Shares</u>. Upon adoption of the Plan and its approval by the Israeli Tax Authorities, and simultaneously with the execution of the Stock Incentive Grant Agreement, the Company shall issue to Employee such amount of Incentive Shares, representing, on the date of their issuance, the Applicable Percent of the amount of the then issued and outstanding Financing Securities.

- 2.3. <u>Issue Price</u>. The issue price of each Incentive Share which shall be issued to Employee in accordance with the provisions of Sections 2 or 4 shall be the par value of the share.
- 2.4. <u>Vesting</u>. Notwithstanding any and all above provisions of this Section 2, Employee acknowledges and agrees that all Incentive Shares are granted and issued based on the understanding that Employee will be fully and continuously engaged with the Company under the Employment Agreement for certain minimum periods of time as set forth herein below, and, accordingly it is hereby covenanted and agreed by Employee that Incentive Shares shall be subject to applicable vesting periods and in accordance with and subject to the following terms and provisions:
  - 2.4.1. 25% (twenty five percent) of the Incentive Shares shall vest after 12 (twelve) months from the Commencement Date, and the remaining 75% (seventy five percent) of the Incentive Shares shall vest in 12 (twelve) equal portions on a quarterly basis over the following period of 36 (thirty six) months. The full period of 4 (four) years from the Commencement Date shall be referred to as the "**Vesting Period**".
  - 2.4.2. In the event that, at any time during the Vesting Period, the Employment Agreement shall be terminated or cancelled for any reason whatsoever (a "**Termination Event**"), then, upon the later of the actual termination of the Employment Agreement and the end of the Notice Period, where applicable, all unvested Incentive Shares at such date shall be subject to one or more Adjustment Actions as shall be determined by the Company, at its sole and absolute discretion in order to cause the Applicable Percent to be adjusted to the applicable percentage as at the time of termination. For example, in the event of a Termination Event at the end of 12 (twelve) months from the Commencement Date, the Applicable Percent shall be 2% (two percent); Employee hereby agrees and confirms that the shareholders of the Company may take all such Adjustment Actions, and hereby empowers the Board of Directors of the Company or any person which may be designated by the Board of Directors of the Company or any persons. For the avoidance of doubt, a Termination Event will have no effect whatsoever with regard to any vested shares, which will include all shares vested in accordance hereof until the later of the actual termination of the Employment Agreement and the end of the Notice Period, where applicable.
- 2.5. Acceleration Events. Notwithstanding the aforesaid provisions of Section 2.4, it is agreed that, during the Vesting Period: (i) upon the closing of an M&A Transaction, all of the Incentive Shares then still subject to vesting shall be deemed fully vested; and (ii) in the event of death of Employee or permanent severe disability of Employee that no longer enables Employee to reasonably work, 50% (fifty percent) of all the Incentive Shares then still subject to vesting shall be deemed fully vested. For the avoidance of doubt, the provisions of Section 2.4 shall no longer apply to any Incentive Shares deemed vested in accordance with the provisions of this Section 2.5.
- 2.6. <u>No Engagement Commitment</u>. For avoidance of doubt, it is clarified that nothing in this Exhibit shall be deemed as an undertaking of the Company to retain Employee's services for any minimum period of time.

<u>Rights and Obligations of the Incentive Shares</u>. The Incentive Shares shall be entitled to all rights and shall be subject to all obligations and restrictions as set forth in the Articles of Association of the Company applicable to the Ordinary A Shares of the Company, as such rights, obligations and restrictions may be from time to time (subject to the following). At all times, the Ordinary A Shares shall have identical rights and obligations, in all material respects, as those attached to the Ordinary Shares of the Company, except that the Ordinary A Shares shall not be entitled to receive notices of general meetings of the shareholders of the Company, to attend such meetings or to vote therein on any matter.

The Company shall not, without Employee's agreement, cancel, modify in any material way, or adversely derogate from in any material way, rights attached to the Ordinary A Shares held by Employee to receive dividends or the like distributions in cash or kind ("**Dividends**") or Dividends upon liquidation of the Company; provided however that nothing herein shall be deemed as derogating in any way from the Company's full and unlimited right and discretion to grant rights - including preferred or superior rights - to Dividends or Dividends upon liquidation to any person or entity investing in the Company. Notwithstanding the above, in the event of an additional fund raising (not covered by the Founders Agreement) from any specific Founder(s) (e.g., equity investments, bridge loans, or any other financing form), the Company may negotiate and effect, inter alia, changes of the rights to Dividends or Dividends upon liquidation attached to the Series A Redeemable Preferred Share of the Company, par value NIS0.1 issued to such Founder(s).

Employee hereby agrees and undertakes that, subject to the above, the Company may, at its discretion, convert the Ordinary A Shares into Ordinary Shares. For the avoidance of doubt, in such case, the provisions of the second paragraph of this Section 2.7 shall apply, *mutatis mutandis*.

- 2.8. <u>Dividend Distributions During the Vesting Period</u>. In the event that during the Vesting Period, the Company shall make any distribution of Dividends to its shareholders (each a "**Given Distribution**"), then: (i) at the time of any Given Distribution, Employee shall receive Dividends based on the portion of vested Incentive Shares as at that time, and (ii) upon vesting of each additional portion of Incentive Shares, Employee shall receive an additional proportionate portion of the Given Distribution. The Company shall set aside, in a segregated trust account, Dividends due but not yet paid to Employee pursuant to this Section 2.8, and shall remit any interest accumulated with regard thereto to Employee together with the Dividend.
- 2.9. <u>Restricted Transfer; Transfer Arrangements</u>. During the Vesting Period, the Incentive Shares may not be transferred, assigned, mortgaged or otherwise disposed of in any manner (a "**Transfer**"), and any unauthorized Transfer shall subject such shares to an Adjustment Action. As of the end of the Vesting Period, the Incentive Shares may be freely Transferred, subject to the general terms and conditions applicable to all shares of the Company as may be set in the Articles of Association of the Company. Employee specifically acknowledges and agrees that the Inventive Shares shall be subject to any and all "Bring Along" or "Tag Along" arrangements which may be set in the Articles of Association of the company to the extent imposed on all or substantially all of the shareholders of the Company.

2.7.

2.10. <u>Taxation</u>. All tax consequences arising from the grant and vesting of the Incentive Shares, or the exercise of any Adjustment Actions or from any other event or act of the Company or Employee hereunder, shall be borne solely by Employee, and Employee will indemnify the Company and hold it harmless against and from any and all liability for any such tax or interest or penalty thereon, including without limitation, liabilities relating to the necessity to withhold, or to have withheld, any such tax. Employee hereby irrevocably authorizes the Company to deduct from any payment, which may be due to Employee from the Company any amount Employee may owe in accordance with the above provisions of this Section 2.10. Notwithstanding the above, the Company shall be liable for any failure to lawfully prepare, file and administer the Plan in accordance with applicable law.

## 3. Equity in Spin-Offs

To the extent that the Company shall spin-off any Spin-Off, the following provisions shall apply:

- 3.1. Upon the incorporation of any Spin-Off, Employee shall be entitled and issued securities of the Spin-Off with substantially similar terms as those of the Incentive Shares (or securities with better terms, at the discretion of the Board of Directors of the founders of the Spin-Off or its Board of Directors) (the "**Spin-Off Shares**"), in an amount equal to the then Applicable Percent times the aggregate amount of Financing Securities of the Spin-Off which shall be issued to the Company's Equity Investors at the time of incorporation of the Spin-Off.
- 3.2. To the extent that the Incentive Shares shall be subject to adjustment in accordance with the provisions of Section 2.4 or in accordance with the provisions of Section 5, then the Spin-Off Shares shall be similarly adjusted as set forth with respect to the Incentive Shares.
- 3.3. For example:
  - 3.3.1. A Spin-Off is incorporated, in which the Company's Equity Investors will hold 50%, and at such time the Applicable Percent is 8%: Employee shall be issued Spin-Off Shares equal to 4% of the share capital of the Spin-Off.
  - 3.3.2. A Termination Event occurs under the Employment Agreement, following which 50% of the Incentive Shares are subject to an Adjustment Action (and, accordingly, the Applicable Percent is reduced to 4%): 50% of the Spin-Off Shares shall be subject to a similar Adjustment Action.
- 3.4. The provisions of Sections 2.3, 2.7-2.10 (inclusive) and 5 shall apply, *mutatis mutandis*, with respect to any and all Spin-Off as well.
- 3.5. The corporate documents and/or shareholders agreement(s) of each Spin-Off may further elaborate on the above matters, as may be required in order to fully implement the above agreements.

#### 4. Anti-dilution Protection

It is agreed that Employee's holdings in the Company and in any Spin-Off shall be protected from dilution until an actual aggregate investment in either of the Company and/or any Spin-Offs, equal to US\$11,000,000 (eleven million U.S. Dollars) is made (adding thereto and taking into account that initial amount invested in the Company prior to the date of issuance of Incentive Shares pursuant to Section 2.2), in accordance with the following terms and provisions:

4.1. Upon the issuance by the Company of any Financing Securities, Employee shall be issued, for no additional consideration, except for payment of the par value thereof, additional Incentive Shares in such amount resulting in an aggregate holding by Employee of Incentive Shares equal to the then Applicable Percent of all Financing Securities issued by the Company to its Equity Investors.

Similarly, upon the issuance by any Spin-Off of any Financing Securities, Employee shall be issued, for no additional consideration, except for payment of the par value thereof, additional Spin-Off Shares of such Spin-Off in such amount resulting in an aggregate holding by Employee of Spin-Off Shares equal to the then Applicable Percent times of Financing Securities issued by such Spin-Off to its Equity Investors.

Any and each of the above referred to issuances shall be referred to as an "Update Issuance".

- 4.2. Employee's right to an Update Issuance shall apply with respect to the Company and each Spin-Off separately, with respect to any issuance therein of Financing Securities, and such right to Update Issuances shall terminate altogether upon an actual aggregate investment in the Company and all Spin-Offs, together, of US\$11,000,000 (eleven million U.S. Dollars).
- 4.3. For example, based on the assumption of the existence of the Company and one Spin-Off:
  - 4.3.1. Employee was initially issued Incentive Shares based on an actual aggregate investment of \$500,000. Thereafter, the Company issues Financing Securities in consideration for an actual aggregate investment by the Company's Equity Investors of \$9,500,000: Employee shall be entitled to an Update Issuance of Incentive Shares, protecting Employee's holdings in the Company from dilution by such entire amount.
  - 4.3.2. The Spin-Off issues Financing Securities in consideration for an actual investment by its Equity Investors of \$1,000,000: Employee shall be entitled to an Update Issuance of Spin-Off Shares of such specific Spin-Off, protecting Employee's holdings in the Spin-Off from dilution by such entire amount.
  - 4.3.3. As of that time and onwards, none of Employee's holdings in any Corporation shall be entitled to any Update Issuances or other protection from dilution with respect to any issuances of securities by any such Corporation.
- 4.4. For the avoidance of doubt it is clarified the anti-dilution protection granted in this section 4 shall continue to apply whether or not Employee is still employed with the Company at such time and shall survive without limitation the termination of the Agreement for any reason whatsoever.

# 5. **Decrease Adjustment**

In the event that any of the Financing Securities shall be subject to actions of the kind of the Adjustment Actions, then a proportionate portion of the Incentive Shares shall be subject to Adjustment Actions so that the ratio between the amount of all remaining Incentive Shares and all remaining Financing Securities remains equal the ratio between the amount of all Incentive Shares and Financing Securities existing prior to occurrence of such Adjustment Actions.

## Exhibit B to the Employment Agreement between BioLine Therapeutics and Dr. Morris Laster

## Proprietary Information; Assignment of Inventions, Confidentiality and Non-Competition

This Proprietary Information, Assignment of Inventions, Confidentiality and Non-Competition Agreement is attached as <u>Exhibit B</u> to that certain Employment Agreement by and between BioLine Therapeutics Ltd. ("**Company**") and Dr. Morris Laster ("**Employee**") (the "**Agreement**"). All the capitalized terms herein shall have the meanings ascribed to them in the Agreement. For purposes hereof, the term "Company" shall mean and include Company any subsidiaries and affiliates of Company.

Employee's obligations and representations and Company's rights under this Exhibit shall apply as of the time it first became engaged with Company, regardless of the date of execution of the Agreement.

## **Confidentiality; Proprietary Information**

- 1. "**Proprietary Information**" means confidential and proprietary information concerning the business and financial activities of Company, including patents, patent applications, trademarks, copyrights and other intellectual property, and information relating to the same, technologies and products (actual or planned), know how, inventions, research and development activities, trade secrets and industrial secrets, and also confidential commercial information such as investments, investors, employees, customers, suppliers, marketing plans, etc., all the above whether documentary, written, oral or computer generated. Proprietary Information shall also include information of the same nature which Company may obtain or receive from third parties.
- 2. Proprietary Information shall be deemed to include any and all proprietary information disclosed by or on behalf of Company and irrespective of form but excluding information that (i) was known to Employee prior to Employee's association with Company and can be so proven; (ii) is or shall become part of the public knowledge except as a result of the breach of the Agreement or this Exhibit by Employee; (iii) reflects general skills and experience gained during Employee's engagement by Company; or (iv) reflects information and data generally known in the industries or trades in which Company operates.
- 3. Employee recognizes that Company received and will receive confidential or proprietary information from third parties, subject to a duty on Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. In connection with such duties, such information shall be deemed Proprietary Information hereunder, *mutatis mutandis*.
- 4. Employee agrees that all Proprietary Information, and patents, trademarks, copyrights and other intellectual property and ownership rights in connection therewith shall be the sole property of Company its subsidiaries and their assigns. At all times, both during the term of Employee's engagement with Company (the "**Term**") and after the termination of the engagement between the parties, Employee will keep in confidence and trust all Proprietary Information, and Employee will not use or disclose any Proprietary Information or anything relating to it without the written consent of Company or its subsidiaries, except as may be necessary in the ordinary course of performing Employee's duties under the Agreement.
- 5. Upon termination of Employee's engagement with Company, Employee will promptly deliver to Company all documents and materials of any nature pertaining to Employee's engagement with Company, and will not take with his any documents or materials or copies thereof containing any Proprietary Information.
- 6. Employee's undertakings set forth in Section 1 through Section 5 of this Exhibit shall remain in full force and effect after termination of the Agreement or any renewal thereof.

# **Disclosure and Assignment of Inventions**

- 7. "**Inventions**" means any and all inventions, improvements, designs, concepts, techniques, methods, systems, processes, know how, computer software programs, databases, mask works and trade secrets, whether or not patentable, copyrightable or protectible as trade secrets; "**Company Inventions**" means any Inventions that are made or conceived or first reduced to practice or created by Employee, whether alone or jointly with others, during the period of Employee's engagement with Company, and which are: (i) developed using equipment, supplies, facilities or Proprietary Information of Company, (ii) result from work performed by Employee for Company, or (iii) related to the field of business of Company, or to specific fields of research and development undertaken by Company.
- 8. Employee undertakes and covenants he will promptly disclose in confidence to Company all Inventions deemed as Company Inventions.
- 9. Employee hereby irrevocably transfers and assigns to Company all worldwide patents, patent applications, copyrights, mask works, trade secrets and other intellectual property rights in any Company Invention, and any and all moral rights that he may have in or with respect to any Company Invention.
- 10. Employee agrees to assist Company, at Company's expense, in every reasonable and proper way with Company's efforts to obtain for Company and enforce patents, copyrights, mask work rights, and other legal protections for Company Inventions in any and all countries. Employee will execute any documents that Company may reasonably request for use in obtaining or enforcing such patents, copyrights, mask work rights, trade secrets and other legal protections. Such obligation shall continue beyond the termination of Employee's engagement with Company, provided that Company appropriately compensates Employee for his time and efforts in this regard. Employee hereby irrevocably designates and appoints Company and its authorized officers and agents as Employee's agent and attorney in fact, coupled with an interest to act for and on Employee's behalf and in Employee's stead to execute and file any document needed to apply for or prosecute any patent, copyright, trademark, trade secret, any applications regarding same or any other right or protection relating to any Proprietary Information (including Company Inventions), with the same legal force and effect as if executed by Employee himself.

## Non-Competition

- 11. Employee agrees and undertakes that he will not, so long as the Agreement is in effect and for a period of nine (9) months following termination of the Agreement, for any reason whatsoever, directly or indirectly, in any capacity whatsoever, materially be engaged in, or employed by, any business or venture that is engaging in the same business as the Business (as defined below) of Company. For purposes hereof, "Business" means the incubation of companies and projects focused on the identification, development and commercialization of new chemical entities in the bio-pharmaceutical field.
- 12. Employee agrees and undertakes that during the Term and for a period of twelve (12) months following termination of his engagement for whatever reason, Employee will not, directly or indirectly, including personally or in any business in which Employee may have a controlling interest, solicit for employment any person who is employed by Company, or any person materially retained by Company as a Employee, advisor or the like who is subject to an undertaking towards Company to refrain from engagement in activities competing with the activities of Company, or was retained as an employee, consultant, advisor or the like during the six months preceding termination of the Term.

# **Reasonableness of Protective Covenants**

13. Insofar as the protective covenants set forth in this Exhibit are concerned, Employee specifically acknowledges, stipulates and agrees as follows: (i) the protective covenants are reasonable and necessary to protect the goodwill, property and Proprietary Information of Company, and the operations and business of Company; and (ii) the time duration of the protective covenants is reasonable and necessary to protect the goodwill and the operations and business of Company, and does not impose a greater restrain than is necessary to protect the goodwill or other business interests of Company. Nevertheless, if any of the restrictions set forth in this Exhibit is found by a court having jurisdiction to be unreasonable or overly-broad as to geographic area, scope or time or to be otherwise unenforceable, the parties hereto intend for the restrictions set forth in this Exhibit to be reformed, modified and redefined by such court so as to be reasonable and enforceable and, as so modified by such court, to be fully enforced.

# **Remedies for Breach**

14. Employee acknowledges that the legal remedies for breach of the provisions of this Exhibit may be found inadequate and therefore agrees that, in addition to all of the remedies available to Company in the event of a breach or a threatened breach of any of such provisions, Company may also, in addition to any other remedies which may be available under applicable law, obtain temporary, preliminary and permanent injunctions against any and all such actions.

# **Intent of Parties**

15. Employee recognizes and agrees: (i) that this Exhibit is necessary and essential to protect the business of Company and to realize and derive all the benefits, rights and expectations of conducting Company's business; (ii) that the area and duration of the protective covenants contained herein are in all things reasonable; and (iii) that good and valuable consideration exists under the Agreement, for Employee's agreement to be bound by the provisions of this Exhibit.

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#### Schedule A

#### Exhibit A to the Employment Agreement between BioLineRx and Dr. Morris Laster

#### Stock Incentive Scheme

This Stock Incentive Scheme is attached as <u>Exhibit A</u> to that certain Employment Agreement by and between BioLineRx Ltd. (the "**Company**") and Dr. Morris Laster ("**Employee**") (the "**Employment Agreement**").

As additional consideration for Employee's employment with the Company, Employee shall be entitled to grant of securities in accordance with the terms and conditions set forth herein below:

### **Definitions**

- 1. <u>Entitlement</u>. Employee shall be entitled to, and issued, 956,522 (nine hundred fifty six thousand and fine hundred twenty two) Ordinary Shares par value NIS 0.01 each of the Company (the "**Incentive Shares**"), in accordance with the following provisions of this Section 1 and the other provisions of this Exhibit.
- 2. Section 102 Grant. The Incentive Shares shall be granted and issued in accordance with the provisions of Section 102 of the Tax Ordinance ("Section 102"), pursuant to the "Capital Gains" track thereof, and subject to and in accordance with the general terms and conditions of a stock incentive plan to be adopted by the Board of Directors of the Company (the "Plan") and to be approved by the Israeli Tax Authorities, and a particular Stock Incentive Grant Agreement to be signed by and between the Company and Employee (the "Stock Incentive Grant Agreement") pursuant to the terms and conditions hereof. In the event of any discrepancy between the provisions of this Exhibit and either of the Plan or the Stock Incentive Grant Agreement, then the provisions hereof shall apply.
- 3. <u>Issue Price</u>. The issue price of each Incentive Share which shall be issued to Employee shall be the par value of the share.
- 4. <u>Vesting</u>. Notwithstanding any and all above provisions of Section 1, Employee acknowledges and agrees that all Incentive Shares are granted and issued based on the understanding that Employee will be fully and continuously engaged with the Company under the Employment Agreement for certain minimum periods of time as set forth herein below, and, accordingly it is hereby covenanted and agreed by Employee that Incentive Shares shall be subject to applicable vesting periods and in accordance with and subject to the following terms and provisions:
  - 4.1 25% (twenty five percent) of the Incentive Shares shall vest after 12 (twelve) months from the Commencement Date, and the remaining 75% (seventy five percent) of the Incentive Shares shall vest in 12 (twelve) equal portions on a quarterly basis over the following period of 36 (thirty six) months. The full period of 4 (four) years from the Commencement Date shall be referred to as the "**Vesting Period**".
  - 4.2 In the event that, at any time during the Vesting Period, the Employment Agreement shall be terminated or cancelled for any reason whatsoever (a "**Termination Event**"), then, upon the later of the actual termination of the Employment Agreement and the end of the Notice Period, where applicable, all unvested Incentive Shares at such date shall be subject to one or more Adjustment Actions (as defined below) as shall be determined by the Company, at its sole and absolute discretion. Employee hereby agrees and confirms that the Company and the shareholders of the Company may take all such Adjustment Actions, and hereby empowers the Board of Directors of the Company or any person which may be designated by the Board of Directors of the Company to vote all the Incentive Shares (to the extent required and applicable for the above purposes only) in any way as he or she may deem fit for the above purposes. For the avoidance of doubt, a Termination Event will have no effect whatsoever with regard to any vested shares, which will include all shares vested in accordance hereof until the later of the actual termination of the Employment Agreement and the end of the Notice Period, where applicable.

For purposes hereof, the term "Adjustment Actions" shall mean any of the following actions which may be taken by the Company with respect to the Incentive Shares (including, for purposes hereof, any additional securities issued on account of such Incentive Shares, such as bonus shares): (i) forfeiture by the Company, (ii) redemption by the Company for the securities' par value (or for less than that amount, if allowed under applicable law), (iii) purchase by the Company or by any other person or entity designated by the Company, for the securities' par value (or for less than that amount, if allowed under applicable law); (iv) conversion into deferred shares entitling their holder only to their par value upon liquidation of the Company, or (v) any other action which may be required in order to achieve similar results – all as shall be determined by the Company, at its sole and absolute discretion.

- 5. <u>Acceleration Events</u>. Notwithstanding the aforesaid provisions of Section 4, it is agreed that, during the Vesting Period: (i) upon the closing of an M&A Transaction (as defined in Section 1.9 of the Employment Agreement), all of the Incentive Shares then still subject to vesting shall be deemed fully vested; and (ii) in the event of death of Employee or permanent severe disability of Employee that no longer enables Employee to reasonably work, 50% (fifty percent) of all the Incentive Shares then still subject to vesting shall be deemed fully vested. For the avoidance of doubt, the provisions of Section 4 shall no longer apply to any Incentive Shares deemed vested in accordance with the provisions of this Section 5.
- 6. <u>No Engagement Commitment</u>. For avoidance of doubt, it is clarified that nothing in this Exhibit shall be deemed as an undertaking of the Company to retain Employee's services for any minimum period of time.
- 7. <u>Rights and Obligations of the Incentive Shares</u>. The Incentive Shares shall be entitled to all rights and shall be subject to all obligations and restrictions as set forth in the Articles of Association of the Company applicable to the Ordinary Shares of the Company, as such rights, obligations and restrictions may be from time to time (subject to the following).
- 8. <u>Power of Attorney</u>. Simultaneously with the execution of this Agreement, you shall execute the irrevocable power of attorney form, attached hereto as <u>Annex I</u>.
- 9. <u>Dividend Distributions During the Vesting Period</u>. In the event that during the Vesting Period, the Company shall make any distribution of dividends or the like distributions in cash or kind ("**Dividends**") to its shareholders (each a "**Given Distribution**"), then: (i) at the time of any Given Distribution, Employee shall receive Dividends based on the portion of vested Incentive Shares as at that time, and (ii) upon vesting of each additional portion of Incentive Shares, Employee shall receive an additional proportionate portion of the Given Distribution. The Company shall set aside, in a segregated trust account, Dividends due but not yet paid to Employee pursuant to this Section 9, and shall remit any interest accumulated with regard thereto to Employee together with the Dividend.
- 10. <u>Restricted Transfer; Transfer Arrangements</u>. During the Vesting Period, the Incentive Shares may not be transferred, assigned, mortgaged or otherwise disposed of in any manner (a "**Transfer**"), and any unauthorized Transfer, shall subject such shares to an Adjustment Action. As of the end of the Vesting Period, the Incentive Shares may be freely Transferred, subject to the general terms and conditions applicable to all shares of the Company as may be set in the Articles of Association of the Company. Employee specifically acknowledges and agrees that the Inventive Shares shall be subject to any and all "Bring Along" or "Tag Along" arrangements which may be set in the Articles of Association of the Company to the extent imposed on all or substantially all of the shareholders of the Company.

- 11. <u>Taxation</u>. All tax consequences arising from the grant and vesting of the Incentive Shares, or the exercise of any Adjustment Actions or from any other event or act of the Company or Employee hereunder, shall be borne solely by Employee, and Employee will indemnify the Company and hold it harmless against and from any and all liability for any such tax or interest or penalty thereon, including without limitation, liabilities relating to the necessity to withhold, or to have withheld, any such tax. Employee hereby irrevocably authorizes the Company to deduct from any payment, which may be due to Employee from the Company any amount Employee may owe in accordance with the above provisions of this Section 11. Notwithstanding the above, the Company shall be liable for any failure to lawfully prepare, file and administer the Plan in accordance with applicable law.
- 12. <u>Equity in Spin-Offs</u>. To the extent that the Company shall spin-off any subsidiary or division of the Company, so that it shall be held, in whole or in part, by the Company's shareholders (a "**Spin-Off**"), the following provisions shall apply:
  - 12.1 Upon the incorporation of any Spin-Off, Employee shall be entitled and issued securities of the Spin-Off with substantially similar terms as those of the Incentive Shares (or securities with better terms, at the discretion of the founders of the Spin-Off or its Board of Directors) (the "**Spin-Off Shares**"), in an amount equal to the proportionate holdings of Employee in the Company at the time of incorporation of the Spin-Off.
  - 12.2 To the extent that at a later stage, any Incentive Shares shall be subject to an Adjustment Action, then an applicable portion of the Spin-Off Shares shall be similarly adjusted as set forth with respect to the Incentive Shares.
  - 12.3 The provisions of Sections 3 and 7-11 (inclusive) shall apply, *mutatis mutandis*, with respect to any and all Spin-Offs as well.
  - 12.4 The corporate documents and/or shareholders agreement(s) of each Spin-Off may further elaborate on the above matters, as may be required in order to fully implement the above agreements.
- 13. <u>Minimum Equity Holding</u>. The amount of the Incentive Shares set forth in Section 1 of this Stock Incentive Scheme reflects 8% (eight percent) of the issued and outstanding share capital of the Company based on the securities issued hereunder to the Employee plus the securities issued to, or for the benefit of, the founders investing in the Company in consideration for a contemplated aggregate equity investment of US\$11,000,000 (eleven million U.S. Dollars) (the "**\$11 Million Investment Amount**"). In the event that raising \$11 Million Investment Amount, whether from the founders or from any additional third parties, shall require the issuance by the Company of any additional Financing Securities (as defined below), the Employee's shall be entitled to additional Incentive Shares so to prevent dilution of his holdings as a result of the issuance of such additional securities. For the avoidance of any doubt, such increased amount of Incentive Shares shall also be taken into account with respect to the Employee's rights under Section 12 above.

For purposes hereof, the term "Financing Securities" means any securities issued to a person or another legal entity making an equity investment in the Company, the principal purpose of which issuance is the raising of capital by the Company through the sale of securities of the Company. Without derogating from the aforesaid definition, the following securities are specifically excluded from the above definition of "Financing Securities": (a) loans, debentures convertible notes, and the like so long as they have not yet been actually exercised, exchanged, or converted into shares of the Company ("Loans"); notwithstanding the aforesaid, it is agreed that any convertible notes which may be issued to Teva under the Founders Agreement shall not be deemed as a Loan for purpose of this provision, but rather shall be deemed Financing Securities; (b) securities issued pursuant to or under various incentive arrangements (e.g., employees and service providers stock incentive plans, stock grants to directors and officers, etc.); (c) securities issued in consideration for goods or services provided and the like issuances to equipment lessors, acquisition of other corporations, etc.); (d) securities issued upon exercise or conversion of shares, options, warrants, convertible notes and the like securities (the "Underlying Securities"), if the Underlying Securities were already included in the definition of Financing Securities or if they were exempt from the definition of Underlying Securities; (e) securities issued to all shareholders of the Company in connection with any stock combination or subdivision or split, issue of bonus shares or stock dividends, or any other similar recapitalization of the share capital of the Company; (f) securities issued in an M&A Transaction; or (g) securities issued to the public.

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#### Annex I

#### **Irrevocable Power of Attorney Form**

Until the consummation of an initial public offering (an "**IPO**") of the securities of BioLineRx Ltd. (the "**Company**"), I, the undersigned, do hereby grant to the person or entity designated by the Company's Board of Directors or by a committee thereof, with full powers of substitution of the Company's Board of Directors (the "**Representative**"), complete and unlimited authority to act on my behalf, and I hereby appoint the Representative as my agent and attorney-infact, with respect to any matter whatsoever related to voting all shares in the Company may choose to enter into, and I irrevocably instruct the Representative to refrain from any vote of the Shares. To the extent that any waiver or the like consent shall be required from the shareholders of the Company with respect to the convening of any shareholders meetings, minimum notice of meetings and votes, and the like procedural aspects of shareholders meetings or votes, the Representative shall be authorized to sign any waiver or the like consent as may be signed by all or substantially all of the shareholders of the Company. I hereby authorize the Representative to take any further action which the Representative shall consider necessary or advisable in connection with any of the foregoing, hereby giving the Representative full power and authority to do and perform each and every act or thing whatsoever requisite or advisable to be done in and about the foregoing as fully as the undersigned might or could do if personally present, and hereby ratifying and confirming all that the Representative shall lawfully do or cause to be done by virtue hereof. I will hold the Representative harmless against any cost or expense reasonably incurred by him arising out of any act or omission to act in connection with the aforesaid, unless arising out of the Representative's own fraud or bad faith.

I acknowledge and agree that this power of attorney: (i) is a special power of attorney coupled with an interest and is irrevocable; (ii) shall survive any event of bankruptcy, death, adjudication of incompetence or the like, and (iii) shall survive the transfer of my shares in the Company, until duly replaced by a similar power of attorney executed by the transferee. Notwithstanding anything herein to the contrary, the power of attorney granted hereunder shall become null and void upon the consummation of an IPO.

Signature: /s/ Morris Laster

Name:

Date:



January 8, 2004

Dr. Moshe Phillip 51 Shimon Ben Tsvi Street Givataim, Israel

#### Re: Engagement Offer

We would like to congratulate you on your offer to join the BioLineRx family and wish you a fulfilling and productive work experience.

Below please find our offer for your employment with us. By signing this letter you indicate your acceptance to the offer and thus turn this letter into a binding employment contract between you and us (this "**Agreement**"). For purposes of convenience, BioLineRx Ltd. will be called in this letter the "Company" or "we" and you will be called the "Employee" or "you".

### General

1. <u>Position</u>. You shall serve in the position described in <u>Exhibit A</u>. In such position you shall report regularly to, and be subject to the direction and control of, the Company's CEO. You shall perform your duties diligently, conscientiously and in furtherance of the Company's best interests. You agree and undertake to inform the Company, immediately after you become aware of it, of any matter that may in any way raise a conflict of interest between yourself and the Company. You shall not receive during your employment by the Company any payment, compensation or benefit from any third party in connection, directly or indirectly, with the execution of your position in the Company. The Company hereby declares its knowledge and acceptance of your employment by third parties and your involvement in research and the academic world (as listed in <u>Exhibit C</u> attached and as amended from time to time in consultation with the Company). The Company is aware that your other employment and activities may impose limitations on your time in the Company's Jerusalem office, subject to specifics outlined below and reflected in Exhibit A attached.

2. <u>Employment</u>. You will be function as an employee of the Company and a member of its management team. You shall devote substantial time and attention to the business of the Company taking into consideration the Company's interests and your commitments to other parties and or activities as listed in Exhibit C and as amended from time to time in consultation with the Company. Recognizing your other commitments, it has been agreed that while you will make best efforts to be available to the Company as needed, your minimum time on site at the Company's facilities in Jerusalem will be as listed in Exhibit A, unless otherwise agreed by the Company or dictated by work requirements (e.g., out of office meetings, travel, etc.). The Company confirms that except as required by specific high level meetings (e.g., Board of Directors) you will be unavailable to the Company on Wednesdays. You confirm and declare that your position is one that requires a special measure of personal trust and loyalty. Accordingly, the provisions of the Hours of Work and Rest Law-1951 shall not apply to you and you shall not be entitled to any compensation for working more than the maximum number of hours per week set forth in said law or any other applicable law.

3. <u>Location</u>. You shall perform your duties hereunder at the Company's facilities in Israel agreed above and as detailed in Exhibit A, but you understand and agree that your position may involve significant domestic and international travel. In light of your commitments to other parties and or activities, such travel shall require your consent.

EXHIBIT 10.2

4. <u>Employee's Representations and Warranties</u>. You represent and warrant that the execution and delivery of this Agreement and the fulfillment of all its terms: (i) will not constitute a default under or conflict with any agreement or other instrument to which you are a party to or by which you are bound; and (ii) to the best of your knowledge do not require the consent of any person or entity. Where approvals are required, you hereby warrant that such approvals shall be received in writing and shared with the Company. Further, with respect to any past engagement you may have had with third parties and with respect to any engagement you may have with any third party during the term of your engagement with the Company (for purposes hereof, such third parties shall be referred to as "**Other Employers**"), you represent, warrant and undertake that: (a) your engagement with the Company is and/or will not be in breach of your undertakings towards Other Employers, and (b) you will not disclose to the Company, or use, in provision of any services to the Company, any proprietary or confidential information belonging to any Other Employers.

# Term of Employment

5. <u>Term</u>. Your employment by the Company shall be deemed to have commenced on the date set forth in <u>Exhibit A</u> (the "Commencement Date") and shall continue until it is terminated pursuant to the terms set forth herein.

6. <u>Termination at Will</u>. Either party may terminate the employment relationship hereunder at any time by giving the other party a written notice (the **"Notice Period**"). The employment relations shall be terminated immediately upon receiving such notice

7. <u>Termination for Cause</u>. In the event of a termination for Cause by the Company (as defined below), the Company may immediately terminate the employment relationship effective as of the time of the notice of same. **"Cause by Company"**, means (a) a serious breach of trust including but not limited to theft, embezzlement, self-dealing, prohibited disclosure to unauthorized persons or entities of confidential or proprietary information of or relating to Company and the engaging by yourself in any prohibited business competitive to the business of the Company; or (b) any willful failure to perform any of your fundamental functions or duties hereunder, which was not cured within thirty (30) days after receipt by you of written notice thereof, or (c) other cause justifying termination or dismissal without severance payment under applicable law.

8. <u>Notice Period; End of Relations</u>. You shall assist the Company with the integration into the Company of the person who will assume your responsibilities

# **Covenants**

9. <u>Proprietary Information; Confidentiality and Non-Competition</u>. By executing this letter you confirm and agree to the provisions of the Company's Proprietary Information, Confidentiality and Non-Competition Agreement attached in **Exhibit B** hereto.

# Salary; Insurance; Advanced Study Fund

10. <u>Salary</u>. The Company shall pay to you as compensation for the employment services, an aggregate monthly compensation in the amount set forth in <u>Exhibit A</u> (the "Salary"). Except as specifically set forth herein, the Salary includes any and all payments to which you are entitled from the Company hereunder and under any applicable law, regulation or agreement. The Salary includes any and all reimbursement of daily travel costs to which you are entitled under applicable law, and any and all other payments to which you are entitled from the Company hereunder and under any applicable law, regulation or agreement. The Salary includes any and all reimbursement of daily travel costs to which you are entitled under applicable law, and any and all other payments to which you are entitled from the Company hereunder and under any applicable law, regulation or agreement. Your Salary and other terms of employment may be reviewed and updated, from time to time by the Company's management, at its discretion. The Salary is to be paid to you no later then the 5<sup>th</sup> day of each calendar month after the month for which the Salary is paid after deduction of applicable taxes and the like payments.

11. <u>Insurance and Social Benefits</u>. The Company will insure you under an "Manager's Insurance Scheme" to be selected by the Company in coordination with you; or if so requested by you under your existing "Manager's Insurance Scheme" (the "**Insurance Scheme**") as follows: (i) the Company will pay an amount equal to 5% of the Salary towards a fund for life insurance and pension, and shall deduct 5% from the Salary and pay such amount towards the Insurance Scheme for your benefit; (ii) the Company will pay an amount of up to 2.5% of the Salary towards a fund for the event of loss of working ability (Ovdan Kosher Avoda); and (iii) the Company will pay an amount equal to 8 1/3% of the Salary towards a fund for severance compensation. It is agreed that in case of termination of your employment under any circumstances other than For Cause by law, the Company shall have released to you the Insurance scheme including that portion of the Insurance Scheme paid towards a fund for severance compensation (sub-clause (iii) above), and the same shall constitute as part of the severance compensation to which you are entitled. The Company shall sign an automatic transfer deed waiving any right to withhold or prevent the transfer of the ownership of the Insurance Scheme to you other than for cause by law.

The Company together with you will maintain an advanced study fund (Keren Hishtalmut Fund) such that you and the Company shall contribute to such fund an amount equal to 2.5% and 7.5%, respectively. Your aforementioned contribution is to be transferred to such fund by the Company from each monthly Salary payment. ..

### **Additional Benefits**

12. <u>Expenses</u>. The Company will reimburse you for pre approved by your superior, business expenses borne by you, in accordance with the Company's policies as determined by the Company from time to time. As a condition to reimbursement, you shall be required to provide the Company with all invoices, receipts and other evidence of expenditure as may be reasonably required by the Company from time to time.

12.1 Professional Literature, Conferences. You shall be entitled to participate in professional conferences and to purchase professional literature on the Company's expense at with prior approval of Company management.

13. <u>Vacation</u>. You shall be entitled to that number of vacation days per year as set forth in **Exhibit A**, and the use of said vacation days will be coordinated with the Company. In the event that the demands of your activities preclude or limit your ability to actually use such vacation days in any year, you shall be entitled to the balance of the unused vacation only in the next succeeding year or, if unable to take the balance in that next succeeding year, to receive an amount equal to the rate of Salary then applicable to the vacation time not taken during such year.

14. <u>Sick Leave; Recreation Pay</u>. You shall be entitled to sick leave and Recreation Pay (Dmei Havra'a) pursuant to applicable law.

15. <u>Options</u>., you shall be granted options to purchase 160,000 Ordinary Shares par value NIS 0.01 each of the Company to be granted pursuant to, and in accordance with, the terms and conditions of a share option plan adopted by the Company (the "Options"). The options shall be purchased in an exercise price of \$0.01 per share (**Exercise Price**) The Options shall be subject to vesting over a period of 4 (four) years as follows: 25% (twenty five percent) of the Options shall be deemed vested at the end of 12 (twelve) months from the Commencement Date, and the remaining 75% (seventy five percent) of the Options shall vest in twelve (12) equal quarterly installments, with eight percent and one third of a percent (8.333%) of such amount of the remaining Options vesting at the end of every three months for a period of three years (the entire four-year period shall be referred to as the "**Vesting Period**"). Upon termination of this Agreement for any reason all of the then unvested Options shall expire immediately and/or may than be re-granted by the Company to retain your services for any minimum period.

Notwithstanding the aforesaid, it is agreed that in the event of death of or permanent severe disability that no longer enables you to reasonably work, 50% (fifty percent) all the Options then still subject to vesting shall be deemed fully vested. The above referred to number of shares assumes completion of a 1:20 split of the share capital of the Company.

16. <u>Automobile</u>. For purposes of performance of your duties and tasks, the Company shall make available to you a leased automobile, of a type 3 (e.g., Mazda 6 2.0 liter) (the "**Leased Car**"). The Company shall bear and pay for the cost of fuel, maintenance and repairs, and any insurance deductibles for the Leased Car. You shall be liable for paying any parking and/or traffic fines received in connection herewith, and for indemnification of the Company in case of negligent use of the Leased Car and/or use of the Leased Car not in accordance with the Company's applicable policies. For the avoidance of doubt, you agree and confirm that the cost of the leasing and/or the cost of the use of the Leased Car shall not constitute a component of your Salary, including with regard to social benefits and/or any other right to which you are entitled by virtue of this Agreement or under law. The Leased Car will remain in the Company's ownership, and will be returned to the Company by you upon termination of your employment with the Company for any reason at the end of the Notice Period.

### **Miscellaneous**

17. The laws of the State of Israel shall apply to this Agreement and the sole and exclusive place of jurisdiction in any matter arising out of or in connection with this Agreement shall be the Tel-Aviv Regional Labor Court; the provisions of this letter are in lieu of the provisions of any collective bargaining agreement, and therefore, no collective bargaining agreement shall apply with respect to the relationship between the parties hereto (subject to the applicable provisions of law); no failure, delay of forbearance of either party in exercising any power or right hereunder shall in any way restrict or diminish such party's rights and powers under this Agreement, or operate as a waiver of any breach or nonperformance by either party of any terms of conditions hereof; in the event it shall be determined under any applicable law that a certain provision set forth in this Agreement is invalid or unenforceable, such determination shall not affect the remaining provisions of this Agreement unless the business purpose of this Agreement is substantially frustrated thereby; this Agreement constitutes the entire understanding and agreement between the parties hereto, supersedes any and all prior discussions, agreements and correspondence with regard to the subject matter hereof, and may not be amended, modified or supplemented in any respect, except by a subsequent writing executed by both parties hereto; you acknowledge and confirm that all terms of your employment are personal and confidential, and undertake to keep such term in confidence and refrain from disclosing such terms to any third party.

18. Advertisement. The company is aware to the importance of your reputation and status. The company shall use your name responsibly in the Company's official or unofficial publication or prints consulting with you in advance. Not derogating from the above, you hereby confirm that your title as listed in Exhibit A has been reviewed and approved by you, and will be reflected on your business card and Company literature and website.

Please indicate your acceptance to the terms of this letter by signing and dating them and returning a counterpart hereof to us. The Company's signature on this letter will bind the Company only if coupled with your signature.

Sincerely yours,

/s/ Morris Laster BioLineRx Ltd. By: Morris Laster

I, the undersigned, Moshe Phillip, hereby agree to all terms of this letter, and in witness hereof have signed this letter on this date of January 13, 2004.

Signature: /s/ Moshe Phillip

# Exhibit A To Personal Employment Agreement by and between BioLineRx Ltd. and the Employee whose name is set forth herein

1.	Name of Employee:	Dr. Moshe Phillip
2.	ID No. of Employee:	52590908
3.	Address of Employee:	51 Shimon Ben Tsvi Street, Givataim, Israel
4.	Position in the Company:	Vice President of Medical Affairs, Senior Medical Advisor
5.	Commencement Date:	7.1.04
6.	Salary:	USD 10,000 (Gross) paid in NIS
7.	Vacation Days Per Year:	20 days
8.	Working Days in Jerusalem at BioLineRx Offices	Sunday afternoon, all day Tuesday (except for miluim service requirements), Thursday afternoon, and as required Monday afternoon.

### Exhibit B To Personal Employment Agreement by and between BioLineRx Ltd. and the Employee whose name is set forth herein

Name of Employee:	Dr. Moshe Phillip
ID No. of Employee:	52590908

# 1. General

All the capitalized terms herein shall have the meanings ascribed to them in the Letter of Agreement to which this Exhibit is attached (the "**Agreement**"). For purposes of any undertaking of the Employee toward the Company, the term Company shall include all subsidiaries and affiliates of the Company that the employee had been exposed to their activities.

The Employee's obligations and representations and the Company's rights under this Exhibit shall apply as of the Commencement Date of the employment relationship between the Company and the Employee, and as of the first time the Employee became engaged with Company, regardless of the date of execution of the Agreement.

# 2. Confidentiality; Proprietary Information

2.1 "**Proprietary Information**" means confidential and proprietary information concerning the business and financial activities of the Company, including patents, patent applications, trademarks, copyrights and other intellectual property, and information relating to the same, technologies and products (actual or planned), know how, inventions, research and development activities, trade secrets and industrial secrets, and also confidential commercial information such as investments, investors, employees, customers, suppliers, marketing plans, etc., all the above - whether documentary, written, oral or computer generated. Proprietary Information shall also include information of the same nature which the Company may obtain or receive from third parties.

2.2. Proprietary Information shall be deemed to include any and all proprietary information disclosed by or on behalf of the Company and irrespective of form but excluding information that (i) was known to Employee prior to Employee's association with the Company and can be so proven; (ii) is or shall become part of the public knowledge except as a result of the breach of the Agreement or this Exhibit by the Employee; (iii) reflects general skills and experience gained during Employee's engagement by the Company; or (iv) reflects information and data generally known in the industries or trades in which the Company operates (v) reflects information and data that shall become part of the employee's knowledge as a result of the employee's other employers, academic status and/or employees individual research without breach of this Exhibit or Agreement .

2.3. Employee recognizes that the Company received and will receive confidential or proprietary information from third parties, subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. In connection with such duties, such information shall be deemed Proprietary Information hereunder, *mutatis mutandis*..

2.4 Employee agrees that all Proprietary Information, and patents, trademarks, copyrights and other intellectual property and ownership rights in connection therewith shall be the sole property of the Company and its assigns. At all times, both during Employee's engagement by the Company and after Employee's termination, Employee will keep in confidence and trust all Proprietary Information, and the Employee will not use or disclose any Proprietary Information or anything relating to it without the written consent of the Company, except as may be necessary in the ordinary course of performing Employee's duties under the Agreement. For the avoidance of all doubts, the employee shall be the sole owner of any Proprietary Information, and patents, trademarks, copyrights and other intellectual property that were created or invented by him not as a result of his employment with the Company and without breach of this Exhibit or Agreement.

2.5. Upon termination of Employee's employment with the Company, Employee will promptly deliver to the Company all documents and materials of any nature pertaining to Employee's work with the Company, and will not take with Employee any documents or materials or copies thereof containing any Proprietary Information.

2.6. Employee's undertakings set forth in this Section 2 shall remain in full force and effect after termination of this Agreement or any renewal thereof.

# 3. Disclosure and Assignment of Inventions

3.1. **"Inventions**" means any and all inventions, improvements, designs, concepts, techniques, methods, systems, processes, know how, computer software programs, databases, mask works and trade secrets, whether or not patentable, copyrightable or protectible as trade secrets; "**Company Inventions**" means any Inventions that are made or conceived or first reduced to practice or created by Employee, whether alone or jointly with others, during the period of Employee's employment with the Company, and which: (i) are developed using equipment, supplies, facilities or Proprietary Information of the Company, (ii) result from work performed by Employee for the Company,

3.2. Employee undertakes and covenants that Employee will promptly disclose in confidence to the Company all Inventions deemed as Company Inventions.

3.3. Employee hereby irrevocably transfers and assigns to the Company all worldwide patents, patent applications, copyrights, mask works, trade secrets and other intellectual property rights in any Company Invention, and any and all moral rights that Employee may have in or with respect to any Company Invention.

3.4. Employee agrees to assist the Company, at the Company's expense, in every proper way to obtain for the Company and enforce patents, copyrights, mask work rights, and other legal protections for the Company Inventions in any and all countries. Employee will execute any documents that the Company may reasonably request for use in obtaining or enforcing such patents, copyrights, mask work rights, trade secrets and other legal protections. Such obligation shall continue beyond the termination of Employee's employment with the Company. Employee hereby irrevocably designates and appoints the Company and its authorized officers and agents as Employee's agent and attorney in fact, coupled with an interest to act for and on Employee's behalf and in Employee's stead to execute and file any document needed to apply for or prosecute any patent, copyright, trademark, trade secret, any applications regarding same or any other right or protection relating to any Proprietary Information (including Company Inventions), and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights, trademarks, trade secrets or any other right or protection relating to any Proprietary Information (including Company Inventions), with the same legal force and effect as if executed by Employee himself.

# 4. Non-Competition

4.1. In consideration of Employee's terms of employment, which include special compensation for Employee's undertakings under this Section 4, and in order to enable the Company to effectively protect its Proprietary Information, Employee agrees and undertakes that unless expressly approved in writing by the Company, he will not, so long as he is employed by the Company and for a period of twelve (9) months following termination of his employment for whatever reason, directly or indirectly, be engaged in, or employed by, any business or venture that is engaged in activities competing directly with the Company and its business activities in which Employee was involved; provided, however, that Employee may own securities of any corporation which is engaged in such business and is publicly owned and traded but in an amount not to exceed at any one time one percent (1%) of any class of stock or securities of such corporation, and so long as Employee has no active role in such corporation as director, employee, consultant or otherwise, unless expressly approved in writing by the Company. For avoidance of doubts, the Employee shall be permited and able to be engaged in the drug development field as long as it doesn't compete directly with the drugs the Company has been involved in at the time of the termination of the employment.

4.2. Employee agrees and undertakes that during the period of Employee's employment and for a period of twelve (12) months following termination of his employment for whatever reason, Employee will not, directly or indirectly, including personally or in any business in which Employee may be an officer, director or shareholder, solicit for employment any person who is employed by the Company, or retained by the Company as a consultant, advisor or the like service provider (collectively, "**Consultant**"), if such Consultant is prevented thereby from continuing to render its services to the Company, on the date of such termination or during the preceding twelve (12) months.

#### 5. Reasonableness of Protective Covenants

Insofar as the protective covenants set forth in this Agreement are concerned, Employee specifically acknowledges, stipulates and agrees as follows: (i) the protective covenants are reasonable and necessary to protect the goodwill, property and Proprietary Information of the Company, and the operations and business of Company; and (ii) the time duration of the protective covenants is reasonable and necessary to protect the goodwill and the operations and business of Company, and does not impose a greater restrain than is necessary to protect the goodwill or other business interests of Company. Nevertheless, if any of the restrictions set forth in this Exhibit is found by a court having jurisdiction to be unreasonable or overly-broad as to geographic area, scope or time or to be otherwise unenforceable, the parties intend for the restrictions set forth in this Exhibit to be reformed, modified and redefined by such court so as to be reasonable and enforceable and, as so modified by such court, to be fully enforced.

### 6. Intent of Parties

Employee recognizes and agrees that: (i) this Exhibit is necessary and essential to protect the business of Company and to realize and derive all the benefits, rights and expectations of conducting Company's business; (ii) the area and duration of the protective covenants contained herein are in all things reasonable; and (iii) good and valuable consideration exists under the Agreement, for Employee's agreement to be bound by the provisions of this Exhibit.

#### Exhibit A To Personal Employment Agreement by and between BioLineRx Ltd. and the Employee whose name is set forth herein

- 1. Name of Employee: Dr. Moshe Phillip
- 2. ID No. of Employee: 52590908

List of current Employement, Consulting, and other Committeents:

\*Director institute of pediatric endocrinology and diabetes and vice dean of medical school – head of the school of continuing medical education. Private consultant in Ped. Endocrinology.

\*Consultant to Dikla, Reshet Rofim, Mushlam, IMA-(workshops organizing group).

\*Consultant to Nilimed – (insulin pump)

\*Consultant to Transfarma (transdermal delivery of hormones)



EXHIBIT 10.3

October 13, 2004

Dr. Kinneret Savitsky 44 Metudela Street <u>Tel Aviv</u>

### Re: Engagement Offer

Further to our discussions, this is to set forth in writing our agreements regarding your engagement as the General Manager of a wholly owned subsidiary company which may be established by us as the management company of a biotechnology incubator in Jerusalem which shall be established by us if and when we shall win a tender of the Office of the Israeli Chief Scientist to establish, operate and manage such an incubator. For purposes of this letter agreement, we shall be referred to as "**BioLine**", the biotechnology incubator shall be referred to as the "**Incubator**", and the Incubator's management company shall be referred to as the "**Management Company**".

Should you accept the terms of this letter agreement, it shall constitute a binding agreement (this "**Agreement**") by and between you and the Management Company, if and when BioLine shall win the tender to establish, operate and manage the Incubator and upon actual incorporation of the Management Company. In such case, immediately following the incorporation of the Management Company, the Management Company shall automatically and without the need to take any action, be deemed to have assumed all of the rights and obligations under this Agreement, and BioLine shall be fully released from any and all liabilities and responsibilities, as of the date of execution of this Agreement, and at such time, BioLine and you shall terminate your engagement as an employee of BioLine.

The terms of your employment with the Management Company shall be as follows:

#### **General**

- 1. <u>Position</u>. You shall serve as the General Manager of the Management Company. In such position you shall report regularly to, and be subject to the direction and control of, the Board of Directors of the Management Company. You shall perform your duties diligently, conscientiously and in furtherance of the best interests of the Management Company. You agree and undertake to inform the Management Company, immediately after you become aware of it, of any matter that may in any way raise a conflict of interest between yourself and the Management Company. You shall not receive during your employment by the Management Company any payment, compensation or benefit from any third party in connection, directly or indirectly, with the execution of your position in the Management Company.
- 2. <u>Full Time Employment</u>. You will be employed on a full time basis. You shall devote your entire business time and attention to the business of the Management Company and you shall not undertake or accept any other paid or unpaid employment or occupation or engage in any other business activity except with the prior written consent of the Management Company, which shall not be unreasonably withheld. You confirm and declare that your position is one that requires a special measure of personal trust and loyalty. Accordingly, the provisions of the Hours of Work and Rest Law-1951 shall not apply to you and you shall not be entitled to any compensation for working more than the maximum number of hours per week set forth in said law or any other applicable law.

3. <u>Employee's Representations and Warranties</u>. You represent and warrant that the execution and delivery of this Agreement and the fulfillment of all its terms: (i) will not constitute a default under or conflict with any agreement or other instrument to which you are a party to or by which you are bound; and (ii) do not require the consent of any person or entity. Further, with respect to any past engagement you may have had with third parties and with respect to any allowed engagement you may have with any third party during the term of your engagement with the Management Company (for purposes hereof, such third parties shall be referred to as "**Other Employers**"), you represent, warrant and undertake that: (a) your engagement with the Management Company is and/or will not be in breach of your undertakings towards Other Employers, and (b) you will not disclose to the Management Company, or use, in provision of any services to the Management Company, any proprietary or confidential information belonging to any Other Employers.

# Term of Employment

- 4. <u>Term</u>. Your employment by the Management Company shall commence upon formal notice which shall be given to you by the Management Company, upon its incorporation (subject to the conditions precedent set forth in the recital to this Agreement) (the "**Commencement Date**") and shall continue until it is terminated pursuant to the terms set forth herein.
- 5. <u>Termination at Will</u>. Either party may terminate the employment relationship hereunder at any time by giving the other party a prior written notice of at least 30 (thirty) days (the "**Notice Period**").
- 6. <u>Termination for Cause</u>. In the event of a termination for Cause (as defined below), the Management Company may immediately terminate the employment relationship effective as of the time of notice of the same. "**Cause**" means (a) a serious breach of trust including but not limited to theft, embezzlement, self-dealing, prohibited disclosure to unauthorized persons or entities of confidential or proprietary information of or relating to the Management Company and the engaging by yourself in any prohibited business competitive to the business of the Management Company; or (b) any willful failure to perform or failure to perform competently any of your fundamental functions or duties hereunder, which was not cured within thirty (30) days after receipt by you of written notice thereof, or (c) other cause justifying termination or dismissal without severance payment under applicable law.
- 7. Notice Period; End of Relations. During the Notice Period, the employment relationship hereunder shall remain in full force and effect and there shall be no change in your position with the Management Company, in your Salary, or in any other obligations of either party hereunder, unless otherwise determined by the Management Company in a written notice to you, and you shall cooperate with the Management Company and assist the Management Company with the integration into the Management Company of the person who will assume your responsibilities. However, the Management Company, at its own discretion, may terminate this Agreement and the employment relationship at any time immediately upon a written notice and pay you a one time amount equal to the Salary and the benefits referred to in Section 10 below that would have been paid to you during the Notice Period in lieu of the prior notice.

### **Covenants**

8. <u>Proprietary Information; Confidentiality and Non-Competition</u>. By executing this Agreement you confirm and agree to the provisions of the Management Company's Proprietary Information, Confidentiality and Non-Competition Agreement attached in <u>Exhibit A</u> hereto.

#### Salary; Insurance; Advanced Study Fund

- 9. Salary. The Management Company shall pay to you as compensation for the employment services, an aggregate monthly compensation in the amount of NIS 62,000 (sixty two thousand New Israeli Shekels) (Gross) (the "Salary"). Except as specifically set forth herein, the Salary includes any and all payments to which you are entitled from the Management Company hereunder and under any applicable law, regulation or agreement. The Salary includes any and all reimbursement of daily travel costs to which you are entitled under applicable law, and any and all other payments to which you are entitled from the Management Company hereunder and under any applicable law, and any and all other payments to which you are entitled from the Management Company hereunder and under any applicable law, regulation or agreement. Your Salary and other terms of employment may be reviewed and updated, from time to time by the Management Company's management, at its discretion. The Salary is to be paid to you no later then the 5<sup>th</sup> day of each calendar month after the month for which the Salary is paid after deduction of applicable taxes and the like payments.
- 10. <u>Insurance and Social Benefits</u>. The Management Company will insure you under an "Manager's Insurance Scheme" to be selected by the Management Company in coordination with you; or if so requested by you under your existing "Manager's Insurance Scheme" (the "**Insurance Scheme**") as follows: (i) the Management Company will pay an amount equal to 5% of the Salary towards a fund for life insurance and pension, and shall deduct 5% from the Salary and pay such amount towards the Insurance Scheme for your benefit; (ii) the Management Company will pay an amount of up to 2.5% of the Salary towards a fund for the event of loss of working ability (Ovdan Kosher Avoda); and (iii) the Management Company will pay an amount equal to 8 1/3% of the Salary towards a fund for severance compensation. The Management Company together with you will maintain an advanced study fund (Keren Hishtalmut Fund) such that you and the Management Company shall contribute to such fund an amount equal to 2.5% and 7.5%, respectively, up to the ceiling dictated by applicable laws. Your aforementioned contribution is to be transferred to such fund by the Management Company from each monthly Salary payment. It is agreed that in case of termination of your employment under any circumstances other than For Cause, the Management Company shall constitute as part of the severance compensation to which you are entitled.

### **Additional Benefits**

- 11. <u>Expenses</u>. The Management Company will reimburse you for pre approved business expenses borne by you, in accordance with the Management Company's policies as determined by the Management Company from time to time. As a condition to reimbursement, you shall be required to provide the Management Company with all invoices, receipts and other evidence of expenditure as may be reasonably required by the Management Company from time to time.
- 12. <u>Vacation</u>. You shall be entitled to 20 (twenty) vacation days per year, and the use of said vacation days will be coordinated with the Management Company. In the event that the demands of your activities preclude or limit your ability to actually use such vacation days in any year, you shall be entitled to the balance of the unused vacation only in the next succeeding year or, if unable to take the balance in that next succeeding year, to receive an amount equal to the rate of Salary then applicable to the vacation time not taken during such year.
- 13. <u>Sick Leave; Recreation Pay</u>. You shall be entitled to sick leave and Recreation Pay (Dmei Havra'a) pursuant to applicable law.



- 14. <u>Options</u>. BioLine has granted you options to purchase 200,000 (two hundred thousand) Ordinary Shares par value NIS 0.01 each of BioLine, which options will be granted pursuant to, and in accordance with, the terms and conditions of a share option plan adopted by BioLine (the "**Options**"). The Options are subject to vesting over a period of 4 (four) years as follows: 25% (twenty five percent) of the Options shall be deemed vested at the end of 12 (twelve) months from August 15, 2004, and the remaining 75% (seventy five percent) of the Options shall vest in twelve (12) equal quarterly installments, with eight percent and one third of a percent (8.333%) of such amount of the remaining Options vesting at the end of every three months for a period of three years (the entire four-year period shall be referred to as the "**Vesting Period**"). The above referred to grant of Options shall remain in force and effect as of the initial date of August 15, 2004. Upon termination of this Agreement for any reason all the then unvested Options shall expire immediately and/or may then be re-granted by BioLine to any person or entity at its discretion. For avoidance of doubt, it is clarified that nothing in this Agreement shall be deemed as an undertaking of either of the Management Company or BioLine to retain your services for any minimum period. Notwithstanding the aforesaid, it is agreed that in the event of death of or permanent severe disability that no longer enables you to reasonably work, 50% (fifty percent) all the Options then still subject to vesting shall be deemed fully vested.
- 15. <u>Automobile</u>. For purposes of performance of your duties and tasks, the Management Company shall make available to you a leased automobile, of a type 3 (e.g., Mazda 6 2.0 liter), in accordance with its policies (the "**Leased Car**"). The Management Company shall bear and pay for the cost of fuel, maintenance and repairs, and any insurance deductibles for the Leased Car. You shall be liable for paying any parking and/or traffic fines received in connection herewith, and for indemnification of the Management Company in case of negligent use of the Leased Car and/or use of the Leased Car not in accordance with the Management Company's applicable policies. For the avoidance of doubt, you agree and confirm that the cost of the leasing and/or the cost of the use of the Leased Car shall not constitute a component of your Salary, including with regard to social benefits and/or any other right to which you are entitled by virtue of this Agreement or under law. The Leased Car will remain in the Management Company's ownership, and will be returned to the Management Company by you immediately upon termination of your employment with the Management Company for any reason or upon notice of termination, if and as of the date on which your services are no longer required by the Management Company.

# **Miscellaneous**

16. The laws of the State of Israel shall apply to this Agreement and the sole and exclusive place of jurisdiction in any matter arising out of or in connection with this Agreement shall be the Tel-Aviv Regional Labor Court; the provisions of this Agreement are in lieu of the provisions of any collective bargaining agreement, and therefore, no collective bargaining agreement shall apply with respect to the relationship between the parties hereto (subject to the applicable provisions of law); no failure, delay of forbearance of either party in exercising any power or right hereunder shall in any way restrict or diminish such party's rights and powers under this Agreement, or operate as a waiver of any breach or nonperformance by either party of any terms of conditions hereof; in the event it shall be determined under any applicable law that a certain provision set forth in this Agreement is invalid or unenforceable, such determination shall not affect the remaining provisions of this Agreement unless the business purpose of this Agreement is substantially frustrated thereby; this Agreement constitutes the entire understanding and agreement between the parties hereto, supersedes any and all prior discussions, agreements and correspondence with regard to the subject matter hereof, and may not be amended, modified or supplemented in any respect, except by a subsequent writing executed by both parties hereto; you acknowledge and confirm that all terms of your employment are personal and confidential, and undertake to keep such term in confidence and refrain from disclosing such terms to any third party.

Please indicate your acceptance to the terms of this letter agreement by signing and dating them and returning a counterpart hereof to us. Our signature on this letter agreement (on behalf of the Management Company to be established) will bind the Management Company only if coupled with your signature.

Sincerely yours,

#### /s/Morris C. Laster

**BioLineRx Ltd.**, on behalf of the Management Company (to be established)

### By: MORRIS C. LASTER

I, the undersigned, Kinneret Savitsky, hereby agree to all terms of this letter agreement, and in witness hereof have signed this letter on this date of [4/10], 2004.

Signature: /s/Kinneret Savitsky KINNERET SAVITSKY

### Exhibit A <u>Proprietary Information, Confidentiality and Non-Competition Agreement</u>

#### 1. <u>General</u>

All the capitalized terms herein shall have the meanings ascribed to them in the letter agreement to which this Exhibit is attached (the "**Agreement**"). The employee shall be referred to as the "**Employee**" and the employer shall be referred to as the "**Company**". For purposes of any undertaking of the Employee toward the Company herein, the term Company shall also include the Incubator and all companies and other legal entities which may be situated in the Incubator or receive funding or services from the Incubator.

The Employee's obligations and representations and the Company's rights under this Exhibit shall apply as of the Commencement Date of the employment relationship between the Company and the Employee, and as of the first time the Employee became engaged with Company, regardless of the date of execution of the Agreement.

### 2. Confidentiality; Proprietary Information

2.1 "**Proprietary Information**" means confidential and proprietary information concerning the business and financial activities of the Company, including patents, patent applications, trademarks, copyrights and other intellectual property, and information relating to the same, technologies and products (actual or planned), know how, inventions, research and development activities, trade secrets and industrial secrets, and also confidential commercial information such as investments, investors, employees, customers, suppliers, marketing plans, etc., all the above - whether documentary, written, oral or computer generated. Proprietary Information shall also include information of the same nature which the Company may obtain or receive from third parties.

2.2. Proprietary Information shall be deemed to include any and all proprietary information disclosed by or on behalf of the Company and irrespective of form but excluding information that (i) was known to Employee prior to Employee's association with the Company and can be so proven; (ii) is or shall become part of the public knowledge except as a result of the breach of the Agreement or this Exhibit by the Employee; (iii) reflects general skills and experience gained during Employee's engagement by the Company; or (iv) reflects information and data generally known in the industries or trades in which the Company operates.

2.3. Employee recognizes that the Company received and will receive confidential or proprietary information from third parties, subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. In connection with such duties, such information shall be deemed Proprietary Information hereunder, *mutatis mutandis*.

2.4 Employee agrees that all Proprietary Information, and patents, trademarks, copyrights and other intellectual property and ownership rights in connection therewith shall be the sole property of the Company and its assigns. At all times, both during Employee's engagement by the Company and after Employee's termination, Employee will keep in confidence and trust all Proprietary Information, and the Employee will not use or disclose any Proprietary Information or anything relating to it without the written consent of the Company, except as may be necessary in the ordinary course of performing Employee's duties under the Agreement.

2.5. Upon termination of Employee's employment with the Company, Employee will promptly deliver to the Company all documents and materials of any nature pertaining to Employee's work with the Company, and will not take with Employee any documents or materials or copies thereof containing any Proprietary Information.

2.6. Employee's undertakings set forth in this Section 2 shall remain in full force and effect after termination of this Agreement or any renewal thereof.

# 3. Disclosure and Assignment of Inventions

3.1. "**Inventions**" means any and all inventions, improvements, designs, concepts, techniques, methods, systems, processes, know how, computer software programs, databases, mask works and trade secrets, whether or not patentable, copyrightable or protectible as trade secrets; "**Company Inventions**" means any Inventions that are made or conceived or first reduced to practice or created by Employee, whether alone or jointly with others, during the period of Employee's employment with the Company, and which: (i) are developed using equipment, supplies, facilities or Proprietary Information of the Company, (ii) result from work performed by Employee for the Company, or (iii) related to the field of business of the Company, or to specific fields of research and development undertake by the Company.

3.2. Employee undertakes and covenants that Employee will promptly disclose in confidence to the Company all Inventions deemed as Company Inventions.

3.3. Employee hereby irrevocably transfers and assigns to the Company all worldwide patents, patent applications, copyrights, mask works, trade secrets and other intellectual property rights in any Company Invention, and any and all moral rights that Employee may have in or with respect to any Company Invention.

3.4. Employee agrees to assist the Company, at the Company's expense, in every proper way to obtain for the Company and enforce patents, copyrights, mask work rights, and other legal protections for the Company Inventions in any and all countries. Employee will execute any documents that the Company may reasonably request for use in obtaining or enforcing such patents, copyrights, mask work rights, trade secrets and other legal protections. Such obligation shall continue beyond the termination of Employee's employment with the Company. Employee hereby irrevocably designates and appoints the Company and its authorized officers and agents as Employee's agent and attorney in fact, coupled with an interest to act for and on Employee's behalf and in Employee's stead to execute and file any document needed to apply for or prosecute any patent, copyright, trademark, trade secret, any applications regarding same or any other right or protection relating to any Proprietary Information (including Company Inventions), and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights, trademarks, trade secrets or any other right or protection relating to any Proprietary Information (including Company Inventions), with the same legal force and effect as if executed by Employee himself.

# 4. Non-Competition

4.1. In consideration of Employee's terms of employment, which include special compensation for Employee's undertakings under this Section 4, and in order to enable the Company to effectively protect its Proprietary Information, Employee agrees and undertakes that he will not, so long as he is employed by the Company and for a period of twelve (12) months following termination of his employment for whatever reason, directly or indirectly, be engaged in, or employed by, any business or venture that is engaged in any activities competing with the Company and its business activities in which Employee was involved, or by providing products or services substantially similar to products or services offered by the Company; <u>provided</u>, <u>however</u>, that Employee may own securities of any corporation which is engaged in such business and is publicly owned and traded but in an amount not to exceed at any one time one percent (1%) of any class of stock or securities of such corporation, and so long as Employee has no active role in such corporation as director, employee, consultant or otherwise.

4.2. Employee agrees and undertakes that during the period of Employee's employment and for a period of twelve (12) months following termination of his employment for whatever reason, Employee will not, directly or indirectly, including personally or in any business in which Employee may be an officer, director or shareholder, solicit for employment any person who is employed by the Company, or retained by the Company as a consultant, advisor or the like service provider (collectively, "**Consultant**"), if such Consultant is prevented thereby from continuing to render its services to the Company, on the date of such termination or during the preceding twelve (12) months.

### 5. Reasonableness of Protective Covenants

Insofar as the protective covenants set forth in this Agreement are concerned, Employee specifically acknowledges, stipulates and agrees as follows: (i) the protective covenants are reasonable and necessary to protect the goodwill, property and Proprietary Information of the Company, and the operations and business of Company; and (ii) the time duration of the protective covenants is reasonable and necessary to protect the goodwill and the operations and business of Company, and does not impose a greater restrain than is necessary to protect the goodwill or other business interests of Company. Nevertheless, if any of the restrictions set forth in this Exhibit is found by a court having jurisdiction to be unreasonable or overly-broad as to geographic area, scope or time or to be otherwise unenforceable, the parties intend for the restrictions set forth in this Exhibit to be reformed, modified and redefined by such court so as to be reasonable and enforceable and, as so modified by such court, to be fully enforced.

# 6. **<u>Remedies for Breach</u>**

Employee acknowledges that the legal remedies for breach of the provisions of this Exhibit may be found inadequate and therefore agrees that, in addition to all of the remedies available to Company in the event of a breach or a threatened breach of any of such provisions, the Company may also, in addition to any other remedies which may be available under applicable law, obtain temporary, preliminary and permanent injunctions against any and all such actions.

# 7. Intent of Parties

Employee recognizes and agrees that: (i) this Exhibit is necessary and essential to protect the business of Company and to realize and derive all the benefits, rights and expectations of conducting Company's business; (ii) the area and duration of the protective covenants contained herein are in all things reasonable; and (iii) good and valuable consideration exists under the Agreement, for Employee's agreement to be bound by the provisions of this Exhibit.

This Employment Agreement, dated January 2, 2007, is between BIOLINERX USA, INC a Delaware corporation (the "Company"), a wholly-owned subsidiary of BioLineRx, Ltd ("BioLineRx") and NIR GAMLIEL an individual residing at 16 Treworthy Road, North Potomac, Maryland 20878 ("Executive").

# POSITION AND RESPONSIBILITIES

**1.1 Position.** Executive is employed by the Company to render services to the Company in the position of Corporate Officer and Vice President of Business Development. Executive shall perform such duties and responsibilities as are normally related to such position in accordance with the standards of the industry and any additional duties now or hereafter assigned to Executive by the Company. Executive shall abide by the rules, regulations, and practices as adopted or modified from time to time in the Company's sole discretion. Executive shall report to the Company President. In the event that there is no President the Executive will report to the Board of Directors of the Company.

**1.2 Other Activities.** Executive shall devote his/her full business time, attention and skill to perform any assigned duties, services and responsibilities while employed by the Company, for the furtherance of the Company's business, in a diligent, loyal and conscientious manner. Except upon the prior written consent of the Company, Executive will not, during the term of this Agreement, (i) accept any other employment, or (ii) engage, directly or indirectly, in any other business activity (whether or not pursued for pecuniary advantage) that might interfere with Executive's duties and responsibilities hereunder or create a conflict of interest with the Company.

**1.3 No Conflict.** Executive represents and warrants that Executive's execution of this Agreement, Executive's employment with the Company, and the performance of Executive's proposed duties under this Agreement shall not violate any obligations Executive may have to any other employer, person or entity, including any obligations with respect to proprietary or confidential information of any other person or entity.

#### **COMPENSATION AND BENEFITS**

2.1 Base Salary. In consideration of the services to be rendered under this Agreement, the Company shall pay Executive a salary equivalent to One Hundred Seventy Thousand Dollars (\$170,000) per year ("Base Salary"). The Base Salary shall be paid in accordance with the Company's regularly established payroll practice. Executive's Base Salary shall be reduced by withholdings required by law. Executive's Base Salary will be reviewed from time to time in accordance with the established procedures of the Company for adjusting salaries for similarly situated employees and may be adjusted in the sole discretion of the Company.

2.2 Bonus Plan. Executive shall be eligible to receive one or more bonuses determined in accordance with this Section 2.2.

2.2.1 Signing Bonus. A signing bonus of US\$ 5,000, payable on the first payroll.

2.2.2 Target Bonus. For each year, Executive will be eligible to receive a Target Bonus as defined by Company's Board of Directors.

2.2.2.1 For the calendar year ending December 31, 2008, the Executive's Target Bonus shall be 25% of the Base Salary for that year for meeting the goals that shall be mutually agreed by the Executive and the Company's Board of Directors within 8 weeks of the date of the execution of this Agreement.

2.2.2.2 For the calendar year ending December 31, 2009 and thereafter, the Executive's Target Bonus shall be (i) 25% of the Base Salary for non-deal goals that shall be mutually agreed by the Executive and the Company's Board of Directors plus (ii) and an additional 35% of the base salary for each "Deal" signed, as such term is defined from time to time by the Company's Board of Directors, payable on the payroll following the Deal, and in each case subject to review and approval by the Company's Board of Directors (the "Deal Bonus").

2.2.3 Participation in Management Bonus Pool. Executive shall also be eligible to participate in any additional Deal related bonus pool then in effect.

2.3 Stock Options. The Company shall recommend to the Board of Directors of BioLineRx that Executive be provided with an option to purchase 150,000 ordinary shares of BioLineRx, subject to vesting in accordance with BioLineRx's standard terms. This recommendation will be considered for approval at the BioLineRx's next Board of Directors' meeting. The exercise price per share of any approved options will be the market price of BioLineRx's ordinary shares at the close of trading on the TASE on the day of the BioLineRx Board of Directors meeting at which such grant is approved. Executive's entitlement to any stock options that may be approved is conditioned upon Executive's signing of the Stock Option Agreement, and is subject to its terms and the terms of the Stock Option Plan under which the options are granted, including vesting requirements.

2.4 **Benefits.** Executive shall be eligible to participate in the benefits made generally available by the Company to similarly-situated employees, in accordance with the benefit plans established by the Company, and as may be amended from time to time in the Company's sole discretion. Notwithstanding anything to the contrary contained herein, the Executive shall be entitled to receive the following social benefits:

2.4.1 Standard US medical and dental insurance;

year;

2.4.2. 401K plan, under which the Company shall match up to 50% of Executive's contribution, and up to a maximum of US\$ 15,500 per

2.4.3 Standard disability and life insurance; and

2.4.4 20 vacation days per calendar year.

**2.5 Expenses.** The Company shall reimburse Executive for reasonable travel and other business expenses incurred by Executive in the performance of Executive's duties hereunder in accordance with the Company's expense reimbursement guidelines, as they may be amended at the Company's sole discretion.

2.5.1 Notwithstanding anything to the contrary contained herein, the Executive shall be entitled to reimbursement of up to \$700 per month for documented expenses associated with the leasing and operating of a car, subject to the Company's standard policies and conditions.

2.5.2 Notwithstanding anything to the contrary contained herein, the Executive shall be entitled to coverage of telecommunication expenses, subject to the Company's standard policies and conditions.

### AT-WILL EMPLOYMENT

**3.1.** Company shall have the right to terminate Executive's employment with Company at any time For Cause or Not For Cause, subject to the notice requirements described in this Section 3. Company shall have the right to terminate Executive's employment with the Company at any time upon written notice delivered to the Executive, which notice shall specify the date of termination of Executive's employment, which date shall be no less than thirty (30) days after the date notice is received by Executive. Similarly, Executive shall have the right to terminate his employment at any time upon written notice delivered to the Company, which notice shall specify the date of termination of Executive's employment which date shall be no less than thirty (30) days after the date notice is received by the Company shall also have the right, in its sole discretion, to pay Executive in lieu of the notice specified above. Notwithstanding anything to the contrary contained in this Agreement, the employment of Executive shall be "at-will" at all times. The Company or Executive may terminate Executive's employment with the Company at any time, subject to the notice provisions specified herein, for any reason or no reason at all. The at-will relationship may not be modified by anything contrary contained in or arising from any statements, policies or practices of the Company relating to the employment, discipline or termination of its employees. Upon and after such termination, all obligations of the Company under this Agreement shall cease, *provided however*, that any Deal entitling Executive to the Deal Bonus, drafts of which have already been prepared prior to termination of Executive's employment, and which is executed within ninety (90) days of Executive's termination hereunder shall entitle Executive to receive the Deal Bonus under Section 2.2.2 above.

#### 3.2. Termination For Cause.

3.2.1. "For Cause" for termination shall mean: if in the sole discretion of the Company: (i) there is a failure by the Executive to follow a lawful direction or order of the Board of Directors of the Company or the Board of Directors of the Company; (ii) there is a serious neglect of duty by the Executive; (iii) Executive exhibits unfitness for service (such as being intoxicated at work), dishonesty related to his work, persistent and material deficiencies in performance or gross incompetence; (iv) Executive is convicted of a felony or other crime involving dishonesty, intentional misconduct or breach of trust; (v) Executive becomes mentally or physically incapacitated and cannot carry out his/her duties for a period of more than one hundred twenty (120) days. No termination For Cause under subsections (i), (ii), or (iii) shall be effective unless Company shall have first given Executive written notice specifying in reasonable detail the event or events giving rise to the alleged For Cause, and Executive has failed to fully cure such event or events during the thirty (30) day period following the provision of such written notice.

3.2.2. In the event Executive's employment is terminated at any time For Cause, he will be entitled to Accrued Obligations, but he will not be entitled to pay in lieu of notice, Severance Pay, pro rata bonus, Deal Bonus, or any other such compensation.

**3.3. Termination Not For Cause**. In the event Executive's employment is terminated by the Company Not For Cause, then Executive shall be entitled to receive an amount equal to the Executive's Base Salary during a three (3) month period (and equal to the Base Salary multiplied by one quarter (¼)) (the "Severance Pay").

### 3.4. Voluntary or Mutual Termination.

3.4.1. Executive may voluntarily terminate his employment with Company at any time after which, other than the Accrued Obligations, no further compensation will be paid to Executive.

3.4.2. In the event Executive voluntarily terminates his employment, other than the Accrued Obligations, he will not be entitled to, pay in lieu of notice, Severance Pay, or any other such compensation.

# **TERMINATION OBLIGATIONS**

4.1 **Return of Property.** Executive agrees that all property (including without limitation all equipment, tangible proprietary information, documents, records, notes, contracts and computer-generated materials) furnished to or created or prepared by Executive incident to Executive's employment belongs to the Company and shall be promptly returned to the Company upon termination of Executive's employment.

**4.2 Resignation and Compensation.** Following any termination of employment, Executive shall, upon the Company's request, cooperate with the Company in the winding up of pending work on behalf of the Company and the orderly transfer of work to other employees. Executive shall also cooperate (at the Company's expense) with the Company in the defense of any action brought by any third party against the Company that relates to Executive's employment by the Company.

# INVENTIONS AND PROPRIETARY INFORMATION; PROHIBITION ON THIRD PARTY INFORMATION

5.1 **Proprietary Information and Non Competition Agreement.** Executive has executed BioLineRx's standard assignment of IP, confidentiality, non disclosure and non competition agreement, dated November \_\_\_, 2007, which is attached as Exhibit B ("Proprietary Information Agreement"). Executive acknowledges and agrees that the Proprietary Information Agreement shall apply during the entire term of this Employment Agreement and thereafter. For purposes of this Agreement the Company is current engaged in the business of drug development in multiple therapeutic areas.

5.2 Non-Disclosure of Third Party Information. Executive represents and warrants and covenants that Executive shall not disclose to the Company, or use, or induce the Company to use, any proprietary information or trade secrets of others at any time, including but not limited to any proprietary information or trade secrets of any former employer, if any; and Executive acknowledges and agrees that any violation of this provision shall be grounds for Executive's immediate termination and could subject Executive to substantial civil liabilities and criminal penalties. Executive further specifically and expressly acknowledges that no officer or other employee or representative of the Company has requested or instructed Executive to disclose or use any such third party proprietary information or trade secrets.

# **ARBITRATION; VENUE**

Executive hereby agrees and acknowledges that any disputes between the parties shall be finally settled under the procedure and rules of the Rules of Conciliation and Arbitration of the International Chamber of Commerce in the English language by one (1) arbitrator appointed in accordance with these rules. If such attempt at arbitration shall fail within a period of six (6) months, the matter shall be subject to the jurisdiction of the competent courts of the State of Delaware. The parties agree that the competent courts of the State of Delaware shall have exclusive jurisdiction to settle any dispute which may arise in connection with this Agreement, and the employment relationship established by this Agreement.

#### **AMENDMENTS; WAIVERS; REMEDIES**

This Agreement may not be amended or waived except by a writing signed by Executive and by a duly authorized representative of the Company. Failure to exercise any right under this Agreement shall not constitute a waiver of such right. Any waiver of any breach of this Agreement shall not operate as a waiver of any subsequent breaches. All rights or remedies specified for a party herein shall be cumulative and in addition to all other rights and remedies of the party hereunder or under applicable law.

# **ASSIGNMENT; BINDING EFFECT**

**9.1 Assignment.** The performance of Executive is personal hereunder, and Executive agrees that Executive shall have no right to assign and shall not assign or purport to assign any rights or obligations under this Agreement. This Agreement may be assigned or transferred by the Company; and nothing in this Agreement shall prevent the consolidation, merger or sale of the Company or a sale of any or all or substantially all of its assets. Notwithstanding the generality of the foregoing, the Company, in its sole discretion, may assign this Agreement to BioLineRx at any time, without the need to obtain Executive's consent.

**9.2 Binding Effect.** Subject to the foregoing restriction on assignment by Executive, this Agreement shall inure to the benefit of and be binding upon each of the parties; the affiliates, officers, directors, agents, successors and assigns of the Company; and the heirs, devisees, spouses, legal representatives and successors of Executive.

#### NOTICES

Any notice under this Agreement must be in writing and addressed to the Company or to Executive at the corresponding address below. Notices under this Agreement shall be effective upon (a) hand delivery, when personally delivered; (b) written verification of receipt, when delivered by overnight courier or certified or registered mail; or (c) acknowledgment of receipt of electronic transmission, when delivered via electronic mail or facsimile. Executive shall be obligated to notify the Company in writing of any change in Executive's address. Notice of change of address shall be effective only when done in accordance with this paragraph.

Company's Notice Address:

BioLineRx USA, Inc 15400 Calhoun Drive, Suite #125 Rockville, Maryland 20855

Executive's Notice Address:

Nir Gamliel 16 Treworthy Road North Potomac, Maryland 20878

#### SEVERABILITY

If any provision of this Agreement shall be held by a court or arbitrator to be invalid, unenforceable, or void, such provision shall be enforced to the fullest extent permitted by law, and the remainder of this Agreement shall remain in full force and effect. In the event that the time period or scope of any provision is declared by a court or arbitrator of competent jurisdiction to exceed the maximum time period or scope that such court or arbitrator deems enforceable, then such court or arbitrator shall reduce the time period or scope to the maximum time period or scope permitted by law.

### TAXES

All amounts paid under this Agreement (including without limitation Base Salary) shall be reduced by all applicable state and federal tax withholdings and any other withholdings required by any applicable jurisdiction.

# **GOVERNING LAW**

The validity, interpretation, enforceability, and performance of this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to Delaware conflict of laws principles.

# **INTERPRETATION**

This Agreement shall be construed as a whole, according to its fair meaning, and not in favor of or against any party. Sections and section headings contained in this Agreement are for reference purposes only, and shall not affect in any manner the meaning or interpretation of this Agreement. Whenever the context requires, references to the singular shall include the plural and the plural the singular.

# **OBLIGATIONS SURVIVE TERMINATION OF EMPLOYMENT**

Executive agrees that Executive's obligations under Section 5 of this Agreement, including Exhibit B referenced therein, shall survive the termination of employment and the termination of this Agreement.

# **COUNTERPARTS**

This Agreement may be executed in any number of counterparts, each of which shall be deemed an original of this Agreement, but all of which together shall constitute one and the same instrument.

# AUTHORITY

Each party represents and warrants that such party has the right, power and authority to enter into and execute this Agreement and to perform and discharge all of the obligations hereunder; and that this Agreement constitutes the valid and legally binding agreement and obligation of such party and is enforceable in accordance with its terms.

# ENTIRE AGREEMENT

This Agreement (including the Exhibits attached hereto, which are incorporated herein by reference) is the final, complete and exclusive agreement of the parties with respect to the subject matter hereof and supersedes and merges all prior or contemporaneous representations, discussions, proposals, negotiations, conditions, communications and agreements, whether written or oral, between the parties relating to the subject matter hereof and all past courses of dealing or industry custom.

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Executive acknowledges Executive has had the opportunity to consult legal counsel concerning this agreement, that Executive has read and understands the agreement, that Executive is fully aware of its legal effect, and that Executive has entered into it freely based on Executive's own judgment and not on any representations or promises other than those contained in this agreement.

IN WITNESS WHEREOF, the parties have duly executed this Agreement as of the date first written above.

BIOLINERX USA, INC.:

**EXECUTIVE:** 

By: /s/ Morris Laster

JALCOINE.

By: /s/ Nir Gamliel

Title: Director



#### EXHIBIT 10.5

#### **Employment Agreement**

This Employment Agreement (this "**Agreement**") is entered into on this 24 day of May, 2009 by and between **BioLineRx Ltd.**, a company organized under the laws of the State of Israel, with its offices at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel ("**BioLine**"), and **Phillip Serlin**, I.D. Number 310550157 with an address at 11 Hachazav Street, Bet Shemesh (the "**Employee**").

WHEREAS, BioLine desires to employ the Employee and the Employee desires to enter into such employment, on the terms and conditions hereinafter set forth.

NOW THEREFORE, in consideration of the mutual covenants and conditions hereinafter set forth, the parties agree as follows:

#### 1. Employment.

- 1.1. The Employee shall serve in the position described in **Exhibit A** commencing on May 24, 2009 (the "**Commencement Date**"). The Employee shall be under the direct supervision of and comply with the directives of the CEO of BioLine and/or any such individual designated by BioLine at its sole discretion (the "**Supervisor**"). The Employee shall perform the duties, undertake the responsibilities and exercises the authority as determined from time to time by the Superviser diligently, conscientiously and in furtherance of BioLine's best interests. Employee's duties and responsibilities hereunder may also include other services performed for affiliates of BioLine.
- 1.2. During the Employment Period, Employee shall honestly, diligently, skillfully and faithfully serve BioLine, and undertakes to devote all of Employee's efforts and the best of his/her qualifications and skills to promoting the business and affairs of BioLine, and shall at all times act in a manner suitable of his position and status in BioLine.
- 1.3. The Employee agrees and undertakes to inform BioLine, immediately after becoming aware of any matter that may in any way raise a conflict of interest between Employee and BioLine. Employee shall not receive during any payment, compensation or benefit from any third party in connection, directly or indirectly, with the execution of Employee's position in BioLine.
- 1.4. Employee will be employed on a full time basis. Employee shall not undertake or accept any other paid or unpaid employment or occupation or engage in any other business activity except with the prior written consent of BioLine, which shall not be unreasonably withheld.
- 1.5. Employee hereby confirms and declares that his/her position is one that requires a special measure of personal trust and loyalty. Accordingly, the provisions of the Hours of Work and Rest Law-1951 shall not apply to Employee, and Employee shall not be entitled to any compensation for working more than the maximum number of hours per week set forth in said law or any other applicable law.
- 1.6. The Employee may also work outside of regular working hours and outside of regular working days, as may be required by BioLine from time to time. The Employee must obtain Supervisor's prior approval for work in excess of the quota of overtime work hours per month set forth in Section 6 below and notify BioLine in the event that this average quota is exceeded.

BioLine Employee



- 1.7. The parties hereby confirm that this is a personal services agreement and that the relationship between the parties hereto shall not be subject to any general or special collective employment agreement or any custom or practice of BioLine with respect to any of its other employees or contractors.
- 2. **Place of Performance**. Employee shall be based at BioLine's facilities in Israel or at such other place as is otherwise appropriate to the functions being performed by BioLine. Employee acknowledges and agrees that his/her position may involve significant domestic and international travel.
- 3. Employee's Representations and Warranties. Employee represents and warrants that the execution and delivery of this Agreement and the fulfillment of all its terms: (i) will not constitute a default under or conflict with any agreement or other instrument to which Employee is a party or by which Employee is bound; and (ii) do not require the consent of any person or entity. Further, with respect to any past engagement Employee may have had with third parties and with respect to any allowed engagement Employee may have with any third party during the term of his/her engagement with BioLine (for purposes hereof, such third parties shall be referred to as "Other Employees"), Employee represents, warrants and undertakes that: (a) Employee's engagement with BioLine is and/or will not be in breach of Employee's undertakings towards Other Employers, and (b) Employee will not disclose to BioLine, or use, in provision of any services to BioLine, any proprietary or confidential information belonging to any Other Employees. Employee further represents and warrants that: (y) he/she does not suffer from any medical condition that may prevent from complying with duties and obligations under this Agreement; (z) to Employee's best knowledge, the employment by BioLine will not cause any hazard to Employee's health.
- 4. **Proprietary Information; Confidentiality and Non-Competition**. The Employee is obligated to keep all the terms and covenants of this Agreement under strict confidentiality. By executing this Agreement Employee confirms and agrees to the provisions of BioLine's Proprietary Information, Confidentiality and Non-Competition Agreement attached as **Exhibit B** hereto. Employee acknowledges and confirms that all terms of his/her employment are personal and confidential, and undertakes to keep such term in confidence and refrain from disclosing such terms to any third party.
- 5. **Period of Employment**. Employee's employment by BioLine commence on the Commencement Date and shall continue for an initial period of three (3) months (the "**Initial Period**") and shall then continue, unless terminated in accordance with the provisions of this Agreement (the "**Employment Period**").
  - 5.1. <u>Death or Disability</u>. The Employee's employment will terminate upon the death of the Employee, and BioLine may terminate the Employee's employment after having established the Employee's disability. For purposes of this Agreement, "disability" means a physical or mental infirmity which impairs the Employee's ability to substantially perform Employee's duties under this Agreement which continues for a period of at least ninety (90) consecutive days. Upon termination for disability, the Employee shall be entitled to severance pay required by law, in accordance with the terms of this Agreement.
  - 5.2. <u>Termination at Will</u>. Either party may terminate the employment relationship hereunder at any time by giving the other party prior written notice as set forth in Exhibit A (the "**Notice Period**").

BioLine Employee



- 5.3. <u>Termination for Cause</u>. In the event of a termination for Cause (as defined below), BioLine may immediately terminate the employment relationship effective as of the time of notice of the same, and without payment in lieu of prior notice. "**Cause**" means (i) a serious breach of trust including but not limited to theft, embezzlement, self-dealing, prohibited disclosure to unauthorized persons or entities of confidential or proprietary information of or relating to BioLine or its affiliates, and the engaging by Employee in any prohibited business competitive to the business of BioLine; (ii) any willful failure to perform or failure to perform competently any of Employee's fundamental functions or duties hereunder, which was not cured within thirty (30) days after receipt by Employee of written notice thereof; (iii) any breach of this Agreement by the Employee; and (iv) any other cause justifying termination or dismissal without severance payment under applicable law.
- 5.4. <u>Notice Period; End of Relations</u>. During the Notice Period, the employment relationship hereunder shall remain in full force and effect and there shall be no change in Employee's position with BioLine, the Salary, or in any other obligations of either party hereunder, unless otherwise determined by BioLine in a written notice to Employee, and Employee shall cooperate with BioLine and assist BioLine with the integration into BioLine of the person who will assume Employee's responsibilities. At the option of BioLine, the Employee shall during such period either continue with Employee's duties or remain absent from BioLine's premises. However, BioLine, at its own discretion, may terminate this Agreement and the employment relationship at any time immediately upon a written notice and pay Employee an amount equal to the Salary referred to in Section 6 below that would have been paid to Employee during the Notice Period in lieu of the prior notice.
- 5.5. Without derogating from all of BioLine's rights according to the provisions of this Agreement and the law, upon the termination of this Agreement, BioLine shall have the right to deduct from any payment to be paid to the Employee any sum owed by the Employee to BioLine.

# 6. Salary.

- 6.1. BioLine shall pay or cause to be paid to the Employee during the term of this Agreement a gross salary in the amount set forth in Exhibit A per month (the "Base Salary"). Since the nature of the work precludes supervision of the Employee's work hours and due to BioLine's anticipation that the Employee may be required to work outside of regular working hours and outside of regular working days as stated in Section 1.5 above, BioLine agrees to pay to the Employee during the term of this Agreement a gross payment in the amount set forth in Exhibit A per month (the "Overtime Payment") on account of forty five (45) global overtime work hours per month. The Base Salary and the Overtime Payment together shall constitute the "Salary" for purposes of this Agreement.
- 6.2. The Salary will be paid no later then the 9<sup>th</sup> day of each calendar month after the month for which the Salary is paid, after deduction of any and all taxes and charges applicable to Employee, as may be in effect or which may hereafter be enacted or required by law. Employee shall notify BioLine of any change which may affect Employee's tax liability.

# 7. Insurance and Social Benefits.

The Employee shall be entitled to the following benefits:

7.1. <u>Manager's insurance; Pension Fund</u>. At the end of the Initial Period, and subject to the continued employment of Employee following the Initial Period, BioLine will insure Employee, retroactive to the Commencement Date, under a "Manager's Insurance Scheme" or pension fund to be selected by BioLine in coordination with Employee (unless otherwise agreed to by the parties) (collectively the "**Policy**"), such that BioLine will pay an amount equal to 13<sup>1</sup>/<sub>3</sub>% of the Salary towards a such Policy, of which 5% shall be for pension fund payments and 8<sup>1</sup>/<sub>3</sub>% shall serve to cover severance compensation. In addition, BioLine shall deduct from the Salary an amount equal to 5% of the Salary, and forward the same to the Policy. Any tax payable in respect of such contributions to the Policy shall be borne and paid by the Employee.

BioLine Employee





- 7.2. The Employee hereby agrees and acknowledges that all of the payments that BioLine shall make to the abovementioned Policy shall be instead of any severance pay to which the Employee or Employee's successors shall be entitled to receive from BioLine with respect to the salary from which these payments were made and the period during which they were made, in accordance with Section 14 of the Severance Pay Law 5723-1963 (the "Law"). The parties hereby adopt the General Approval of the Minister of Labor and Welfare, published in the Official Publications Gazette No. 4659 on June 30, 1998, attached hereto as Exhibit C. BioLine hereby waives in advance any claim it has or may have to be refunded any of the payments made to the manager's insurance policy, unless (i) the Employee's right to severance pay is invalidated by a court ruling on the basis of Sections 16 or 17 of the Law (and in such case only to the extent it is invalidated), or (ii) the Employee withdrew funds from the manager's insurance policy for reasons other than an "Entitling Event". An "Entitling Event" means death, disability or retirement at the age of sixty (60) or more.
- 7.3. <u>Disability Insurance</u>. In addition to the foregoing, during the Employment Period BioLine will bear the cost of disability insurance with an insurance company (*Ovdan Kosher Avoda*). The amount paid by BioLine for such insurance shall be as generally accepted, but shall not exceed 2.5% of the Salary.
- 7.4. <u>Advanced Study Fund</u>. At the end of the Initial Period, and subject to the continued employment of Employee following the Initial Period, BioLine will maintain an advanced study fund (*Keren Hishtalmut*) recognized by the Israeli Income Tax Authorities, retroactive to the Commencement Date, such that BioLine and Employee shall contribute to such fund an amount equal to 7.5% of the Salary and 2.5% of the Salary, respectively. Any tax payable in respect of such contributions to such fund shall be borne and paid by the Employee.
- 7.5. <u>Convalescence</u>. During the Employment Period, Employee shall be entitled to receive convalescence allowance (*Dmei Havra'a*) pursuant to applicable law.
- 7.6. <u>Sick Leave</u>. The Employee shall be entitled to be absent from work each year due to illness for the number of days allowed pursuant to the Sick Pay Law 5736 1976, and shall be entitled to fully paid sick leave upon presentation of appropriate medical documentation regarding said illness. Any amounts paid to the Employee on account of the disability insurance indicated in subsection 7.3 above, will be on account of Sick Leave payment.
- 7.7. <u>Reserve Service</u>. During the Employment Period, BioLine shall pay the full salary of the Employee during the period of the Employee's military reserve service. National Insurance Institute transfers in connection with such military reserved duty shall be retained by BioLine.
- 7.8. <u>Vacation</u>. During the Employment Period, Employee shall be entitled to vacation in the number of working days per year as set forth in Exhibit A, as adjusted in accordance with applicable law. A "working day" shall mean Sunday to Thursday inclusive, and the use of said vacation days will be coordinated with BioLine. Employee shall be entitled to accumulation and redemption of vacation days in accordance with BioLine's employees' handbook, which may be amended from time to time in BioLine's sole discretion.

BioLine Employee

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- 7.9. <u>Mobile Phone</u>. During the Employment Period, the Employee shall be entitled to receive a mobile phone. Employee shall use the mobile phone in a standard and reasonable manner, and in accordance with BioLine's policies.
- 7.10. Automobile. For purposes of performance of Employee's duties and tasks, and during the Employment Period, BioLine shall make available to Employee a company vehicle, leased or owned by BioLine of a type to be elected by BioLine, in accordance with its policies which may be amended from time to time (the "Company Car"). Employee shall use the Company Car in accordance with BioLine's car policy then in effect, as well as the requirements of the leasing company and the insurance company. BioLine shall bear the cost of maintenance and repairs, and any insurance deductibles for the Company Car, in accordance with its policies and the Car Agreement which will be signed between Employee and BioLine. Employee shall be liable for paying for fuel, as well as any parking and/or traffic fines received in connection herewith, and for any damages and expenses in case of negligent use of the Company Car and/or use of the Company Car not in accordance with BioLine's applicable policies. All taxes arising out of the use of the Company Car shall be borne by Employee, and Employee acknowledges that such taxes will be withheld from Employee's salary as required by law. Employee further acknowledges that the tax treatment of the benefit through use of the Company Car is subject to change, and any economic impact resulting from such changes will be in Employee's sole responsibility .For the avoidance of doubt, Employee agrees and confirms that the cost of the leasing and/or the cost of the use of the Company Car shall not constitute a component of Employee's Salary, including with regard to social benefits and/or any other right to which Employee is entitled by virtue of this Agreement or under law. The Employee shall be required to follow rules and regulations as to the usage of the Company Car as described in the "Company Car Lease Agreement" or "Car Addendum" provided to the Employee prior to receipt of the Company Car. The Company Car will remain in BioLine's ownership, and will be returned to BioLine immediately upon termination of Employee's employment with BioLine for any reason, as of the date of termination. The Employee shall not be entitled to use a Company Car during unpaid leaves or absences, unless specifically approved by BioLine in writing.

7.11.

Notwithstanding anything to the contrary herein, all payments and contributions of BioLine under this Agreement shall be limited to the applicable deductible amount required by the tax authorities.

- 8. **BioLine Property**. Employee acknowledges and agrees that the computer, telephone, email account and any other device providing for transmittal and storage of information, which are placed at Employee's disposal by BioLine during the Employment Period are and shall remain the property of BioLine. Employee confirms its understanding that BioLine regularly reviews email correspondence and other information transmitted and stored by using the equipment stated above, and Bioline reserves the right to copy, store, present to others, and use such information.
- 9. **Expenses**. Employee shall be reimbursed for all direct business expenses borne by Employee, in accordance with BioLine's policies as determined by BioLine from time to time, provided that such expenses were approved by Employee's Superior in advance. As a condition to reimbursement, Emploee shall be required to provide BioLine with all invoices, receipts and other evidence of expenditure as may be reasonably required by BioLine from time to time.
- 10. **Options**. Subject to the approval of the BioLine Board of Directors, Employee shall be granted options to purchase Ordinary Shares par value NIS 0.01 each of BioLine, in the amount set forth in Exhibit A, to be granted pursuant to, and in accordance with, the terms and conditions of the share option plan adopted by BioLine (the "**Options**").

BioLine Employee

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# 11. General.

- 11.1. The laws of the State of Israel shall apply to this Agreement and the sole and exclusive place of jurisdiction in any matter arising out of or in connection with this Agreement shall be the Jerusalem Regional Labor Court. The provisions of this Agreement are in lieu of the provisions of any collective bargaining agreement, and therefore, no collective bargaining agreement shall apply with respect to the relationship between the parties hereto (subject to the applicable provisions of law).
- 11.2. This Agreement constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof, and supersedes all prior written or oral agreements with respect thereto. This Agreement may not be modified except by written instrument signed by a duly authorized representative of each party hereto. No failure, delay of forbearance of either party in exercising any power or right hereunder shall in any way restrict or diminish such party's rights and powers under this Agreement, or operate as a waiver of any breach or nonperformance by either party of any terms of conditions hereof. In the event that it shall be determined under any applicable law that a certain provision set forth in this Agreement is invalid or unenforceable, such determination shall not affect the remaining provisions of this Agreement.
- 11.3. This Agreement may be assigned by BioLine. Employee may not assign or delegate his/her duties under this Agreement without the prior written consent of BioLine. This agreement shall be binding upon the heirs, successors and permitted assignees of Employee. The provisions of this Agreement shall survive the termination of the Employment Period and the assignment of this Agreement by BioLine to any successor or other assignee.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first set forth above.

/s/ Morris Laster	/s/ Philip Serlin					
BioLineRx Ltd.	Employee					
By: MORRIS LASTER						
Title: CEO	Name: <u>PHILIP SERLIN</u>					
	BioLine Employee					
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# Exhibit A

# Particulars of Employment

1.	Name of Employee:	Philip Serlin				
2.	ID No. of Employee:	310550157				
3.	Address of Employee:	11 Hachazav Street, Bet Shemesh				
4.	Position in BioLine:	Chief Financial Officer				
5.	Commencement Date:	May 24, 2009				
6.	Notice Period:	60 days				
7.	Base Salary:	NIS 31,500				
8.	Overtime Payment:	NIS 10,500				
9.	Car Maintenance Expenses	NIS 4,097				
10.	Vacation Days Per Year:	21 days				
11.	Options	130,000 Options				
		BioLine Employee				
		DioLine Linployee				

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# Exhibit B

# **Proprietary Information, Confidentiality and Non-Competition Agreement**

# 1. General.

- 1.1. All capitalized terms herein shall have the meanings ascribed to them in the Employment Agreement to which this Exhibit B is attached (the "Employment Agreement"). For purposes of any undertaking of the Employee toward BioLine, the term BioLine shall include all subsidiaries and affiliates of BioLine including its General and Limited Partners
- 1.2. The Employee's obligations and representations and BioLine's rights under this Exhibit B (this "Agreement") shall apply as of the Commencement Date of the employment relationship between BioLine and the Employee, and as of the first time in which Employee became engaged with BioLine, regardless of the date of execution of the Employment Agreement.
- 1.3. Employees undertakings hereunder shall remain in full force and effect after termination of this Agreement or the Employment Agreement, or any renewal thereof.
- Employee acknowledges that he/she has received and/or may receive information of a confidential and proprietary nature regarding the activities and business of BioLine, its parent companies, subsidiaries and/or affiliates, all whether in oral, written, graphic, or machine-readable form, or in any other form, including, but not limited to, (i) patents and patent applications and related information, (ii) trade secrets and industrial secrets, and (iii) drugs, compounds, molecules, building blocks, chemical libraries, reaction protocols for chemical libraries, chemical structures, chemical design and model relationship data, chemical databases, assays, samples, media and other biological materials, procedures and formulations for producing any such materials, products, processes, ideas, know-how, trade secrets, drawings, inventions, improvements, formulas, equations, methods, developmental or experimental work, research or clinical data, discoveries, developments, designs, techniques, instruments, devices, computer software and hardware related to the current, future and/or proposed products and services, and including, without limitation, information regarding research, development, new service offerings or products, marketing and selling, business plans, forecasts, business methods, budgets, finances, licensing, collaboration and development arrangements, prices and costs, buying habits and practices, contact and mailing lists and databases, vendors, customers and clients, and potential business opportunities, and personnel (collectively, "Confidential Information"). Confidential Information of BioLine. Notwithstanding the aforesaid, information that is in the public domain, through no act or omission of the Employee shall not be deemed Confidential Information. The Confidential Information and all right, title and interest therein will remain at all times the exclusive property of BioLine (or any third party entrusting its own Confidential Information to BioLine).
- 3. At all times during the Employment Period and thereafter, Employee will hold all Confidential Information in strictest confidence and will not disclose, use, or make any copies thereof. Employee hereby assigns to BioLine any rights that the Employee may have or acquire in such Confidential Information and recognize that all Confidential Information shall be the sole property of BioLine and its assigns or licensors, as applicable.

BioLine Employee

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- 4. Employee represents that he/she has assigned to BioLine all inventions, original works of authorship, developments, improvements, and trade secrets which were conceived, developed, made or reduced to practice by Employee prior to the date of the this Agreement or the Commencement Date, whichever is earlier (collectively referred to as "**Prior Inventions**"), in which Employee has or purports to have any ownership interest in or a license to use, and which relate to BioLine's current or proposed business, products or research and development.
- 5. Employee will promptly disclose and describe to BioLine all inventions, improvements, designs, concepts, techniques, methods, processes, know how, and trade secrets, whether or not patentable, copyrightable or protectible as trade secrets that are made, developed, conceived or first reduced to practice or created by Employee, whether alone or jointly with others, during the provision of Consulting Services (i) which relate to BioLine's business or actual or demonstrably anticipated research or development, (ii) which are developed in whole or in part on BioLine's time or with the use of any of BioLine's Confidential Information or other information, equipment, supplies, facilities or trade secret information, or (iii) which result directly or indirectly from any work performed by Employee for BioLine (the "Inventions", and each an "Invention").
- 6. Employee hereby assigns and agrees to assign in the future (when any such Inventions or Proprietary Rights (defined below) are first reduced to practice or first fixed in a tangible medium, as applicable) to BioLine or its designee(s) all of Employee's right, title and interest in and to any and all Inventions (and all Proprietary Rights with respect thereto) whether or not patentable or registrable under copyright or similar statutes. Employee further specifically assigns to BioLine all original works of authorship, including any related moral rights, which are made by the Employee (solely or jointly with others) during the Employment Period which are protectable by copyright pursuant to applicable copyright law. Employee also agrees to assign all of his/her right, title and interest in and to any particular Invention to any third party, including without limitation government agency, as directed by BioLine.

The term "**Proprietary Rights**" shall mean: (i) patents, whether in the form of utility patents or design patents and all pending applications for such patents; (ii) trademarks, trade names, service marks, designs, logos, trade dress, and trade styles, whether or not registered, and all pending applications for registration of the same; (iii) copyrights or copyrightable material, including moral rights, including but not limited to books, articles and publications, whether or not registered, and all pending applications for registration of the same; and (iv) all other intellectual property rights throughout the world.

7. Employee will assist BioLine in every proper way to obtain, and from time to time enforce, any Proprietary Rights relating to any Inventions in any and all countries. To that end Employee will execute, verify and deliver such documents and perform such other acts (including appearances as a witness) as BioLine may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Proprietary Rights and the assignment thereof. In addition, Employee will execute, verify and deliver assignments of such Proprietary Rights to BioLine or its designee. Employee's obligation to assist BioLine with respect to Proprietary Rights relating to any such Inventions in any and all countries shall continue indefinitely beyond termination of the Employment Period for any reason (the "**Termination Date**"), but BioLine shall compensate Employee at a reasonable rate after the Termination Date for the time actually spent by Employee at BioLine's request on such assistance.

-	BioLine	Employee
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- 8. In the event that BioLine is unable for any reason, after reasonable effort, to secure Employee's signature on any document needed in connection with the actions specified in the preceding paragraph, Employee hereby irrevocably designates and appoints BioLine and its duly authorized officers and agents as Employee's agent and attorney in fact, which appointment is coupled with an interest, to act for and in Employee's behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by the Employee. Employee hereby waives and holds BioLine harmless from any and all claims, of any nature whatsoever, which Employee now or may hereafter have for infringement of any Proprietary Rights assigned hereunder to BioLine.
- 9. Employee agrees to keep and maintain adequate and current records (in the form of notes, sketches, drawings and in any other form that may be required by BioLine) of all Confidential Information developed by the Employee and all Inventions made by the Employee during the Employment Period to BioLine, which records shall be available to and remain the sole property of BioLine at all times.
- 10. During the Employment Period, Employee will not improperly use or disclose any confidential information or trade secrets, if any, of any former employer or any other person to whom Employee has an obligation of confidentiality, and Employee will not bring onto the premises of BioLine any unpublished documents or any property belonging to any former employer or any other person to whom Employee has an obligation of confidentiality unless consented to in writing by that former employer or person.
- 11. Upon the earlier of (i) a written request by BioLine; or (ii) the expiration or termination of the employment, Employee shall promptly return to BioLine all Confidential Information, together with any and all copies or excerpts thereof and any and all other information directly or indirectly derived therefrom. Return or destruction of the Confidential Information as required hereunder shall not affect Employee's remaining obligations pursuant to this Agreement.

# 12. Non Competition; Non Solicitation.

12.1. In consideration of Employee's terms of employment, which include special compensation for Employee's undertakings under this Section 12, and in order to enable BioLine to effectively protect its Proprietary Information, Employee undertakes that during the Employment Period and for a period of twelve (12) months from the Termination Date, Employee will not directly or indirectly: (i) carry on or hold an interest in any company, venture, entity or other business (other than a minority interest in a publicly traded company) which directly competes with the products or services of BioLine, (a "**Competing Business**") (including, without limitation, as a shareholder); (ii) act as a consultant or employee or officer or in any managerial capacity in a Competing Business, or supply in direct competition with BioLine services to any person who, to Employee's knowledge, was provided with services by BioLine any time during the twelve (12) months immediately prior to the Termination Date; (iii) solicit, canvass or approach or endeavor to solicit, canvass or approach any person who, to Employee's knowledge, was provided with services by BioLine at the Termination Date, for the purpose of offering services or products which directly compete with the services or products supplied by BioLine at the Termination Date; or (iv) employ, solicit or entice away or endeavor to solicit or entice away from BioLine any person employeed by BioLine any time during the twelve (12) months immediately prior the Termination Date with a view to inducing that person to leave such employment and to act for another employer in the same or a similar capacity.

BioLine Employee

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- 12.2. Insofar as the protective covenants set forth in this Agreement are concerned, Employee specifically acknowledges, stipulates and agrees as follows: (i) the protective covenants are reasonable and necessary to protect the goodwill, property and Proprietary Information of BioLine, and the operations and business of BioLine; and (ii) the time duration of the protective covenants is reasonable and necessary to protect the goodwill and the operations and business of BioLine, and does not impose a greater restrain than is necessary to protect the goodwill or other business interests of BioLine. Nevertheless, if any of the restrictions set forth in this Agreement is found by a court having jurisdiction to be unreasonable or overlybroad as to geographic area, scope or time or to be otherwise unenforceable, the parties intend for the restrictions set forth in this Agreement to be reformed, modified and redefined by such court so as to be reasonable and enforceable and, as so modified by such court, to be fully enforced.
- 13. Employee represents that Employee's performance of all the terms of the Employment Agreement and this Agreement does not and will not breach any agreement to keep in confidence information acquired by Employee in confidence or in trust prior to Employee's relationship with BioLine. Employee has not entered into, and agrees that he/she will not enter into, any agreement either written or oral in conflict herewith.
- 14. Employee hereby consents that in the event that the Employee leaves the employ of BioLine. Employee shall notify any new employer of Employee's rights and obligations under this Agreement.
- 15. Employee acknowledges that any violation or threatened violation of this Agreement may cause irreparable injury to BioLine, entitling BioLine to seek injunctive relief in addition to all other legal remedies.
- 16. Employee recognizes and agrees that: (i) this Agreement is necessary and essential to protect the business of BioLine and to realize and derive all the benefits, rights and expectations of conducting BioLine's business; (ii) the area and duration of the protective covenants contained herein are in all things reasonable; and (iii) good and valuable consideration exists under the Employment Agreement, for Employee's agreement to be bound by the provisions of this Agreement.
- 17. The General terms of the Employment Agreement (Section 11) shall apply to this Agreement, mutatis mutandis.
- 18. EMPLOYEE ACKNOWLEDGES THAT HE/SHE HAS READ THIS AGREEMENT CAREFULLY, UNDERSTANDS ITS TERMS, AND HAS BEEN GIVEN THE OPPORTUNITY TO DISCUSS IT WITH INDEPENDENT LEGAL COUNSEL.

BioLine

Employee

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# TRANSLATION FROM HEBREW

### Exhibit C

### General Approval Regarding Payments by Employers to a Pension Fund and Insurance Fund in lieu of Severance Pay under the Severance Pay Law 5723-1963

By virtue of my power under Section 14 of the Severance Pay Law, 5723-1963 (hereinafter: the "Law"), I certify that payments made by an employer commencing from the date of the publication of this approval for the sake of his employee to a comprehensive pension provident fund that is not an insurance fund within the meaning set forth in the Income Tax Regulations (Rules for the Approval and Conduct of Provident Funds), 5724-1964 (hereinafter: the "**Pension Fund**") or to managers' insurance which includes the possibility to receive annuity payments under an insurance fund as aforesaid, (hereinafter: the "**Insurance Fund**"), including payments made by the employer by a combination of payments to a Pension Fund and an Insurance Fund (hereinafter: "**Employer's Payments**"), shall be made in lieu of severance pay due to said employee with respect to the salary from which said payments were made and for the period they were paid (hereinafter: the "**Exempt Salary**"), provided that all the following conditions are fulfilled:

(1) The Employer's Payments –

(a) to the Pension Fund are not less than  $14\frac{1}{3}\%$  of the Exempt Salary or 12% of the Exempt Salary if the employer pays, for the sake of his employee, in addition thereto, payments to supplement severance pay to a severance pay provident fund or to an Insurance Fund in the employee's name, in the amount of  $2\frac{1}{3}\%$  of the Exempt Salary. In the event that the employer has not paid the above mentioned  $2\frac{1}{3}\%$  in addition to said 12%, his payments shall come in lieu of only 72% of the employee's severance pay;

(b) to the Insurance Fund are not less than one of the following:

(i) 13<sup>1</sup>/<sub>3</sub>% of the Exempt Salary, provided that, in addition thereto, the employer pays, for the sake of his employee, payments to secure monthly income in the event of disability, in a plan approved by the Commissioner of the Capital Market, Insurance and Savings Department of the Ministry of Finance, in an amount equivalent to the lower of either an amount required to secure at least 75% of the Exempt Salary or in an amount of 2<sup>1</sup>/<sub>2</sub>% of the Exempt Salary (hereinafter: "Disability Insurance Payment");

(ii) 11% of the Exempt Salary, if the employer paid, in addition, the Disability Insurance Payment; and in such case, the Employer's Payments shall come in lieu of only 72% of the employee's severance pay. In the event that the employer has made payments in the employee's name, in addition to the foregoing payments, to a severance pay provident fund or to an Insurance Fund in the employee's name, to supplement severance pay in an amount of 2<sup>1</sup>/<sub>3</sub>% of the Exempt Salary, the Employer's Payments shall come in lieu of 100% of the employee's severance pay.

(2) No later than three months from the commencement of the Employer's Payment, a written agreement was executed between the employer and the employee, which includes:

(a) the employee's consent to an arrangement pursuant to this approval, in an agreement specifying the Employer's Payments, the Pension Fund and the Insurance Fund, as the case may be; said agreement shall also incorporate the text of this approval;

(b) an advance waiver by the employer of any right which he may have to a refund of monies from his payments, except in cases in which the employee's right to severance pay was denied by a final judgment pursuant to Section 17 of the Law, and in such a case or in cases in which the employee withdrew monies from the Pension Fund or Insurance Fund, other than by reason of an entitling event; for these purposes an "Entitling Event" means death, disability or retirement at or after the age of 60.

(3) This approval shall not derogate from the employee's right to severance pay pursuant to any law, collective agreement, extension order or employment agreement with respect to compensation in excess of the Exempt Salary.

15th Sivan 5758 (June 9th, 1998).

BioLine

Employee

### CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. ASTERISKS DENOTE OMISSIONS.

#### LICENSE AGREEMENT

This License Agreement is entered into as of this 10th day of January, 2005 (the "Effective Date"), by and among BioLine Innovations Jerusalem L.P., an Israeli limited partnership, having a place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem , 91450, Israel ("BioLine"); and B.G. Negev Technologies and Applications Ltd., a company formed under the laws of Israel, having a place of business at I Henrietta Szold St., Beer Sheva, 84105 ("BGN") on behalf of Ben Gurion University ("BGU").

WHEREAS, BGN is the owner of rights in the Licensed Technology (as hereinafter defined) relating to Injectible Alginate Biomaterials and the uses thereof; and

WHEREAS, BioLine wishes to obtain an exclusive license with respect to such Licensed Technology, in order to develop, obtain regulatory approval for and commercialize products based on the Licensed Technology, and BGN wishes to grant BioLinc a license with respect to such Licensed Technology, all in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, the parties hereto, intending to be legally bound, hereby agree as follows:

#### 1. Definitions

The capitalized terms defined in this Section 1, whether used in the singular or the plural, shall have the meanings specified below: "Additional Ingredient" shall mean any compound or substance which (i) is contained in a Licensed Product, and (ii) when administered to a patient has a therapeutic or prophylactic clinical effect, either directly or by acting synergistically with or otherwise enhancing the effect of other compounds or substances contained in such product.

"Affiliate" shall mean, with respect to a party, any person, organization or entity controlling, controlled by or under common control with, such party. For purposes of this definition only, "control" of another person, organization or entity shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the activities, management or policies of such person, organization or entity, whether through the ownership of voting securities, by contract or otherwise. Without limiting the foregoing, control shall be presumed to exist when a person, organization or entity, i) owns or directly controls fifty percent (50%) or more of the outstanding voting stock or other ownership interest of the other organization or entity, or (ii) possesses , directly or indirectly, the power to elect or appoint fifty percent (50%) or more of the members of the governing body of the organization or other entity.

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"BioLine Royalty Payments" shall mean payments payable by BioLine to BGN with respect to Net Sales of Products by an Invoicing Entity, as set forth in Section 7.5 below.

"Calendar Quarter" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31, for so long as this Agreement is in effect.

"**Combination Product**" shall mean a product, substance or devise which comprises a Licensed Product and at least one other essential Additional Ingredient.

"**Commercially Reasonable Efforts**" **shall mean** (i) with respect to any objective by an entity, reasonable, diligent, good faith efforts to accomplish such objective as such entity (together with its Affiliates as a group) would normally use in the ordinary course of business and research to accomplish a similar objective under similar circumstances; and (ii) with respect to research, development and commercialization of any Licensed Product hereunder, shall mean those efforts and resources normally used by such entity (together with its Affiliates as a group) for a product owned by it or to which it has rights, which is of similar market potential at a similar stage in its development or product life as such Licensed Product.

"Current Invention" the invention disclosed in the patent application described in Exhibit A.

"**Development Plan**" shall mean the non-binding plan for the development of Licensed Products attached hereto as Exhibit B, as such plan may be amended from time to time pursuant to Section 6.2 below. The Development Plan shall include an estimated budget setting forth BioLine's anticipated development costs as of the date hereof. To avoid doubt, the Development Plan may be subject to change from time to time as determined by BioLine, in light of business, financial, scientific and/or technical considerations.

"FDA" shall mean the United States Food and Drug Administration and/or the corresponding licensing authorities in Europe, and/or Japan.

"Government Programs" shall mean the Biotech Incubators Program of the Office of the Chief Scientist of the Israeli Ministry of Industry and Trade, and any other funding programs sponsored by the Israeli or other governments.

"Grants" shall mean any funds or benefits received by BioLine from governmental, quasi-governmental or other non-profit sources for the development of the Licensed Technology or other benefits, including but not limited to grants provided within the context of Government Programs.

"License" shall mean the license granted pursuant to Section 2.

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"Licensed Patent Rights" shall mean the Patent Rights described in Exhibit C attached hereto. Exhibit C shall include and shall be updated from time to time to reflect inclusion of new Licensed Patent Rights.

"Licensed Product" shall mean any therapeutic product that comprises, contains or incorporates Licensed Technology as a component.

"Licensed Technology" shall mean the Current Invention and the Licensed Patent Rights; all improvements, updates, modifications and enhancements thereto made by BGN by the Effective Date (if any); and all inventions, know-how and other intellectual property owned or licensed by BGN and covered thereby or related thereto.

"Milestones" shall mean the milestones and performance dates for development and commercialization of Licensed Products set forth in Exhibit D. "NDA" shall mean an FDA New Drug Application or Product License Application (or Biologics License Application), as appropriate, and all supplements filed pursuant to the requirements of the FDA, including all documents, data and other information concerning Licensed Products that are necessary for or included in FDA approval to market a Licensed Product.

"**Net Sales**" shall mean the gross amount billed or invoiced by or on behalf of BioLine and/or its Affiliates (**the "Invoicing Entity**") on sales of Licensed Products, less the following: (a) customary trade, quantity, or cash discounts to the extent actually allowed and taken; (b) amounts repaid or credited by reason of rejection or return; (c) to the extent separately stated on purchase orders, invoices, or other documents of sale, any taxes or other governmental charges levied on the production, sale, transportation, import, export, delivery, or use of a Licensed Product which is paid by or on behalf of the Invoicing Entity; (d) outbound transportation, packing and delivery charges, as well as prepaid freight (including shipping insurance) actually incurred; and (e) payments to one or more third parties to obtain a Third Party License from such third party(ies) in order to practice the Licensed Technology; provided however, that:

(i) in any transfers of Licensed Products between the Invoicing Entity and an Affiliate of the Invoicing Entity, Net Sales shall be equal to the higher of. (x) the fair market value of the Licensed Products so transferred, assuming an arm's length transaction made in the ordinary course of business, and (y) the total amount invoiced by such Affiliate on resale to an independent third party purchaser, in each case, after deducting the amounts referred to in clauses (a) through (d) above, to the extent applicable;

(ii) In the event that the Invoicing Entity, or the Affiliate of the Invoicing Entity, receives non-monetary consideration for any Licensed Products or in the case of transactions not at arm's length with a non-Affiliate of the Invoicing Entity, Net Sales shall be calculated based on the fair market value of such consideration or transaction. assuming an arm's length transaction made in the ordinary course of business; and

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(iii) In the event a Licensed Product is sold by BioLine, an Affiliate of BioLine in the form of a Combination Product, Net Sales from such Combination Product, for purposes of determining BioLine Royalty Payments, shall be determined by multiplying the actual Net Sales of such Combination Product during the applicable royalty reporting period, by the fraction A/(A+B) where: A is the average sale price of the Licensed Product contained in the Combination Product when sold separately by BioLine or its Affiliate or its sublicense; and B is the average price of the other Additional Ingredients included in the Combination Product when sold separately by its supplier, in each case during the applicable royalty reporting period or if sales of both the Licensed Product and/or other Additional Ingredients did not occur in such period, then in the most recent royalty reporting period in which sales of both occurred. In the event that such average sale price cannot be determined for both the Licensed Product and all other Additional Ingredients included in the Combination Product, Net Sales for the purpose of determining BioLine Royalty Payments shall be calculated by multiplying the Net Sales of the Combination Products by the fraction of C/C+D where C is the fair market value of the Licensed Product and D is the fair market value of all other Additional Ingredients included in the Combination Product. In such event, the parties shall negotiate in good faith to arrive at a determination of the respective fair market values of the Licensed Product and all other Additional Ingredients included in the Combination Product.

"**Patent Rights**" shall mean any and all (a) patents, (b) pending patent applications, including, without limitation, all provisional applications, continuations, continuations-inpart, divisions, reissues, renewals, and all patents granted thereon, and (c) all patents-of addition, reissue patents, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including, without limitation, supplementary protection certificates or the equivalent thereof.

"Regulatory Agency" shall mean the FDA or equivalent licensing agency or overnment body in Europe, and/or Japan.

"Sublicense Consideration" shall mean the actual cash income or other consideration forms actually received by BioLine in exercising its rights under the License, including, but not limited to, cash income and other consideration received for or consequent to any sublicensing or co-marketing or co-promotion arrangement or permitted assignment of the License or any portion thereof to a third party of the rights under the License provided however, that "Sublicense Consideration" shall not include any amounts received by BioLine in respect of (i) Grants and (ii) Net Sales.

"Sublicensee" shall mean a person or entity to whom BioLine or its sublicensee grants a sublicense or co-marketing or co-promotion rights with respect to some or all of the rights granted to BioLine under Section 2.

"Third Party License" shall mean a license from an unaffiliated third party to one or more valid and enforceable patents issued in the United States or any other jurisdiction, the claims of which cover one or more components that is essential for the efficacy of the Licensed Product.

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# 2. License Grant

BGN hereby grants to BioLine an exclusive, worldwide, sublicensable license under BGN's rights in the Licensed Technology to research, have researched, develop, have developed, manufacture, have manufactured, use, market, distribute, offer for sale, sell, have sold, export and import Licensed Products and/or provide services relating thereto in accordance with the terms and conditions of this Agreement (the "License"). For purposes of this Section 2, the term "exclusive" means that BGN shall not have any right to grant such licenses or rights to any third party or engage in any of the foregoing. To avoid doubt, BGU will retain the right to use the Licensed Technology solely for noncommercial research purposes which do not, in BioLine's opinion, in any manner interfere with, impede, or place at risk BioLine's exclusive rights under the License.

3. Title.

**3.1 Licensed Technology**. Subject to the License granted to BioLine, all rights, title and interest in and to the Licensed Technology are and shall be owned solely and exclusively by BGN.

**3.2 BioLine Inventions**. As between the parties, BioLine shall own all inventions conceived, discovered or developed by BioLine or its subcontractors or Sub-Licensees in connection with activities under this Agreement, including without limitation all intellectual property rights therein, subject to BGN's rights in the Licensed Technology. Except as may be otherwise agreed in writing between the parties with respect to specific inventions, any inventions conceived jointly by BioLine or its subcontractors, on the one hand, and BGN or BGU, on the other hand, shall be jointly owned by BGN and BioLine and, during the term of this Agreement shall be exclusively licensed to BioLine on the terms set forth herein. Subsequent to termination of this Agreement, neither party will have any right to commercialize, utilize, exploit and/or license such jointly owned inventions without the express written permission of the other party, which will not be unreasonably withheld. The foregoing is subject to any restrictions or terms applying to Grants, which shall supercede these provisions.

**3.3 Determination**. All determinations of inventorship under this Agreement shall be made in accordance with United States patent law. In case of dispute between BGN and BioLine in respect of inventorship, a mutually acceptable independent patent counsel shall make the determination of the inventor(s) by applying the standards contained in United States patent law.

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# 4. Patent Filing, Prosecution and Maintenance.

**4.1 Filing**. BioLine shall have the first right to prepare, file, prosecute and maintain any patent applications and patents, in respect of the Licensed Technology and/or any part thereof, and at the BioLine's sole expense. BioLine shall provide BGN with copies of all patent applications and BGN undertakes to cooperate in a timely manner with the BioLine's efforts to register the patent, including by executing any documents as may be required for such purpose.

**4.2 Consultation**. BGN and BioLine shall consult each other regarding the preparation, filing and prosecution of all patent applications, and the maintenance of all patents, included within the Licensed Patent Rights, including, without limitation, the content, timing and jurisdiction of the filing of such patent applications and their prosecution, and other details and overall global strategy pertaining to the procurement and maintenance of the Licensed Patent Rights. All Licensed Patent Rights shall be filed, prosecuted and maintained by the parties through a law or patent attorney firm selected by BioLine, and subject to BGN's approval.

4.3 [\*\*\*]

**4.4. Abandonment**. Should BioLine elect not to pursue the filing, prosecution or maintenance of a patent application in any country, on any invention or claim included in the Licensed Technology in any such country (an "**Abandoned Country**"), BioLine shall provide BGN and the parties' outside patent counsel with prompt written notice of such election. Upon written receipt of such notice by BGN, BioLine shall be released from any obligation with respect to such Abandoned Country in conjunction with such Patent Rights. [\*\*\*]

**4.5 No Warranty**. Nothing contained herein shall be deemed to be a warranty by any of the parties that they can or will be able to obtain patents on patent applications included in the Licensed Patent Rights, or that any of the Licensed Patent Rights will afford adequate or commercially worthwhile protection.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

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### 5. Sublicenses

**5.1 Right to Grant Sublicenses.** Subject to the terms and conditions of this Section 5 BioLine shall be entitled to grant sublicenses or other rights to third parties under the License. Such sublicenses shall be made for consideration and in arm's length transactions.

**5.2** Sublicense Agreements. Sublicenses shall only be granted pursuant to written agreements, which shall be in compliance and not inconsistent with the terms and conditions of this Agreement.

**5.2.1** BioLine shall inform BGN of any negotiations to grant a sublicense to a third party and provide BGN with the proposed form of sublicense agreement prior to its execution, for BGN's approval. BGN shall have the right to withhold its approval for any proposed sublicensing agreement solely to the extent that it reasonably determines that (a) the proposed sublicensing agreement does not comply in any substantive manner with the provisions of this Section 5; or (b) execution and performance of the proposed sublicense agreement will jeopardize or expose to non-prosecutable infringement BGN's proprietary rights in the Licensed Technology. In such case BGN shall provide written notice to BioLine within three business days of receipt of the proposed sublicense agreement, detailing the grounds for withholding its approval in accordance with this Section 5.2.1. In the event that BGN does not provide such a written notice within said three business days, it will be deemed for all purposes to have approved the proposed sublicense agreement.

**5.2.2** Each such sublicense agreement shall contain *inter alia*, provisions necessary to ensure BioLine's ability to perform its obligations under this Agreement, including with respect to reporting requirements and audit rights.

**5.2.3** In the event of termination of the License , any existing agreements that contain a sublicense of, or other grant of right with respect to, Licensed Technology shall terminate to the extent of such sublicense or other grant of right; provided, however, that, for each Sublicensee, upon termination of the sublicense agreement with such Sublicensee, if Sublicensee is not then in breach of such sublicense agreement with BioLine such that BioLine would have the right to terminate such sublicense, BGN shall be obligated, at the request of such Sublicensee, to enter into a new agreement with such Sublicensee on substantially the same terms as those contained in such sublicense agreement, and provided further that such terms shall be amended, if necessary, to the extent required to ensure that such sublicense agreement does not impose any obligations or liabilities on BGN which are not included in this Agreement.

**5.2.4** A Sublicensee shall be entitled to sublicense its rights under a sublicense agreement, and so forth through a chain of sublicenses, provided that each such sublicense shall be subject to execution of a written agreement consistent with the terms of this Section 5 (other than Section 5.2.1 above), and shall be made for consideration and at arm's length transactions. To avoid doubt, BGN's approval will not be required in any such instance.

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**5.3 Delivery of Sublicense Agreement.** BioLine shall furnish BGN with a fully executed copy of any such sublicense agreement promptly after its execution, and shall ensure that any Sublicensee who further sublicenses its rights furnishes BGN with a fully executed copy of any such sublicense agreement promptly after its execution.

**5.4 Contractors**. BioLine shall have the right to utilize third party contractors in connection with BioLine's activities in exploiting the License. Provided that such contractors perform activities on BioLine's behalf, the provisions of this Section shall not apply with respect to such contractors. Sublicenses to Affiliates and third party contractors of BioLine shall not be considered Sub-Licenses under this Agreement, *provided however*, that such Affiliates and contractors shall act under the strict control, supervision and responsibility of BioLine. BioLine hereby agrees and undertakes that it shall remain solely responsible towards BGN for all acts and omissions performed, or omitted, by any such contractor (" **the Acts**"), relating to BioLine's undertakings under this Agreement, and that, for all purposes, it shall be considered as if the said Acts were performed, or omitted, by BioLine. BioLine hereby specifically renounces any argument and/or claim, that any undertaking and/or statement it has given under this Agreement, has no effect since it has no control of acts and/or omissions of any such contractor.

# 6. Development and Information Exchange.

**6.1 Diligence**. BioLine shall use all Commercially Reasonable Efforts, and/or shall cause its Affiliates and/or Sublicensees to use their Commercially Reasonable Efforts to develop Licensed Products in accordance with the applicable Development Plan during the periods and within the timetable specified therein. Without limiting the foregoing, BioLine and/or its Affiliates and/or Sublicensees shall meet the Milestones set forth in Exhibit D hereto.

**6.2 Modifications**. BioLine shall be entitled, from time to time, to make such adjustments to the then applicable Development Plan as BioLine believes, in its good faith judgment, are needed in order to improve BioLine's ability to meet the Milestones.

**6.2A Development Plan Reporting and Approval**. BioLine hereby undertakes to provide BGN with an updated Development Plan at least once a year, no later then 30 (thirty) days following the beginning of each calendar year.

**6.3 Failure**. If BioLine fails to achieve a Milestone by its designated performance date ("**Failure**"), unless and to the extent a delay in achievement of a Milestone is necessitated by a Regulatory Agency or by an event beyond the control of BioLine, BGN may notify BioLine in writing of BioLine's Failure and shall allow BioLine [\*\*\*] to cure such failure. BioLine's failure to cure such failure to BGN's reasonable satisfaction within such [\*\*\*] period shall constitute a material breach of this Agreement and BGN shall have the right to terminate this Agreement.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

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**6.4 Steering Committee, Consultation and Progress Reports. The** parties shall establish a steering committee (the "Committee") to oversee the exercise of the License. Each party shall be entitled to designate one representative to the Committee (the "Representative"), which shall meet at least once every six (6) months. The Representatives shall be bound by the confidentiality arrangements set out in this Agreement. BioLine agrees to consult with BGN, via the BGN Representative, in respect of significant decisions related to the exercise of the License. BioLine shall (i) provide BGN via BGN's Representative with periodic reports not less than once per every six (6) months concerning all material activities undertaken in respect of the exercise of the License, and (ii) keep BGN fully informed via BGN's Representative on a current basis concerning all material activities undertaken in respect of the exercise of the License.

**6.5 Research Employees and Consultants.** BioLine hereby undertakes that any and all research activity that BioLine may wish to have performed in connection with the Licensed Technology that entails the services of BGU's employees including, without limitation, any employee, who has been employed or engaged by BGU shall be contracted though and provided solely and exclusively via BGN on such terms and conditions as shall be agreed upon by BGN and BioLine. For the avoidance of any doubt, BioLine hereby undertakes not to solicit, engage as subcontractor or agent, or employ, directly or indirectly, any of BGU's employees and/or consultant and/or service providers, other than in terms and conditions of this section 6.5.

7. Consideration for Grant of License . In consideration of the License, BioLine shall pay BGN the following fees and payments:

**7.1 Initial and First Year Payments**. BioLine shall reimburse BGN for expenses incurred by BGN to date in connection with the Licensed Technology by payment of an initial fee of [\*\*\*], within fourteen (14) days of the Effective Date. For the avoidance of doubt it is hereby clarified that such an amount is an amount agreed upon by the parties and BGN shall not be required to justify such an amount in any manner, *inter alia*, to present receipts.

**7.2** In addition, BioLine shall pay BGN additional fees of [\*\*\*] on each of the following dates: March 31 2005, September 30, 2005, and December 31, 2005 (for a total of [\*\*\*]).

**7.2 Annual License** Fee. As of December 31, 2005 and on subsequent anniversaries thereof, BioLine shall pay BGN an annual fee of thirty thousand U.S. dollars (\$30,000) as an annual maintenance fee for the license. Such annual fee will cease to be payable once BGN has received cumulative Payments on Sublicense Consideration and/or BioLine Royalties equal to or exceeding [\*\*\*] in any calendar year.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

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**7.3 Milestone Payment**. In addition, BioLine shall pay BGN a one-time milestone payment of [\*\*\*] (the "**Milestone Payment**"), within fourteen (14) days of upon the earlier of the occurrence of either of the following: [\*\*\*]

# 7.4 Payments on Sublicensing Consideration and BioLine Royalty Payments

**7.4.1** BioLine shall pay BGN an amount equal to twenty-eight percent (28%) of any and all Sublicense Consideration ("**Payments on Sublicense Consideration**"). To avoid doubt, Payments on Sublicense Consideration shall not be payable with respect to an M&A transaction in which all or substantially all of BioLine's assets or share capital are acquired by a third party.

7.4.2 [\*\*\*]

**7.5 BioLine Royalties** In addition to the amounts set forth in Sections 7.1, through 7.4 above, in the event that BioLine will actually manufacture and/or sell Licensed Products under the License, BioLine will pay to BGN [\*\*\*] of BioLine's and/or its Affiliates' Net Sales ("**BioLine Royalty Payments**"). Such amounts shall be payable, on a Licensed Product-by-Licensed Product and country-by-country basis, during the period in which a valid patent on the Licensed Technology underlying a product or service generating Net Sales in a given country remains in force in such country. To avoid doubt, in the event that BioLine continues sell products or services in any country based upon the Licensed Patent Rights with respect to which no patent remains in force as a result of abandoned pursuant to Section 4.4, BioLine Royalty Payments will **nonetheless** be payable with respect to such sales.

**7.6 Permitted Deductions**; Third-Party Royalties. In the event that BioLine or an Affiliate of BioLine is legally required to make royalty payments to one or more third parties to obtain a Third Party License from such third party(ies) in order to practice the Licensed Technology in a particular country, BioLine may offset such third-party payments against the BioLine Royalty Payments that are due to BGN pursuant to Section 7.5 with respect to sales in such country.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

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7.7 Multiple Sublicenses. In the event that BioLine will seek to sublicense rights under the License to a third party together with technologies unrelated to the Licensed Technology (a "Multiple Sublicense"), and BGN believes that the fact that the Licensed Technology is being sublicensed in the context of the Multiple Sublicense will substantially reduce the remuneration receivable by the BGN with respect to the sublicense of the Licensed Technology, the parties shall seek an independent evaluation ("Arbitration") by a mutually agreed upon third party ("the Arbitrator"), whose decision will be limited solely to determination of the independent valuation of the License, and the economic effect of the sublicensing of the License in the context of the proposed Multiple Sublicense, and will be binding on the parties. In the event that the parties do not agree on the identity of the Arbitrator within 30 (thirty) days, or any other period agreed upon in writing by both parties, from the date in which a written request for Arbitration was sent by at least one party to the other party, the Arbitrator shall be nominated by the head of Kost Forer, Gabbay and Kasirer's (Ernst &Young Israel) Life Science Department.

**7.8 Government Programs**. BioLine may submit applications for Grants, and BGN undertakes to provide all necessary **assistance** to BioLine, in a timely manner, with respect to any such applications and in order to ensure BioLine's compliance with the terms and conditions of any Grants or benefits under Government Programs. Any (i) costs incurred in respect of obtaining Grants, and (ii) financial obligations assumed in respect thereof (such as, for example, repayment of the principal of a Grant, interest payments or royalties in respect thereof) shall be solely for the account of BioLine. The parties acknowledge that BioLine's obligations hereunder shall be subject to the terms of any applicable Grant, including without limitation, and if applicable any consents or approvals required pursuant to the Law for the Encouragement of Research and Development in Industry (1984) and related regulations. To avoid doubt, BioLine shall be entitled to execute any such documents, make any such representations and perform any such actions as may be necessary or desirable to fulfill its obligations and exercise its rights under any Government Program, and nothing in this Agreement shall be construed as restricting in any manner its ability to comply with the terms of any Government Program.

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# 8. Reports ; Payments ; Records.

#### 8.1 Reports and Payments.

**8.1.1 Reports**. Within [\*\*\*] after the conclusion of each Calendar Quarter commencing with the first Calendar Quarter in which BioLine or an Affiliate of BioLine first receives consideration from Net Sales and/or Sublicense Consideration, BioLine shall deliver to BGN a report containing the following information:

(a) the number of units of Licensed Products sold by BioLine and its Affiliates in each country for the applicable Calendar Quarter;

(b) the gross amount billed for the Licensed Product sold by BioLine and its Affiliates in each country during the applicable Calendar Quarter;

(c) a calculation of Net Sales for the applicable Calendar Quarter in each country, including a listing of applicable deductions;

(d) the amount of Sublicense Consideration received by BioLine and/or Affiliates for the applicable Calendar Quarter; and

(e) the total amount payable to BGN in U.S. dollars for the applicable Calendar Quarter, together with exchange rates used for conversion, if any. The report shall state if no amounts are due to BGN for any Calendar Quarter.

**8.1.2 Payment**. Concurrent with the delivery of each report delivered pursuant to Section 8.1.1, BioLine shall remit to BGN all amounts due to BGN for the applicable Calendar Quarter. All payments due under this Agreement shall be payable in the currency in which they were received. Any and all payments shall be performed by BioLine no later then [\*\*\*] days following receipt of relevant payments by BioLine.

**8.2 Records and Audit**. BioLine shall maintain, and shall cause its Affiliates to maintain, complete and accurate records of Licensed Products that are made, used, marketed or sold under this Agreement, any amounts payable to BGN in relation to such Licensed Products and all Sublicense Consideration received by BioLine and its Affiliates, which records shall contain sufficient information to permit BGN to confirm the accuracy of any reports or notifications delivered to BGN under Section 8.1. The relevant party shall retain such records relating to a given Calendar Quarter for at least three (3) years after the conclusion of that Calendar Quarter. During such three (3) year period, BGN shall have the right, at BGN's expense, to cause an independent, certified public accountant, who is bound by a suitable confidentiality arrangement with BioLine, to inspect BioLine's and the relevant Affiliates' relevant records during normal business hours for the sole purpose of verifying any reports and payments delivered under this Agreement. Such accountant shall not disclose to BGN or any third party any information gained during the course of such inspection that does not directly relate to the accuracy of reports and payments delivered under this Agreement. The parties shall reconcile any underpayment or overpayment within thirty (30) days after the accountant delivers the results of the audit. BGN may exercise its rights under this Section 8.2 only once every year per audited party and only with reasonable prior notice to the audited party. BioLine shall cause its Affiliates to fully comply with the terms of this Section 8.2.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

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**8.3 Payment Method**. Each payment due to BGN under this Agreement shall be made by wire transfer of funds to BGN accounts in accordance with written instructions provided by BGN.

**8.4 Withholding and Similar Taxes**. If applicable laws require that taxes be withheld from any amounts due to BGN under this Agreement, BioLine shall (a) deduct these taxes from the remittable amount, (b) pay the taxes to the proper tax authority, and (c) promptly deliver to BGN a statement including the amount of tax withheld and justification therefore, and such other information as may be necessary for tax credit purposes. Each party agrees to assist the other party in claiming exemption from such deductions or withholdings under any double taxation or similar agreement or treaty from time to time in force.

# 9. Confidential Information

# 9.1 Confidentiality.

9.1.1 BGN Confidential Information. BioLine agrees that, without the prior written consent of BGN, in each case, during the term of this Agreement, and for five (5) years thereafter, it will keep confidential, and not disclose or use BGN Confidential Information (as defined below) other than for the purposes of this Agreement or as detailed below. BioLine shall treat such BGN Confidential Information with the same degree of confidentiality as it keeps its own confidential information, but in all events no less than a reasonable degree of confidentiality. BioLine may disclose the BGN Confidential Information only to employees, consultants or researchers of BioLine or of its Affiliates who have a "need to know" such information in order to enable BioLine to exercise its rights or fulfill its obligations under this Agreement and provided such parties are legally bound by agreements which impose confidentiality and non-use obligations comparable to those set forth in this Agreement. For purposes of this Agreement, "BGN Confidential Information" means any scientific, technical, trade or business information relating to the subject matter of this Agreement designated as confidential or which otherwise should reasonably be construed under the circumstances as being confidential disclosed by or on behalf of BGN, or any of its employees, consultants or researchers to BioLine, whether in oral, written, graphic or machinereadable form, except to the extent such information: (i) was known to BioLine at the time it was disclosed, other than by previous disclosure by or on behalf of BGN or any of its employees, consultants or researchers, as evidenced by BioLine's written records at the time of disclosure; (ii) is at the time of disclosure or later becomes publicly known under circumstances involving no breach of this Agreement; (iii) is lawfully and in good faith made available to BioLine by a third party who is not subject to obligations of confidentiality to BGN with respect to such information; (iv) is independently developed by BioLine without the use of or reference to BGN Confidential Information, as demonstrated by documentary evidence, or (v) is disclosed pursuant to a court or administrative order, provided however that BioLine will first notify BGN of any such order and afford BGN the opportunity to seek a protective order relating to such disclosure.

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Notwithstanding anything to the contrary in this Section 9.1.1, BioLine may disclose BGN Confidential Information to actual and potential business partners, collaborators, investors, contractors, service providers and consultants, provided, in each case, that such recipient of Confidential Information first enters into a legally binding agreement with BioLine which imposes confidentiality and non-use obligations with respect to Confidential Information comparable to those set forth in this Agreement for a period of at least five (5) from the date of disclosure of BGN Confidential Information to such recipient.

**9.1.2 BioLine Confidential Information**. BGN agrees that, without the prior written consent of BioLine, in each case, during the term of this Agreement, and for five (5) years thereafter, it will keep confidential, and not disclose or use BioLine Confidential Information (as defined below) other than for the purposes of this Agreement. BGN shall treat such BioLine Confidential Information with the same degree of confidential Information only to employees, consultants or researchers of BGN or its Affiliates who have a "need to know" such information in order to enable BGN to exercise its rights or fulfill its obligations under this Agreement and provided such parties are legally bound by agreements which impose confidentiality and non-use obligations comparable to those set forth in this Agreement. For purposes of this Agreement, "BioLine Confidential Information" means any scientific, technical, trade or business information relating to the subject matter of this Agreement designated as confidential or which otherwise should reasonable form, except to the extent such information: (i) was known to BGN at the time it was disclosed, other than by previous disclosure by or on behalf of BioLine within the solucing no breach of this Agreement; (iii) is a the time of disclosure or later becomes publicly known under circumstances involving no breach of this Agreement; (iii) is lawfully and in good faith made available to BGN by a third party who is not subject to obligations of confidential Information; (iv) is independently developed by BGN without the use of or reference to the BioLine Confidential Information, as demonstrated by documentary evidence; or (v) is disclosed pursuant to a court or administrative order, provided however that BGN will first notify BioLine of any such order and afford BioLine the opportunity to seek a protective order relating to such disclosure.

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**9.2 Disclosure of Agreement**. Each party may disclose the terms of this Agreement to the extent required, in the reasonable opinion of such party's legal counsel, to comply with applicable laws, as well as to sublicensees and prospective and current investors, pursuant to appropriate non-disclosure arrangements . If a party discloses this Agreement or any of the terms hereof in accordance with this Section 9.2, such party agrees, at its own expense , to seek confidential treatment of portions of this Agreement or such terms, as may be reasonably requested by the other party.

**9.3 Publicity.** Except as expressly permitted under Section 9.2, no party will make, directly or indirectly, any announcement, publication, presentation or similar disclosure, regarding this Agreement or the Licensed Technology without the prior approval of the other party.

# 10. Patent Infringement.

# 10.1 Enforcement of Patent Rights.

**10.1.1 Notice.** In the event any party becomes aware of any possible or actual infringement or unauthorized possession, knowledge or use of any Licensed Patent Rights (collectively, an "Infringement"), that party shall promptly notify the other party and provide it with details regarding such Infringement.

**10.1.2 Suit by BioLine**. BioLine shall have the right, but not the obligation, to take action in the prosecution, prevention, or termination of any Infringement of Licensed Patent Rights. Should BioLine elect to bring suit against an infringer and BGN is joined as party plaintiff in any such suit, BGN shall have the right to approve the counsel selected by BioLine to represent BioLine and BGN, such approval not to be unreasonably withheld. The expenses of such suit or suits that BioLine elects to bring, including any expenses of BGN incurred in conjunction with the prosecution of such suits or the settlement thereof, shall be paid for entirely by BioLine and BioLine shall hold BGN free, clear and harmless from and against any and all costs of such litigation, including reasonable attorney's fees. BioLine shall not compromise or settle such litigation without the prior written consent of BGN, which consent shall not be unreasonably withheld or delayed. In the event BioLine exercises its right to sue pursuant to this Section 10.1.2, it shall first reimburse itself out of any sums recovered in such suit or in settlement thereof for all costs and expenses of every kind and character, including reasonable attorney's fees, necessarily involved in the prosecution of any such suit. If, after such reimbursement, any funds shall remain from said recovery, then BGN shall receive an amount equal to [\*\*\*] of such funds shall be retained by BioLine.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

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**10.1.3 Suit** by BGN. If BioLine does not take action in the prosecution, prevention, or termination of any Infringement pursuant to Section 10.1.2 above, and has not commenced negotiations with the infringing party for the discontinuance of said Infringement, within sixty (60) days after receipt of notice to BioLine by BGN of the existence of an Infringement, BGN may elect to do so. If BGN elects to bring suit against an infringing party and BioLine is joined as party plaintiff in any such suit, BioLine shall have the right to approve the counsel selected by BGN to represent BGN and BioLine, such approval not to be unreasonably withheld. The expenses of such suit or suits that BGN elect to bring, including any expenses of BioLine incurred in conjunction with the prosecution of such suits or the settlement thereof, shall be paid for entirely by BGN and BGN shall hold BioLine free, clear and harmless from and against any and all costs of such litigation, including reasonable attorney's fees. BGN shall not compromise or settle such litigation without the prior written consent of BioLine, which consent shall not be unreasonably withheld or delayed. In the event BGN exercise their right to sue pursuant to this Section 10.1.3, they shall first reimburse themselves out of any sums recovered in such suit or in settlement thereof for all costs and expenses of every kind and character, including reasonable attorney's fees, necessarily involved in the prosecution of any such suit. If, after such reimbursement, any funds shall remain from said recovery, then BioLine shall receive an amount equal to [\*\*\*] of such funds and the remaining [\*\*\*] of such funds shall be retained by BGN.

**10.1.4 Own Counsel.** Each party shall always have the right to be represented by counsel of its own selection and at its own expense in any suit instituted under this Section 10 for Infringement.

**10.1.5** Cooperation. Each party agrees to cooperate fully in any action under this Section 10 which is controlled by another party, provided that the controlling party reimburses the cooperating party promptly for any costs and expenses incurred by the cooperating party in connection with providing such assistance.

**10.1.6 Standing**. If a party lacks standing and another party has standing to bring any such suit, action or proceeding, then such other party shall do so at the request of and at the expense of the requesting party. If a party determines that it is necessary or desirable for another party to join any such suit, action or proceeding, the other party shall execute all papers and perform such other acts as may be reasonably required in the circumstances.

10.1.7 Delegation. BioLine may delegate the performance of its obligations under this Section 10.1 to Subticensees.

**10.2 Legal Action Against a Party**. Each Party will provide the others with prompt notice of any action, suit or proceeding brought against it, alleging the infringement of the intellectual property rights of a third party by reason of the discovery, development, manufacture, use, sale, importation, or offer for sale of a Licensed Product or otherwise due to the use or practice of the Licensed Technology.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

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# 11. Warranties; Limitation of Liability.

**11.1 Representations and Warranties**. BGN hereby represents and warrants that (i) to its best knowledge BGU is the sole owner of the Licensed Patent Rights; (ii) it has not granted any rights in or to Licensed Technology which are inconsistent with the rights granted to BioLine under this Agreement; (iii) it has full right and authority to grant the License granted under this Agreement; (iv) it will not transfer, assign, encumber, grant, sell, lease or otherwise dispose of the Licensed Technology other than as may be expressly permitted herein; and (v) it has no knowledge as of the date hereof of any legal suit or proceeding by a third party against BGN and/or BGU contesting the ownership or validity of the Licensed Patent Rights, or claiming that the practice of the Licensed Patent Rights in the manner contemplated by this Agreement would infringe the rights of such third party.

**11.2 No Warranty**. Except as otherwise expressly provided in this Agreement, no party makes any warranty with respect to any technology, patents, goods, services, rights or other subject matter of this Agreement and hereby disclaims warranties of merchantability, fitness for a particular purpose and non-infringement with respect to any and all of the foregoing.

**11.3 Limitation of Liability**. Notwithstanding anything else in this Agreement or otherwise, neither BGN nor BioLine will be liable to the other with respect to any subject matter of this Agreement under any contract, negligence, strict liability or other legal or equitable theory for (i) any indirect, incidental, consequential or punitive damages or lost profits, and (ii) the cost of procurement of substitute goods, technology or services.

# 12. Indemnification.

**12.1 Indemnity**. BioLine shall indemnify, defend, and hold harmless BGN and its respective directors, officers, employees, and agents and their respective successors, heirs and assigns (the "BGN Indemnitees "), from and against any liability, damage, loss, or expense (including reasonable attorney's fees and expenses of litigation) incurred by or imposed upon any of the BGN Indemnitees in connection with any claims, suits, actions, demands or judgments (" Claims") concerning the use of any Licensed Technology by BioLine, or any of its Affiliates or Sublicensees, or concerning any product, process, or service that is made, used, or sold pursuant to any right or license granted by BGN to BioLine under this Agreement (except in cases where, and to the extent that, such claims, suits, actions, demands or judgments result from gross negligence or willful misconduct on the part of any of the BGN Indemnitees).

**12.2 Conditions for Indemnification**. BioLine undertakings under Section 12.1 above shall be subject to: (a) receipt of prompt written notice of any Claim by a BGN Indemnitee, (b) the cooperation of BGN and the BGN Indemnitee(s) regarding the response to and the defense of any such Claim, and (c) BioLine's right to assume the defense or represent the interests of the BGN Indemnitee in respect of such Claim, that shall include the right to select and direct legal counsel and other consultants to appear in proceedings on behalf of the BGN Indemnitee and to propose, accept or reject offers of settlement, all at its sole cost; provided however, that no such settlement shall be made without the written consent of the BGN Indemnitee, such consent not to be unreasonably withheld. Nothing herein shall prevent the BGN Indemnitee from retaining its own counsel and participating in its own defense at its own cost and expense.

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**12.3 Insurance**. BioLine shall maintain insurance that is reasonably adequate to fulfill any potential obligation to the BGN Indemnitees consistent with industry standards. BioLine shall provide BGN, upon request, with written evidence of such insurance.

# 13. Term and Termination.

**13.1 Term.** The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Section 13, shall continue in full force and effect on until the expiration of all payment obligations pursuant to Section 7 for such Licensed Product, and as.

**13.2 Effect of Expiration**. Following the expiration of the last valid patent on the Licensed Technology underlying a product or service generating Net Sales in a given country, on a country-by-country basis, (a) BioLine shall have a fully-paid up, nonexclusive, worldwide license (with the right to grant sublicenses) under the BGN Technology in such country solely to develop, have developed, manufacture, have manufactured, use, market, offer for sale, sell, have sold, import, export, otherwise transfer physical possession- of or otherwise transfer title to Licensed Products; and (b) BGN shall be free to use the Licensed Technology in such country to develop, make and have made, use, offer to sell, sell, have sold, import, export, otherwise transfer physical possession of or otherwise transfer title to Licensed Products and to grant others licenses under the Licensed Technology to do the same. To avoid doubt, to the extent that BioLine continues to receive Sublicense Consideration following such expiration, BGN shall continue to be entitled to receive Payments on Sublicense Consideration with respect thereto, notwithstanding the foregoing.

# 13.3 Termination.

**13.3.1 Termination By BioLine**. BioLine may terminate this Agreement within the first two years of the term of the Agreement, with sixty (60) days prior written notice to BGN, for commercial, economic, scientific or technological reasons, as it shall determine at its sole and absolute discretion. After such initial two year period, BioLine may terminate this Agreement without cause with sixty (60) days prior written notice to BGN.

# 13.3.2 Termination for Default.

**13.3.2.1** In the event that BioLine commits a material breach of its obligations under this Agreement and fails to cure that breach within sixty (60) days after receiving written notice thereof from BGN, BGN may terminate this Agreement immediately upon written notice to BioLine. In the event that BGN commits a material breach of its obligations under this Agreement and fails to cure that breach. within sixty (60) days after receiving written notice thereof from BioLine, BioLine may terminate this Agreement and fails to cure that breach. within sixty (60) days after receiving written notice thereof from BioLine, BioLine may terminate this Agreement immediately upon written notice to BGN. Notwithstanding the foregoing, in the event that any breach is not susceptible of cure within the stated period and the breaching party uses diligent good faith efforts to cure such breach, the stated period will be extended by an additional thirty (30) days.

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**13.3.2.2** In the event of an uncured material breach by any party as described in the foregoing paragraph, the other party may elect not to terminate this Agreement but, instead, to sue the breaching party for damages arising from such breach.

# 13.3.3 Bankruptcy.

**13.3.3.1** Either BioLine or BGN may terminate this Agreement upon notice to the other if the other party becomes insolvent, is adjudged bankrupt, applies for judicial or extra-judicial settlement with its creditors, makes an assignment for the benefit of its creditors, voluntarily files for bankruptcy or has a receiver or trustee (or the like) in bankruptcy appointed by reason of its insolvency, or in the event an involuntary bankruptcy action is filed against the other party and not dismissed within ninety (90) days, or if the other party becomes the subject of liquidation or dissolution proceedings or otherwise discontinues business.

**13.3.3.2** Notwithstanding the foregoing, in the event a receiver or trustee (or the like) is appointed or BioLine has entered into a settlement with its creditors and BioLine is otherwise meeting its obligations pursuant to this Agreement, BGN shall not be entitled to terminate this Agreement as contemplated under Section 13.3.3.1 during such period.

# 13.4 Effect of Termination.

**13.4.1 Termination of Rights**. Upon termination by BioLine pursuant to Sections 13.3.1, 13.3.2 or 13.3.3 hereof or by BGN pursuant to Sections 13.3.2 or 13.3.3 hereof (except in the circumstances set out in Section 13.3.3.2): (a) the rights and licenses granted to BioLine under Section 2 shall terminate; (b) all rights in and to the Licensed Technology shall revert to BGN and BioLine shall not be entitled to make any further use whatsoever of the BGN Technology nor shall BioLine develop, make, have made, use, offer to sell, sell, have sold, import, export, otherwise transfer physical possession of or otherwise transfer title to Licensed Products developed in whole or in part under the rights granted hereunder; and (c) any existing agreements that contain a sublicense of the Licensed Technology shall terminate to the extent of such sublicense provided however, that, for each Sublicensee, upon termination of the sublicense agreement with such Sublicensee, BGN shall be obligated, at the request of such Sublicensee, to enter into a new license agreement with such Sublicensee on substantially the same terms as those contained in such sublicense agreement, provided that such terms shall be amended, if necessary, to the extent required to ensure that such sublicense agreement does not impose any obligations or liabilities on BGN which are not included in this Agreement.

**13.4.2** Accruing Obligations. Termination of this Agreement shall not relieve the parties of obligations occurring prior to such termination, including obligations to pay amounts accruing hereunder up to the date of termination.

**13.5 Survival**. The parties' respective rights, obligations and duties under Sections 3, 9, 11.4 and 14, as well as any rights, obligations and duties which by their nature extend beyond the expiration or termination of this Agreement, shall survive any expiration or termination of this Agreement.

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## 14. Miscellaneous.

**14.1 Entire Agreement**. This Agreement is the sole agreement with respect to the subject matter hereof and except as expressly set forth herein, supersedes all other agreements and understandings between the parties with respect to same.

**14.2 Publicity Restrictions**. Subject to Section 9.3, BioLine and its Affiliates and Sublicensees shall not use the name of BGN or any of its directors, officers, employees, or agents, or any adaptation of such names, in any promotional material or other public announcement or disclosure relating to the subject matter of this Agreement or in connection with the marketing or sale of any Licensed Products, without the prior written consent of BGN. Subject to Section 9.3, BGN and its Affiliates shall not use the name of BioLine and its Affiliates and Sublicensees or any of their employees, directors, stockholders and/or representatives or any adaptation of such names, in any promotional material or other public announcement or disclosure relating to the subject matter of this Agreement, without the prior written consent of BioLine.

**14.3 Notices**. Unless otherwise specifically provided, all notices required or permitted by this Agreement shall be in writing and may be delivered personally, or may be sent by facsimile or certified mail, return receipt requested, to the following addresses, unless the parties are subsequently notified of any change of address in accordance with this Section 14.3:

If to BioLine: BioLine Innovations Jerusalem L.P 19 Hartum Street P.O. Box 45158 Jerusalem 91450 Israel Attention: CEO and VP Finance Fax: 972-2-548-9101

With a copy (which Yigal Arnon & Co., Law Offices shall not constitute 22 Rivlin Street notice) to: Jerusalem, 94263 Israel Attention: Barry Levenfeld Fax: 972-2-623-9236

If to BGN: B.G.Negcv Technologies and Applications Ltd. 1, Henrietta Sold street P.O.Box 653 Beer-Sheva, 84105 Israel

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Attn: Ora Horovitz Fax: 972-8-6276420 With a copy (which Bach, Arad, Sharf and Co. shall not constitute 2 Hashalom Rd. notice) to: Tel-Aviv Israel Attention: Adv. Eytan Liraz Fax: 972-3-5625304

Any notice shall be deemed to have been received as follows: (i) by personal delivery, upon receipt; (ii) by facsimile, one business day after transmission or dispatch; (iii) by airmail, three (3) business days after delivery to the postal authorities by the party *serving* notice. If notice is sent by facsimile, a confirming copy of the same shall be sent by mail to the same address.

**14.4 Governing Law and Jurisdiction**. This Agreement shall be governed by and construed in accordance with the laws of the State of Israel, without regard to the application of principles of conflicts of law, except for matters of patent law, which, other than for matters of inventorship on patents, shall be governed by the patent laws of the relevant country of the patent. The parties hereby consent to personal jurisdiction in Israel and agree that any lawsuit they file to enforce their respective rights under this Agreement shall be brought in the competent court in Tel Aviv, Israel.

**14.5 Binding Effect.** This Agreement shall be binding upon and inure to the benefit of the parties and their respective legal representatives, successors and permitted assigns.

**14.6 Headings**. Section and subsection headings are inserted for convenience of reference only and do not form a part of this Agreement.

14.7 Counterparts. This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed an original.

**14.8 Amendment; Waiver**. This Agreement may be amended, modified, superseded or canceled, and any of the terms may be waived, only by a written instrument executed by each party or, in the case of waiver, by the party waiving compliance. The delay or failure of any party at any time or times to require performance of any provisions hereof shall in no manner affect the rights at a later time to enforce the same. No waiver by either party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

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**14.9** No Agency or Partnership. Nothing contained in this Agreement shall give any party the right to bind another, or be deemed to constitute either parties as agents for each other or as partners with each other or any third party.

**14.10** Assignment and Successors. This Agreement may not be assigned by either party without the consent of the other party, which consent shall not be unreasonably withheld or delayed; provided however, that each party (including its successors or assigns) may, without such consent, assign this Agreement and the rights, obligations and interests of such party, in whole or in part, to any of its Affiliates, to any purchaser of all or substantially all of its assets or research to which the subject matter of this Agreement relates, or to any successor corporation resulting from any merger or consolidation of such party with or into such corporation.

**14.11 Force Majeure**. Neither party will be responsible for delays resulting from causes beyond the reasonable control of such party, including without limitation fire, explosion, flood, war, strike, or riot, provided that the nonperforming party uses commercially reasonable efforts to avoid or remove such causes of nonperformance and continues performance under this Agreement with reasonable dispatch whenever such causes are removed.

**14.12 Interpretation**. The parties hereto acknowledge and agree that: (i) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting party shall not be employed in the interpretation of this Agreement; and (iii) the terms and provisions of this Agreement shall be construed fairly as to both parties hereto and not in favor of or against either party, regardless of which party was generally responsible for the preparation of this Agreement.

**14.13** Severability. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the parties that the remainder of this Agreement shall not be affected.

14.14 Exhibits. The following exhibits form an integral part of this Agreement:

Exhibit A: Current Invention

Exhibit B: Development Plan

Exhibit C: Patent Rights

Exhibit D: Milestones

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IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

**B.G. Negev Technologies and Applications Ltd.** 

By: /s/ Moti Herskowitz /s/ Netta Cohen Name: Moti Herskowitz, Netta Cohen Title: Director, CEO Date: 16/01/05 **BioLine Innovations Jerusalem L.P.** 

By its General Partner: BioLine Innovations Jerusalem Ltd. By: /s/ Morris Laster, /s/ Aharon Schwartz Name: Morris Laster, Aharon Schwartz Title: Director , Director Date: 10/01/05

I hereby confirm that I have read and understood the Agreement, that its contents are acceptable to me and that I will act in accordance with its terms.

Prof. Smadar Cohen By: /s/ Smadar Cohen Date : 22/01/05

Prof. Jonathan Leor By: /s/ Jonathan Leor Date: 22/01/05

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Ex	hit	oit	A

# **Current Invention**

Patent No. Application Invention

# [\*\*\*]

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

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# Exhibit B

# **Development Plan**

2010	2008	2007	2006	2005	Cost	Finish	Start	Task	ID
								Name	
					<u> </u>	<u> </u>		Name	

# [\*\*\*]

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

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ID	Task Name	Start	Finish	Cost	2005	2006	2007	2008	2009	2010
[***]										
			-							

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

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Exhibit C

# Patent Rights

Patent No.

Application Invention

[\*\*\*]

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

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Exhibit D

# Milestones

Milestone

Date

# [\*\*\*]

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

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# ASSIGNMENT OF BL-1040 PROJECT

THIS ASSIGNMENT (the "Assignment") is made effective as of January 1, 2009, by and between BioLine Innovations Jerusalem, Limited Partnership ("Assignor") and BioLineRx, Ltd. ("Assignee").

WHEREAS, Assignor entered into that certain License Agreement dated as of January 10, 2005 with B.G. Negev Technologies and Applications, Ltd. (the *"License Agreement"*); and

WHEREAS, Assignor desires to assign the License Agreement to Assignee pursuant to Section 14.10 thereof, and Assignee desires to accept such assignment;

NOW, THEREFORE, the parties hereto hereby agree as follows:

1. Assignor hereby assigns the License Agreement, and all of Assignor's rights, obligations and interests thereunder to Assignee.

2. Assignee hereby accepts the foregoing assignment and agrees to be bound by the terms of the License Agreement.

3. This Assignment shall be construed in accordance with the laws of the State of Israel.

IN WITNESS WHEREOF, the parties hereto have caused this Assignment to be duly executed as of the date first above written.

# ASSIGNOR

<u>ASSIGNEE</u>

BioLine Innovations Jerusalem, LP By It s General Partner BioLine Innovations Jerusalem, Ltd. BioLineRx, Ltd.

<u>/s/ Yuri</u> Shoshan Date: 21.4.09 <u>/s/ Yuri</u> Shoshan Date: 21.4.09

## CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. ASTERISKS DENOTE OMISSIONS

#### **RESEARCH AND LICENSE AGREEMENT**

This License Agreement is entered into as of this 15 day of April, 2004 (the "Effective Date"), by and among BioLineRx Ltd., a company formed under the laws of Israel, having a place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem, 91450, Israel ("BioLine"); Bar-Ilan Research and Development Company Ltd., a company formed under the laws of Israel, having a place of business at Bar-Ilan University, Ramat Gan, 52900 ("BIRAD"); and Ramot at Tel Aviv University Ltd., a company formed under the laws of Israel, having a place of business at Tel Aviv University in Ramat-Aviv, Tel Aviv 61392, Israel ("Ramot"). BIRAD and Ramot shall be referred to together as the "Licensors".

WHEREAS, the Licensors are joint owners of an invention developed by Professor Abraham Weizman, Dr. Irit Gil-Ad and Dr. Ada Rephaeli of the Felsenstein Medical Research Center of Tel Aviv University ("TAU") and Professor Abraham Nudelman of Bar-Ilan University ("BIU"), relating to conjugated anti-psychotic drugs and the use thereof; and

WHEREAS, BioLine wishes to fund further research at TAU and BIU through Ramot and BIRAD, respectively, for the purpose of furthering research related to such invention; and

WHEREAS, BioLine wishes to obtain a license with respect to such invention and the results of such research, in order to develop, obtain regulatory approval for and commercialize products based on such invention, and the Licensors wish to grant BioLine a license with respect to such technology and the results of such research, all in accordance with the terms and conditions of this Agreement.

**NOW, THEREFORE,** the parties hereto, intending to be legally bound, hereby agree as follows:

# 1. Definitions.

Whenever used in this Agreement with an initial capital letter, the terms defined in this Section 1, whether used in the singular or the plural, shall have the meanings specified below.

**1.1. "Additional Ingredient"** shall mean any compound or substance which (i) is contained in a product and (ii) when administered to a patient has a therapeutic or prophylactic clinical effect, either directly or by acting synergistically with or otherwise enhancing the effect of other compounds or substances contained in such product.

**1.2 "Affiliate"** shall mean, with respect to a party, any person, organization or entity controlling, controlled by or under common control with, such party. For purposes of this definition only, "control" of another person, organization or entity shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the activities, management or policies of such person, organization or entity, whether through the ownership of voting securities, by contract or otherwise. Without limiting the foregoing, control shall be presumed to exist when a person, organization or entity, or (ii) possesses, directly or indirectly, the power to elect or appoint twenty percent (20%) or more of the members of the governing body of the organization or other entity.

**1.3. "BIRAD Research"** shall mean the research actually conducted by the BIU Team under the terms of this Agreement in accordance with the BIRAD Research Plan.

**1.4. "BIRAD Research Plan"** shall mean the research plan attached hereto as Exhibit 1.4, as amended from time to time in accordance with the provisions of this Agreement with the mutual agreement of the parties, which sets forth the research to be undertaken by the BIU Team under the direction of the BIU Principal Investigator during the Research Period.

**1.5. "BIU Principal Investigator"** shall mean Professor Abraham Nudelman, or such other principal investigator who may replace Professor Nudelman pursuant to Section 2.2.1.2.

1.6. "BIU Team" shall mean the BIU Principal Investigator and those students, scientists and technicians working at BIU under his direction on the BIRAD Research.

**1.7. "Calendar Quarter"** shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31, for so long as this Agreement is in effect.

**1.8 "Combination Product"** shall mean a product, substance or devise which comprises a Licensed Product and at least one other essential Additional Ingredient.

**1.9. "Commercially Reasonable Efforts"** shall mean (i) with respect to any objective by an entity, reasonable, diligent, good faith efforts to accomplish such objective as such entity (together with its Affiliates as a group) would normally use in the ordinary course of business and research to accomplish a similar objective under similar circumstances; and (ii) with respect to research, development and commercialization of any Licensed Product hereunder, shall mean those efforts and resources normally used by such entity (together with its Affiliates as a group) for a product owned by it or to which it has rights, which is of similar market potential at a similar stage in its development or product life as such Licensed Product.

**1.10.** "Current Inventions" the inventions disclosed in the patent application described in Exhibit 1.20.

**1.11. "Development Plan"** shall mean the plan for the development of Licensed Products attached hereto as Exhibit 1.11, as such plan may be amended from time to time pursuant to Sections 6.2.

**1.12. "Far East Countries"** shall mean Australia, New Zealand, Japan, North Korea, South Korea, Mongolia, the People's Republic of China (including Hong Kong and Macau), Taiwan, Quemoy, and Matsu, Brunei, Cambodia, East Timor, Indonesia, India, Laos, Malaysia, Myanmar (Burma), The Philippines, Singapore, Thailand and Vietnam.

**1.13. "First Commercial Sale"** shall mean the first sale of a Licensed Product by BioLine, an Affiliate of BioLine or a Sublicensee to an unaffiliated third party after Regulatory Approval has been achieved in the country in which such Licensed Product is sold. Sales for test marketing, sampling and promotional uses, clinical trial purposes or compassionate or similar use shall not be considered to constitute a First Commercial Sale.

1.14. "FDA" shall mean the United States Food and Drug Administration.

**1.15. "IND"** shall mean (i) an Investigational New Drug Application, as defined in the U.S. Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder, that is required to be filed with the FDA before beginning clinical testing of a Licensed Product in human subjects, or any successor application or procedure and (ii) any comparable application filed with a Regulatory Agency in any other country or jurisdiction.

**1.16.** "Joint Inventions" shall mean any and all inventions made jointly by one or more members of the Licensor Teams and one or more employees or consultants of BioLine.

1.17. "Joint Patent Rights" shall mean any and all Patent Rights claiming Joint Inventions.

1.18. "Joint Technology" shall mean Joint Patent Rights and Joint Inventions.

**1.19.** "Licensed Patent Rights" shall mean the Licensor Patent Rights and the Joint Patent Rights.

**1.20.** "Licensor Patent Rights" shall mean (i) the Patent Rights described on Exhibit 1.20(a) attached hereto, and (ii) all Patent Rights owned by Ramot and/or BIRAD which claim, and only to the extent they so claim, any of the Research Results. Exhibit 1.20(b) shall include and shall be updated from time to time to include new Licensor Patent Rights.

**1.21.** "Licensed Product" shall mean any therapeutic product that comprises, contains or incorporates a compound described in Exhibit 1.21.

**1.22.** "Licensor Proposed Product" shall mean a potential Licensed Product proposed by one or both of the Licensors that (a) does not incorporate a compound included in a Licensed Product being developed, manufactured, used, marketed or sold by BioLine or any of its Affiliates or Sublicensees and (b) is aimed at an indication that is not targeted by any Licensed Product being developed, manufactured, used, manufactured, used, marketed or sold by BioLine or any of its Affiliates or Sublicensees.

1.23. "Licensor Teams" shall mean the TAU Team and the BIU Team.

1.24. "Licensor Technology" shall mean the Current Invention, the Licensor Patent Rights and the Research Results.

**1.25. "NDA"** shall mean an FDA New Drug Application or Product License Application (or Biologics License Application), as appropriate, and all supplements filed pursuant to the requirements of the FDA, including all documents, data and other information concerning Licensed Products that are necessary for or included in FDA approval to market a Licensed Product, or the equivalent application in any other country or jurisdiction.

**1.26. "Net Sales"** shall mean the gross amount billed or invoiced by or on behalf of BioLine and/or its Affiliates (the "**Invoicing Entity**") on sales of Licensed Products (whether made before or after the First Commercial Sale of the Licensed Product), less the following: (a) customary trade, quantity, or cash discounts to the extent actually allowed and taken; (b) amounts repaid or credited by reason of rejection or return; (c) to the extent separately stated on purchase orders, invoices, or other documents of sale, any taxes or other governmental charges levied on the production, sale, transportation, import, export, delivery, or use of a Licensed Product which is paid by or on behalf of the Invoicing Entity; and (d) outbound transportation, packing and delivery charges, as well as prepaid freight (including shipping insurance) actually incurred; provided that:

(i) In any transfers of Licensed Products between the Invoicing Entity and an Affiliate of the Invoicing Entity, Net Sales shall be equal to the higher of: (x) the fair market value of the Licensed Products so transferred, assuming an arm's length transaction made in the ordinary course of business, and (y) the total amount invoiced by such Affiliate on resale to an independent third party purchaser, in each case, after deducting the amounts referred to in clauses (a) through (d) above, to the extent applicable; and

(ii) In the event that the Invoicing Entity, or the Affiliate of the Invoicing Entity, receives non-monetary consideration for any Licensed Products or in the case of transactions not at arm's length with a non-Affiliate of the Invoicing Entity, Net Sales shall be calculated based on the fair market value of such consideration or transaction, assuming an arm's length transaction made in the ordinary course of business.

**1.27. "Orphan Drug"** shall mean a Licensed Product that is protected (a) by "Orphan Drug" status under the U.S. Orphan Drug Act, (b) by a Supplementary Protection Certificate, as such term is defined in Council Regulation (EU) No. 1768/92, or (c) by a similar status granted under similar statutory provisions of another jurisdiction granting exclusive marketing rights in such jurisdiction.

**1.28. "Patent Rights"** shall mean any and all (a) patents, (b) pending patent applications, including, without limitation, all provisional applications, continuations, continuations-in-part, divisions, reissues, renewals, and all patents granted thereon, and (c) all patents-of-addition, reissue patents, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including, without limitation, supplementary protection certificates or the equivalent thereof.

1.29. "Principal Investigators" shall mean the TAU Principal Investigators and the BIU Principal Investigator.

**1.30. "Ramot Research"** shall mean the research actually conducted by the TAU Team under the terms of this Agreement in accordance with the Ramot Research Plan.

**1.31. "Ramot Research Plan"** shall mean the research plan attached hereto as Exhibit 1.31, as amended from time to time in accordance with the provisions of this Agreement, with the mutual agreement of the parties, which sets forth the research to be undertaken by the TAU Team under the direction of the TAU Principal Investigators during the Research Period.

**1.32. "Research Period"** shall mean a period of two (2) years commencing on the Effective Date, or such longer period as the parties may mutually agree upon in writing.

**1.33.** "**Research Results**" shall mean any and all inventions, materials, methods, processes, know-how and results discovered or acquired by, or on behalf of, members of the Licensor Teams in the course of the performance of the BIRAD Research and/or the Ramot Research during the Research Period.

1.34. "Regulatory Agency" shall mean the FDA or equivalent agency or government body of another country.

**1.35. "Regulatory Approval"** shall mean (i) approval of an NDA by the FDA permitting commercial sale of a Licensed Product or (ii) any comparable approval permitting commercial sale of a Licensed Product granted by the applicable Regulatory Agency in any other country or jurisdiction.

**1.36. "Sublicense Receipts"** shall mean any payments or other consideration that BioLine or an Affiliate of BioLine actually received in connection with the sublicense or other grant of rights with respect to some or all of the rights granted to BioLine under Section 5.1, or the grant of an option to obtain such sublicense or other rights, including without limitation royalties, license fees, milestone payments, license maintenance fees and equity; provided that in the event that BioLine or an Affiliate of BioLine receives non-monetary consideration for any such sublicense or other grant of rights or in the case of transactions not at arm's length, Sublicense Receipts shall be calculated based on the fair market value of such consideration or transaction, assuming an arm's length transaction made in the ordinary course of business; and provided further that Sublicensing Receipts will be reduced by any amounts returned by BioLine or an Affiliate to a Sublicense on account of refunds or rebates given in respect of Sublicense Receipts. For the avoidance of doubt, research grants received by BioLine from national or international not-for-profit funding bodies shall not be considered Sublicensing Receipts.

**1.37. "Sublicensee"** shall mean a person or entity to whom BioLine or its Sublicensee grants a sublicense or other rights with respect to some or all of the rights granted to BioLine under Section 5.1, pursuant to Section 5.2.

**1.38. "TAU Principal Investigators"** shall mean Professor Abraham Weizman, Dr. Irit Gil-Ad and Dr. Ada Rephaeli, or such other principal investigator(s) who may replace them pursuant to Section 2.1.1.2.

**1.39. "TAU Team"** shall mean the Principal Investigators and those students, scientists and technicians working at TAU or at the TAU Felsenstein Medical Research Center under their direction on the Research.

**1.40. "Third Party License"** shall mean a license from an unaffiliated third party to one or more valid and enforceable patents issued in the United States or any other jurisdiction, the claims of which cover one or more functional components that is essential for the efficacy of the Licensed Product.

# 2. Research.

#### 2.1. Ramot Research.

#### 2.1.1. Performance.

**2.1.1.1.** Ramot shall cause the TAU Team, under the direction of the TAU Principal Investigators, to use reasonable efforts to perform the Ramot Research in accordance with the Ramot Research Plan; however, Ramot and the TAU Team make no warranties regarding the achievement of any particular results.

**2.1.1.2.** The Ramot Research will be directed and supervised by the TAU Principal Investigators, who shall have primary responsibility for the performance of the Ramot Research. If any of the TAU Principal Investigators cease to supervise the Ramot Research for any reason, Ramot will promptly so notify BioLine. If any two (2) or more of the TAU Principal Investigators cease to supervise the Ramot Research for any reason, Ramot shall endeavor to find among the scientists at TAU, a scientist or scientists, as the case may be, acceptable to BioLine to continue the supervision of the Ramot Research in place of such TAU Principal Investigator(s). If (i) Ramot is unable to find such a scientist or scientists, as the case may be, acceptable to BioLine within sixty (60) days after such notice to BioLine, or (ii) BioLine notifies Ramot that as a result of the cessation of such TAU Principal Investigator's(s') supervision of the Research Ramot need not find a replacement, BioLine shall have the option to terminate the funding of the Ramot Research. BioLine shall promptly advise Ramot in writing if BioLine so elects. Such termination of funding shall terminate Ramot's and TAU's obligations pursuant to Section 2.1.1.1 above with respect to the Ramot Research, but shall not terminate this Agreement or any of the other rights or obligations of the parties under this Agreement. Nothing contained in this Section 2.1.1.2, shall be deemed to impose an obligation on Ramot or TAU to successfully find a replacement for the Principal Investigator(s), as opposed to the obligation to endeavor to do so.

**2.1.2. Funding of Ramot Research.** BioLine shall fund the Ramot Research during the Research Period in accordance with the payment schedule set forth in Exhibit 2.1.2.

# 2.2. BIRAD Research.

## 2.2.1. Performance.

2.2.1.1. BIRAD shall cause the BIU Team, under the direction of the BIU Principal Investigator, to use reasonable efforts to perform the BIRAD Research in accordance with the BIRAD Research Plan; however, BIRAD and the BIU Team make no warranties regarding the achievement of any particular results.

**2.2.1.2.** The BIRAD Research will be directed and supervised by the BIU Principal Investigator, who shall have primary responsibility for the performance of the BIRAD Research. If the BIU Principal Investigator ceases to supervise the BIRAD Research for any reason, BIRAD will so notify BioLine, and BIRAD shall endeavor to find among the scientists at BIU, a scientist or scientists acceptable to BioLine to continue the supervision of the BIRAD Research in place of BIU Principal Investigator. If (i) BIRAD is unable to find such a scientist acceptable to BioLine within sixty (60) days after such notice to BioLine, or (ii) BioLine notifies BIRAD that as a result of the cessation of BIU Principal Investigator's supervision of the BIRAD Research BIRAD need not find a replacement, BioLine shall have the option to terminate the funding of the BIRAD Research. BioLine shall promptly advise BIU in writing if BioLine so elects. Such termination of funding shall terminate BIRAD's and BIU's obligations pursuant to Section 2.2.1.1 above with respect to the BIRAD Research, but shall not terminate this Agreement or any of the other rights or obligations of the BIU Principal Investigator, as opposed to the obligation to endeavor to do so.

**2.2.2. Funding of BIRAD Research.** BioLine shall fund the BIRAD Research during the Research Period in accordance with the payment schedule set forth in Exhibit 2.2.2.



2.3 Credit of Sublicense Receipts. Notwithstanding the foregoing, in the event BioLine receives Sublicense Receipts that are specifically earmarked to fund further research and development with respect to a Licensed Product, any and all amounts paid by BioLine to Licensors pursuant to Section 7.2 with respect to such Sublicense Receipts that are so specifically earmarked shall be creditable against future amounts to be paid by BioLine to Licensors pursuant to Sections 2.1 and 2.2.

## 2.4. Other Funding.

Nothing in this Agreement shall be interpreted to prohibit Ramot, TAU, BIRAD, BIU, or the Principal Investigators from seeking and receiving funding from non-commercial sources, including government agencies and foundations, or from commercial entities for non-commercial purposes, to further support the Ramot Research and/or the BIRAD Research; *provided* that such funding shall not (i) be on terms that give such entity(ies) any rights to any Research Results (subject to any non-exclusive license for non-commercial governmental purposes or other governmental rights as may be generally required as a condition for such non-commercial funding), and (ii) limit in any manner the scope or terms of the license and rights granted to BioLine hereunder. Ramot or BIRAD, as applicable, shall notify BioLine upon such application for and receiving any such funding, which notice shall include a copy of any notices awarding such funding.

#### 3. Title.

**3.1. Licensor Technology.** Subject to the licenses granted to BioLine pursuant to Section 5 below, all rights, title and interest in and to the Licensor Technology are and shall be owned solely and exclusively by Licensors.

**3.2. Joint Technology.** All rights, title and interest in and to the Joint Technology are and shall be owned jointly by Licensors and BioLine, subject to the license in such Joint Technology granted to BioLine hereunder.

**3.3. Determination.** All determinations of inventorship under this Agreement shall be made in accordance with United States patent law. In case of dispute between Ramot and BioLine over inventorship, a mutually acceptable outside patent counsel shall make the determination of the inventor(s) by applying the standards contained in United States patent law.

# 4. Patent Filing, Prosecution and Maintenance.

**4.1. Consultation.** Licensors and BioLine shall consult each other regarding the preparation, filing and prosecution of all patent applications, and the maintenance of all patents, included within the Licensed Patent Rights, including, without limitation, the content, timing and jurisdiction of the filing of such patent applications and their prosecution, and other details and overall global strategy pertaining to the procurement and maintenance of the Licensed Patent Rights. Subject to the payments pursuant to Section 4.3 below, if BioLine requests that an application be filed or maintained in a given country, Licensors shall cooperate with BioLine to do so and Licensors will not abandon any application in any country without BioLine's written consent.

**4.2. Filing.** All Licensed Patent Rights shall be filed, prosecuted and maintained by the parties through a law or patent attorney firm mutually agreed upon by Licensors and BioLine. Such counsel shall be charged with the duty to act in the best interests of each of BioLine and the Licensors, taking into account their relative status as licensors/licensee under this Agreement and the parties' intention to prepare, file, prosecute, obtain and maintain the Licensed Patent Rights in a manner that will provide the maximum economic advantage and return to the parties. Such counsel shall confer with each of Licensors and BioLine and attempt to achieve a consensus in all decisions made relative to the content of applications, the prosecution of the Licensed Patent Rights and the content of communications with the relevant patent agencies, prior to any communications with such agencies.

# 4.3. Expenses. Subject to Section 4.4 below, [\*\*\*]

**4.4. Abandonment.** Should BioLine elect not to pay for the filing, prosecution or maintenance of a patent application in any country, on any invention or claim included in the Licensed Technology or to cease reimbursing Licensors for the prosecution, protection and/or maintenance of any such Patent Right in any such country (an "**Abandoned Country**"), BioLine shall provide Licensors and the parties' outside patent counsel with prompt written notice of such election. Upon written receipt of such notice by Licensors, BioLine shall be released from its obligations to reimburse Licensors for the expenses incurred thereafter as to such Abandoned Country in conjunction with such Patent Rights. [\*\*\*]

## [\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

# [\*\*\*]

**4.5. No Warranty.** Nothing contained herein shall be deemed to be a warranty by any of the parties that they can or will be able to obtain patents on patent applications included in the Licensed Patent Rights, or that any of the Licensed Patent Rights will afford adequate or commercially worthwhile protection.

## 5. License Grant.

**5.1.** License. Subject to the terms and conditions set forth in this Agreement, Licensors hereby grant to BioLine an exclusive, worldwide, royaltybearing license under Licensors' rights in the Licensor Technology and their interest in the Joint Technology solely to develop, have developed, manufacture, have manufactured, use, market, offer for sale, sell, have sold, export and import Licensed Products. For purposes of this Section 5.1, the term "exclusive" means that, subject to Section 6.5, Licensors shall not have any right to grant such licenses or rights to any third party or engage in any of the foregoing, *subject, however*, to Licensors' rights to license TAU, BIU and members of the TAU Team and BIU Team to practice and utilize such rights and licenses to conduct the Ramot Research and BIRAD Research.

## 5.2 Sublicense.

**5.2.1. Sublicense Grant.** BioLine shall be entitled to grant sublicenses or other rights to third parties under the license granted pursuant to Section 5.1 on terms and conditions in compliance and not inconsistent with the terms of this Agreement (except that the royalty rates may be different than those set forth in this Agreement). Such sublicenses shall be made for consideration and in arm's length transactions.

**5.2.2. Sublicense Agreements.** Sublicenses shall only be granted pursuant to written agreements, which shall be in compliance and not inconsistent with and shall be subject and subordinate to the terms and conditions of this Agreement. Each such sublicense agreement shall contain, among other things, provisions to the following effect:

**5.2.2.1.** All provisions necessary to ensure BioLine's ability to perform its obligations under this Agreement, including without limitation its obligations under Sections 6, 8.5 and 8.6;

**5.2.2.2.** In the event of termination of the license (in whole or in part - e.g. termination in a particular country) set forth in Section 5.1 above, any existing agreements that contain a sublicense of, or other grant of right with respect to, Licensor Technology or Joint Technology shall terminate to the extent of such sublicense or other grant of right; <u>provided</u>, <u>however</u>, that, for each Sublicensee, upon termination of the sublicense agreement with such Sublicensee, if the Sublicensee is not then in breach of such sublicensee agreement with BioLine such that BioLine would have the right to terminate such sublicense, Licensors shall be obligated, at the request of such Sublicensee, to enter into a new agreement with such Sublicensee on substantially the same terms as those contained in such sublicense agreement, and <u>provided further</u> that such terms shall be amended, if necessary, to the extent required to ensure that such sublicense agreement does not impose any obligations or liabilities on Licensors which are not included in this Agreement; and

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

5.2.2.3. The Sublicensee shall not be entitled to sublicense its rights under such sublicense agreement, except as follows:

**5.2.2.3.1** the Sublicensee may grant a sublicense to a third party solely to market, offer for sale, sell, have sold, export and/or import Licensed Products in and to a particular country for the purpose of effecting the distribution of Licensed Products in such country; and

**5.2.2.3.2** as part of a co-development agreement between Sublicensee and a third party located in a Far East Country pursuant to which such third party will participate in the development of Licensed Products for Far East Countries, Sublicensee may grant such third party (in addition to the sublicense described in Section 5.2.2.3.1) a sublicense to develop and manufacture Licensed Products solely within one or more Far East Countries. Such third party shall not be entitled to further sublicense its rights under such sublicense agreement.

The parties agree that in the event that (a) BioLine is in the final stages of negotiations with a potential Sublicensee regarding the grant by BioLine of a sublicense under BioLine's rights hereunder to such Sublicensee, and such Sublicensee refuses to enter into such a sublicense agreement unless the restrictions set forth in this sub-Section 5.2.2.3 are limited or removed and (b) BioLine provides Licensors with a written request to amend or remove this sub-Section 5.2.2.3 in order to enable BioLine to consummate the proposed transaction which request shall include the reasoning for accepting such request under the circumstances, Licensors shall not unreasonably withhold their approval to make such amendment to this Agreement, which amendment shall be contingent on the execution of the contemplated sublicense agreement.

Section 5.2.

**5.2.2.4.** Any such sublicense granted by a Sublicensee shall be pursuant to a sublicense agreement that complies with the terms of this

**5.2.2.5.** No sublicense agreement may be assigned by Sublicensee without the prior written consent of BioLine, except that Sublicensee may assign the sublicense agreement to an Affiliate or to a successor in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business to which the sublicense agreement relates; provided that any such assignee agrees in writing to be bound by the terms of such sublicense agreement.

**5.2.2.6** Each Sublicensee shall agree to indemnify Licensors to the same extent as BioLine agrees to indemnify Licensors pursuant to Section 12 hereunder.

**5.2.3.** Delivery of Sublicense Agreement. BioLine shall furnish Licensors with a fully executed copy of any such sublicense agreement, promptly after its execution and shall ensure that any Sublicensee who further sublicenses its rights furnishes Licensors, with a fully executed copy of any such sublicense agreement, promptly after its execution.

**5.2.4. Breach by Sublicensee.** BioLine undertakes to take all actions necessary to enforce its rights under its agreements with Sublicensees and shall ensure that Sublicensees which grant further sublicenses in accordance with Section 5.2.2.3 take all actions necessary to enforce their rights under such further sublicense agreements. Any act or omission by a Sublicensee, which would have constituted a breach of this Agreement had it been an act or omission by BioLine, shall constitute a breach of this Agreement; <u>provided</u>, <u>however</u>, that any such breach shall be subject to a cure period consistent with the terms of this Agreement. BioLine shall indemnify Licensors for, and hold them harmless from, any and all damages or losses caused to Licensors as a result of any such breach by a Sublicensee.

## 6. Development and Commercialization.

**6.1. Diligence.** BioLine shall use all Commercially Reasonable Efforts, and/or shall cause its Affiliates and/or Sublicensees to use their Commercially Reasonable Efforts, including funding consistent with such efforts: (i) to develop Licensed Products in accordance with the applicable Development Plan during the periods and within the timetable specified therein, (ii) to introduce Licensed Products into the commercial market, and (iii) to market Licensed Products following such introduction into the market. Without limiting the foregoing, BioLine and/or its Affiliates and/or Sublicensees shall fulfill the following obligations:

6.1.1. BioLine, by itself or through Affiliates or Sublicensees, shall meet the milestones set forth in Exhibit 6.1.1 hereto; and

**6.1.2.** Licensee, by itself or through Affiliates or Sublicensees, undertakes to employ Commercially Reasonable Efforts, including funding consistent therewith, to carry out all efficacy, pharmaceutical, safety, toxicological and clinical tests, trials and studies and all other activities necessary in order to obtain Regulatory Approval for the production, use and sale of Licensed Products in each country in which Licensee, its Affiliates or Sublicensees intend to produce, use, offer to sell and sell Licensed Products and in any case, BioLine shall use Commercially Reasonable Efforts to obtain Regulatory Approval for the use and sale of Licensed Products in the United States, the European Union and Japan.

**6.2.** BioLine shall be entitled, from time to time, to make such adjustments to the then applicable Development Plan as BioLine believes, in its good faith judgment, are needed in order to improve BioLine's ability to meet the milestones set forth in Exhibit 6.1.1.

**6.3.** The Principal Investigators, a BioLine representative and representatives of the Licensors (the "**Steering Committee**") shall meet no less than once every six (6) months during the term commencing with the Effective Date and ending upon the First Commercial Sale of a Licensed Product, at locations and times to be mutually agreed upon by the parties, (i) to review the progress being made under the Development Plan and the progress being made in any other research and development activities conducted by BioLine, its Affiliates and Sublicensees relating to Licensed Products, (ii) to review and agree upon any necessary or desired revisions to the then current Development Plan, (iii) to review the progress being made towards fulfilling the milestones set forth in Section 6.1.1, and (iv) to discuss intended efforts for fulfilling such milestones. For the avoidance of doubt, the Steering Committee shall be a forum for the exchange of information between the parties with respect to the foregoing, shall act only in an advisory capacity in respect of the Development Plan, and shall not have any decision-making powers.

**6.4.** Within sixty (60) days after the end of each calendar year, Licensee shall furnish Licensors with a written report on the progress of its, its Affiliate's and Sublicensees' efforts during the prior year to develop and commercialize Licensed Products, including without limitation research and development efforts, efforts to obtain Regulatory Approval and marketing efforts.

**6.5. Failure.** If BioLine breaches its obligations pursuant to Section 6.1, unless and to the extent such delay is necessitated by regulatory agencies or by an event beyond the control of BioLine, Ramot may notify BioLine in writing of BioLine' failure and shall allow BioLine [\*\*\*] to cure its failure. BioLine's failure to cure such failure to Ramot's reasonable satisfaction within such [\*\*\*] period shall constitute a material breach of this Agreement and Ramot shall have the right to terminate this Agreement in accordance with Section 13.3.2.

# 6.6 Licensor Proposed Product.

6.6.1. [\*\*\*] 6.6.1 [\*\*\*] 6.6.2.1. [\*\*\*]

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

[\*\*\*]

# 6.6.2.2. [\*\*\*]

**6.6.3.** [\*\*\*]

# 7. Consideration for Grant of License

**7.1.** License Maintenance Fee. BioLine shall pay Licensors an annual license maintenance fee in the amount of \$25,000 per year during the term of this Agreement, of which [\*\*\*] shall be paid to Ramot and [\*\*\*] shall be paid to BIRAD. The first such payment shall be made within fifteen (15) days of the execution of this Agreement and the additional payments shall be made no later than the first and each subsequent anniversary of this Agreement.

**7.2. Royalty Payments.** BioLine shall pay Licensors amounts equal to [\*\*\*] of all Net Sales. Such amounts shall be payable, on a Licensed Product-by-Licensed Product and country-by-country basis, for the longer of: (a) fifteen (15) years from the date of the First Commercial Sale of such Licensed Product in such country; (b) until the last to expire of any patent included within the Licensed Technology in such country; and (c) the expiration of Licensed Product's Orphan Drug status in such country.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

**7.2.1** Notwithstanding anything to the contrary set forth herein, in the event a Licensed Product is sold by BioLine or an Affiliate of BioLine in the form of a Combination Product, Net Sales from such Combination Product, for purposes of determining royalty payments, shall be determined by multiplying the actual Net Sales of such Combination Product during the applicable royalty reporting period, by the fraction A/(A+B) where: A is the average sale price of the Licensed Product contained in the Combination Product when sold separately by BioLine or its Affiliate; and B is the average price of the other Additional Ingredients included in the Combination Product when sold separately by its supplier, in each case during the applicable royalty reporting period or if sales of both the Licensed Product and/or other Additional Ingredients did not occur in such period, then in the most recent royalty reporting period in which sales of both occurred. In the event that such average sale price cannot be determined for both the Licensed Product and all other Additional Ingredients included in the Combination Product. Net Sales for the purpose of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product, Net Sales for the purpose of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Products by the fraction of C/C+D where C is the fair market value of the Licensed Product and D is the fair market value of all other Additional Ingredients included in the Combination Product. In such event, the parties shall negotiate in good faith to arrive at a determination of the respective fair market values of the Licensed Product and all other Additional Ingredients included in the Combination Product.

# 7.2.2. Third-Party Royalties.

**7.2.2.1.** In the event that BioLine or an Affiliate of BioLine is legally required to make royalty payments, at fair market terms after arms' length negotiations, to one or more third parties to obtain a Third Party License from such third party(ies) in order to practice the Licensor Technology in a particular country, BioLine may offset such third-party payments against the royalty payments that are due to Licensors pursuant to Section 7.1 with respect to sales in such country; *provided that* royalty payments under Section 7.1 to Licensors may not be reduced by a greater percentage than the percent reduction for any third party; and *provided further*, that in no event, shall the royalty payments to Licensors under Section 7.1 with respect to such Licensed Product be reduced to less than an amount equal to [\*\*\*] of all Net Sales with respect to such Licensed Product in such country.

**7.2.2.2.** Notwithstanding Section 7.2.2.1, in the event the royalties BioLine or its Affiliate are legally required to pay for a Third Party License as described in Section 7.2.2.1 relate to an Additional Ingredient included in a Combination Product, BioLine shall not be entitled to reduce the royalty payments under Section 7.2.2.1.

7.3. Sublicense Receipts. BioLine shall pay Licensors an amount equal to [\*\*\*] of all Sublicense Receipts.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

# 8. Reports; Payments; Records.

# 8.1. Net Sales: Reports and Payments.

**8.1.1. Reports.** Within thirty (30) days after the conclusion of each Calendar Quarter commencing with the first Calendar Quarter in which BioLine or an Affiliate of BioLine first receives Net Sales or Sublicense Receipts, BioLine shall deliver to Ramot a report containing the following information:

(a) the number of units of Licensed Products sold by BioLine and its Affiliates in each country for the applicable Calendar Quarter;

Calendar Quarter;

(b) the gross amount billed for the Licensed Product sold by BioLine and its Affiliates in each country during the applicable

(c) a calculation of Net Sales for the applicable Calendar Quarter in each country, including a listing of applicable deductions;

(d) the total amount payable to Licensors in U.S. dollars on Net Sales for the applicable Calendar Quarter, together with the exchange rates used for conversion; and

(e) a calculation of any Sublicense Receipts for the applicable Calendar Quarter.

If no amounts are due to Licensors for any Calendar Quarter, the report shall so state.

**8.1.2. Payment.** Concurrent with the delivery of each report delivered pursuant to Section 8.1.1, BioLine shall remit to Licensors all amounts due with respect to Net Sales for the applicable Calendar Quarter, as follows: 75% (seventy-five percent) of such amounts to Ramot and 25% (twenty-five percent) of such amounts to BIRAD. For the avoidance of doubt, the foregoing allocation (i) has been specifically agreed to as between Ramot and BIRAD, and (ii) any change thereto shall only be accepted by BioLine if it is in writing and duly signed by both Ramot and BIRAD.

**8.2.** Sublicense Receipts: Notification and Payment. Concurrent with the delivery of each report delivered pursuant to Section 8.1.1, BioLine shall remit to Licensors all amounts due with respect to such Sublicense Receipts. Such amounts shall be paid as follows: 75% (seventy-five percent) of such amounts to Ramot and 25% (twenty-five percent) of such amounts to BIRAD. For the avoidance of doubt, the foregoing allocation (i) has been specifically agreed to as between Ramot and BIRAD, and (ii) any change thereto shall only be accepted by BioLine if it is in writing and duly signed by both Ramot and BIRAD.

**8.3.** Payments in U.S. Dollars. All payments due under this Agreement shall be payable in United States dollars or in the currency in which they were received. Conversion of foreign currency to U.S. dollars shall be made at the conversion rate existing in the United States (as reported in the <u>Wall Street</u> <u>Journal</u>) on the last working day of the applicable Calendar Quarter. Any expenses incurred in respect of exchange, collection, or other charges, including transfer costs, shall be borne by BioLine and will not be deducted from payments made hereunder.

**8.4. Payments in Other Currencies.** If by law, regulation, or fiscal policy of a particular country, conversion into United States dollars or transfer of funds of a convertible currency to the United States is restricted or forbidden, BioLine shall give Licensors prompt written notice of such restriction, which notice shall satisfy the thirty-day payment deadlines described in Sections 8.1 and 8.2. In such case, BioLine shall pay any amounts due Licensors through whatever lawful methods Licensors reasonably designate.

**8.5. Records.** Licensee shall maintain, and shall cause its Affiliates and Sublicensees to maintain, complete and accurate records of Licensed Products that are made, used, marketed or sold under this Agreement, any amounts payable to Licensors in relation to such Licensed Products and all Sublicense Receipts received by BioLine and its Affiliates, which records shall contain sufficient information to permit Ramot to confirm the accuracy of any reports or notifications delivered to Licensors under Sections 8.1 and 8.2. The relevant party shall retain such records relating to a given Calendar Quarter for at least three (3) years after the conclusion of that Calendar Quarter. During such three (3) year period, Ramot shall have the right, at Licensors' expense, to cause an independent, certified public accountant, who is bound by a suitable confidentiality arrangement with BioLine, to inspect BioLine's and the relevant Affiliates' records during normal business hours for the sole purpose of verifying any reports and payments delivered under this Agreement. Such accountant shall not disclose to Licensors or any third party any information gained during the course of such inspection, except that such accountant may disclose to Licensors and BioLine information gained during the course of such inspection relating to the accuracy of reports and payments delivered under this Agreement. The parties shall reconcile any underpayment or overpayment within thirty (30) days after the accountant delivers the results of the audit. In the event that any audit performed under this Section 8.5 reveals an underpayment in excess of five percent (5%) in any calendar year, the audited party shall bear the full cost of such audit. Ramot may exercise its rights under this Section 8.5 only once every year per audited party and only with reasonable prior notice to the audited party. BioLine shall cause its Affiliates and Sublicensees to fully comply with the terms of this Section 8.5.

**8.6. Audited Report.** BioLine shall furnish Licensors, and shall cause its Affiliates who make, use, market or sell Licensed Products to furnish Licensors, within ninety (90) days after the end of each calendar year, commencing at the end of the calendar year of the first sale of a Licensed Product, with a report, certified by an independent certified public accountant, relating to royalties and other payments due to Licensors pursuant to this Agreement in respect to the previous calendar year and containing the same details as those specified in Sections 8.1 and 8.2 in respect to the previous calendar year.

**8.7. Late Payments.** Any payments to be paid under this Agreement that are not paid on or before the date such payments are due under this Agreement shall bear interest at an annual interest, compounded monthly, equal to three percent (3%) above the London Interbank Offer Rate (LIBOR) as determined for each month on the last business day of that month, assessed from the day payment was initially due until the date of payment.

**8.8.** Payment Method. Each payment due to Licensors under this Agreement shall be made by wire transfer of funds to Licensors' accounts in accordance with written instructions provided by Licensors.

**8.9.** Withholding and Similar Taxes. If applicable laws require that taxes be withheld from any amounts due to Licensors under this Agreement, BioLine shall (a) deduct these taxes from the remittable amount, (b) pay the taxes to the proper taxing authority, and (c) promptly deliver to Licensors a statement including the amount of tax withheld and justification therefor, and such other information as may be necessary for tax credit purposes.

## 9. Confidential Information

## 9.1 Confidentiality.

**9.1.1. Licensor Confidential Information**. BioLine agrees that, without the prior written consent of Licensors, in each case, during the term of this Agreement, and for five (5) years thereafter, it will keep confidential, and not disclose or use Licensor Confidential Information (as defined below) other than for the purposes of this Agreement. BioLine shall treat such Licensor Confidential Information with the same degree of confidentiality as it keeps its own confidential information, but in all events no less than a reasonable degree of confidentiality. BioLine may disclose the Licensor Confidential Information only to employees and consultants of BioLine or of its Affiliates or Sublicensees who have a "need to know" such information in order to enable BioLine to exercise its rights or fulfill its obligations under this Agreement and are legally bound by agreements which impose confidentiality and non-use obligations comparable to those set forth in this Agreement. For purposes of this Agreement, "Licensor Confidential or which otherwise should reasonably be construed under the circumstances as being confidential disclosed by or on behalf of Ramot, BIRAD, TAU, BIU, or any of their employees, researchers or students to BioLine, whether in oral, written, graphic or machine-readable form, except to the extent such information: (i) was known to BioLine at the time it was disclosed, other than by previous disclosure by or on behalf of Ramot, BIRAD, TAU, BIU or any of their employees, researchers to students, as evidenced by BioLine's written records at the time of disclosure; (ii) is at the time of disclosure or later becomes publicly known under circumstances involving no breach of this Agreement; (iii) is lawfully and in good faith made available to BioLine by a third party who is not subject to obligations of confidentiality to Ramot, BIRAD, TAU or BIU with respect to such information; or (iv) is independently developed by BioLine without the use of or reference to the Licensor Confidential Information, as de

#### 9.1.2. BioLine Confidential Information.

**9.1.2.1.** Licensors agree that, without the prior written consent of BioLine, in each case, during the term of this Agreement, and for five (5) years thereafter, they will keep confidential, and not disclose or use BioLine Confidential Information (as defined below) other than for the purposes of this Agreement. Licensors shall treat such BioLine Confidential Information with the same degree of confidentiality as they keep their own confidential information, but in all events no less than a reasonable degree of confidentiality. Licensors may disclose the BioLine Confidential Information only to employees and consultants of Licensors or of their Affiliates who have a "need to know" such information in order to enable Licensors to exercise their rights or fulfill their obligations under this Agreement and are legally bound by agreements which impose confidentiality and non-use obligations comparable to those set forth in this Agreement. For purposes of this Agreement, "BioLine Confidential Information" means any scientific, technical, trade or business information relating to the subject matter of this Agreement designated as confidential or which otherwise should reasonably be construed under the circumstances as being confidential disclosed by or on behalf of BioLine pursuant to Section 6.2, 6.3 or 8 of this Agreement, whether in oral, written, graphic or machine-readable form, except to the extent such information: (i) was known to Licensors at the time it was disclosed, other than by previous disclosure by or on behalf of BioLine as evidenced by Ramot's or BIRAD's written records at the time of disclosure; (ii) is at the time of disclosure or later becomes publicly known under circumstances involving no breach of this Agreement; (iii) is lawfully and in good faith made available to Ramot or BIRAD by a third party who is not subject to obligations of confidential Information, as demonstrated by documentary evidence.

**9.1.2.2.** Ramot shall cause all members of the TAU Team to execute a team agreement in the form attached hereto as Exhibit 9.1.2.2(a). BIRAD shall cause all members of the BIU Team to execute a team agreement in the form attached hereto as Exhibit 9.1.2.2(b).

**9.1.3. Disclosure of Agreement**. Each party may disclose the terms of this Agreement to the extent required, in the reasonable opinion of such party's legal counsel, to comply with applicable laws, as well as to sublicensees and prospective and current investors, pursuant to appropriate nondisclosure arrangements. If a party discloses this Agreement or any of the terms hereof in accordance with this Section 9.1.3, such party agrees, at its own expense, to seek confidential treatment of portions of this Agreement or such terms, as may be reasonably requested by the other party.

**9.1.4. Publicity.** Except as expressly permitted under Section 9.1.3, no party will make any public announcement regarding this Agreement without the prior written approval of the other party.

**9.2.** Academic Publications. Licensors shall have the right to allow the Principal Investigators and other members of the Licensor Teams to publish the Research Results, if any, in scientific publications or to present such results at scientific symposia, provided that the following procedure is followed:

**9.2.1.** Licensors shall cause the members of the Licensor Teams to comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publications relating to the Research Results.

**9.2.2.** No later than thirty (30) days prior to submission for publication of any scientific articles, abstracts or papers concerning Research Results and prior to the presentation of such results at any scientific symposia, Licensors shall send to BioLine a written copy of the material to be so submitted or presented, and shall allow BioLine to review such submission to determine whether the publication or presentation contains subject matter for which patent protection should be sought prior to publication or presentation for the preservation of Licensed Patent Rights.

**9.2.3.** BioLine shall provide its written comments with respect to such publication or presentation within fourteen (14) days following its receipt of such written material.

**9.2.4.** If BioLine, in its written comments, identifies material for which patent protection should be sought, then Licensors shall cause the publication or presentation of such submission to be delayed for a further period of up to sixty (60) days from the receipt of such written comments to enable the parties, through the parties' patent counsel to make the necessary patent filings in accordance with Section 4, provided, however, that if such counsel determines in good faith that more time is required the submission shall be delayed for an additional period of up to thirty (30) days.

**9.2.5.** After compliance with the foregoing procedures with respect to an academic, scientific or medical publication and/or public presentation, members of the Licensor Teams shall not have to resubmit any such information for re-approval should it be republished or publicly disclosed in another form.

## **10.** Patent Infringement.

## 10.1 Enforcement of Patent Rights.

**10.1.1.** Notice. In the event any party becomes aware of any possible or actual infringement or unauthorized possession, knowledge or use of any Licensed Patent Rights (collectively, an "Infringement"), that party shall promptly notify the other parties and provide them with details regarding such Infringement.

**10.1.2. Suit by BioLine.** BioLine shall have the right, but not the obligation, to take action in the prosecution, prevention, or termination of any Infringement of Licensed Patent Rights. Should BioLine elect to bring suit against an infringer and either Licensor is joined as party plaintiff in any such suit, such Licensor shall have the right to approve the counsel selected by BioLine to represent BioLine and such Licensor(s), such approval not to be unreasonably withheld. The expenses of such suit or suits that BioLine elects to bring, including any expenses of Licensors incurred in conjunction with the prosecution of such suits or the settlement thereof, shall be paid for entirely by BioLine and BioLine shall hold Licensors free, clear and harmless from and against any and all costs of such litigation, including attorney's fees. BioLine shall not compromise or settle such litigation without the prior written consent of Licensors, which consent shall not be unreasonably withheld or delayed. In the event BioLine exercises its right to sue pursuant to this Section 10.1.2, it shall first reimburse itself out of any sums recovered in such suit or in settlement thereof for all costs and expenses of every kind and character, including reasonable attorney's fees, necessarily involved in the prosecution of any such suit. If, after such reimbursement, any funds shall remain from said recovery, then Licensors shall receive an amount equal to [\*\*\*] of such funds (75% of which shall be paid to Ramot and 25% of which shall be paid to BIRAD) and the remaining [\*\*\*] of such funds shall be retained by BioLine.

**10.1.3.** Suit by Ramot. If BioLine does not take action in the prosecution, prevention, or termination of any Infringement pursuant to Section 10.1.2 above, and has not commenced negotiations with the infringer for the discontinuance of said Infringement, within ninety (90) days after receipt of notice to BioLine by Ramot of the existence of an Infringement, Licensors may elect to do so. Should Licensors elect to bring suit against an infringer and BioLine is joined as party plaintiff in any such suit, BioLine shall have the right to approve the counsel selected by Licensors to represent Licensors and BioLine, such approval not to be unreasonably withheld. The expenses of such suit or suits that Licensors elect to bring, including any expenses of BioLine incurred in conjunction with the prosecution of such suits or the settlement thereof, shall be paid for entirely by Licensors and Licensors shall hold BioLine free, clear and harmless from and against any and all costs of such litigation, including attorney's fees. Licensors shall not compromise or settle such litigation without the prior written consent of BioLine, which consent shall not be unreasonably withheld or delayed. In the event Licensors exercise their right to sue pursuant to this Section 10.1.3, they shall first reimburse themselves out of any sums recovered in such suit or in settlement thereof for all costs and expenses of every kind and character, including reasonable attorney's fees, necessarily involved in the prosecution of any such suit. If, after such reimbursement, any funds shall remain from said recovery, then BioLine shall receive an amount equal to [\*\*\*] of such funds and the remaining [\*\*\*] of such funds shall be retained by Licensors (of which 75% shall be retained by Ramot and 25% shall be retained by BIRAD).

**10.1.4. Own Counsel.** Each party shall always have the right to be represented by counsel of its own selection and at its own expense in any suit instituted under this Section 10 by the another party for Infringement.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

**10.1.5.** Cooperation. Each party agrees to cooperate fully in any action under this Section 10 which is controlled by another party, provided that the controlling party reimburses the cooperating party promptly for any costs and expenses incurred by the cooperating party in connection with providing such assistance.

**10.1.6. Standing.** If a party lacks standing and another party has standing to bring any such suit, action or proceeding, then such other party shall do so at the request of and at the expense of the requesting party. If a party determines that it is necessary or desirable for another party to join any such suit, action or proceeding, the other party shall execute all papers and perform such other acts as may be reasonably required in the circumstances.

**10.2** Legal Action Against a Party. Each Party will provide the others with prompt notice of any action, suit or proceeding brought against it, alleging the infringement of the intellectual property rights of a third party by reason of the discovery, development, manufacture, use, sale, importation, or offer for sale of a Licensed Product or otherwise due to the use or practice of the Licensed Technology.

## 11. Warranties; Limitation of Liability.

**Representations and Warranties.** Licensors hereby represents and warrant that (i) that they are the owners of the Licensor Patent Rights set forth in Exhibit 1.20; (ii) they have not granted any rights in or to Licensed Technology which are inconsistent with the rights granted to BioLine under this Agreement; (iii) they have the right to grant the license granted under this Agreement; (iv) they will not transfer, assign, encumber, grant, sell, lease or otherwise dispose of the Licensor Technology or their interest in the Joint Technology other than as may be expressly permitted herein; and (v) they have no actual knowledge as of the date hereof of any legal suit or proceeding by a third party against Ramot, BIRAD, TAU or BIU contesting the ownership or validity of the Licensor Patent Rights, or claiming that the practice of the Licensor Patent Rights in the manner contemplated by this Agreement would infringe the rights of such third party.

**11.1. Compliance with Law.** BioLine warrants that it will comply with, and shall ensure that its Affiliates and Sublicensees comply with, all local, state, federal, and international laws and regulations relating to the development, manufacture, use, and sale of Licensed Products.

# 11.2. No Warranty.

**11.2.1.** Nothing in this Agreement (including, without limitation, any exhibits or attachments hereto) shall be construed as a warranty on the part of Licensors that any results or inventions will be achieved in the Ramot Research or BIRAD Research. Furthermore, Licensors make no warranties whatsoever as to the commercial or scientific value of the Licensed Technology. Licensors make no representation that the manufacture, use or sale of the Licensed Technology or any Licensed Product, or any element thereof, will not infringe the patent or proprietary rights of any third party.

**11.2.2.** Except as otherwise expressly provided in this Agreement, no party makes any warranty with respect to any technology, patents, goods, services, rights or other subject matter of this Agreement and hereby disclaims warranties of merchantability, fitness for a particular purpose and noninfringement with respect to any and all of the foregoing.

**11.3. Limitation of Liability.** Notwithstanding the anything else in this Agreement or otherwise, neither Licensors nor BioLine will be liable to the other with respect to any subject matter of this Agreement under any contract, negligence, strict liability or other legal or equitable theory for (i) any indirect, incidental, consequential or punitive damages or lost profits or (ii) cost of procurement of substitute goods, technology or services.

## 12. Indemnification.

12.1 Indemnity. BioLine shall indemnify, defend, and hold harmless Ramot, BIRAD, TAU, BIU, the Principal Investigators, the other members of the Licensor Teams, and their respective governors, directors, officers, employees, and agents and their respective successors, heirs and assigns (the "Licensor Indemnitees"), against any liability, damage, loss, or expense (including reasonable attorneys fees and expenses of litigation) incurred by or imposed upon any of the Licensor Indemnitees in connection with any claims, suits, actions, demands or judgments ("Claims") arising out of any theory of liability (including without limitation actions in the form of tort, warranty, or strict liability and regardless of whether such action has any factual basis) concerning the use of any Licensed Technology by BioLine, or any of its Affiliates or Sublicensees, or concerning any product, process, or service that is made, used, or sold pursuant to any right or license granted by Licensors to BioLine under this Agreement (except in cases where, and to the extent that, such claims, suits, actions, demands or judgments result from gross negligence or willful misconduct on the part of any of the Licensor Indemnitee).

12.2. Procedures. If any Licensor Indemnitee receives notice of any Claim, such Licensor Indemnitee shall, as promptly as is reasonably possible, give BioLine notice of such Claim; provided, however, that failure to give such notice promptly shall only relieve BioLine of any indemnification obligation it may have hereunder to the extent such failure diminishes the ability of BioLine to respond to or to defend the Licensor Indemnitee against such Claim. Licensors and BioLine shall consult and cooperate with each other regarding the response to and the defense of any such Claim and BioLine shall, upon its acknowledgment in writing of its obligation to indemnify the Licensor Indemnitee, be entitled to and shall assume the defense or represent the interests of the Licensor Indemnitee and to propose, accept or reject offers of settlement, all at its sole cost; provided, however, that no such settlement shall be made without the written consent of the Licensor Indemnitee, such consent not to be unreasonably withheld. Nothing herein shall prevent the Licensor Indemnitee from retaining its own counsel and participating in its own defense at its own cost and expense.

**12.3. Insurance.** BioLine shall maintain insurance that is reasonably adequate to fulfill any potential obligation to the Licensor Indemnitees consistent with industry standards. The Licensors shall be listed as co-insured parties under any such insurance policy(ies). BioLine shall provide Ramot, upon request, with written evidence of such insurance.

# 13. Term and Termination.

**13.1. Term.** The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Section 13, shall continue in full force and effect on until the expiration of all payment obligations pursuant to Section 7 for such Licensed Product.

**13.2. Effect of Expiration.** Following the expiration of this Agreement pursuant to Section 13.1 on a Licensed Product-by-Licensed Product and country-by-country basis (and provided the Agreement has not been earlier terminated pursuant to Section 13.3, in which case Section 13.4.1 shall apply): (a) BioLine shall have a fully-paid up, nonexclusive, worldwide license (with the right to grant sublicenses) under the Licensor Technology solely to develop, have developed, manufacture, have manufactured, use, market, offer for sale, sell, have sold, import, export, otherwise transfer physical possession of or otherwise transfer title to Licensed Products; (b) Licensors shall be free to use the Licensed Technology to develop, make and have made, use, offer to sell, sell, have sold, import, export, otherwise transfer physical possession of or otherwise transfer title to Licensed rechnology to do the same; and (c) each of BioLine and Licensors shall have a fully-paid up, non-exclusive, worldwide license (with the right to grant sublicenses) under the other party's interest in the Joint Technology for any and all purposes.

#### 13.3. Termination.

**13.3.1. Termination Without Cause.** BioLine may terminate this Agreement upon sixty (60) days prior written notice to Ramot, *provided however*, that if BioLine terminates the Agreement prior to the end of the first nine (9) month period of the Agreement, BioLine will not be obligated to fund the second year of the Research Period; and provided further that if BioLine terminates the Agreement following the end of such nine (9) month period but during the Research Period, it will only be required to pay for the period preceding the termination and the ninety (90) day period following such termination (in the event that termination is to become effective on a date other than the last day of a calendar quarter, BioLine shall pay the pro-rated amount of the research funding for such quarter based on the number of days between the beginning of such quarter and the date of termination).

#### 13.3.2. Termination for Default.

**13.3.2.1** In the event that BioLine commits a material breach of its obligations under this Agreement and fails to cure that breach within thirty (30) days after receiving written notice thereof from Ramot, Ramot may terminate this Agreement immediately upon written notice to BioLine. In the event that Ramot or BIRAD commits a material breach of its obligations under this Agreement and fails to cure that breach within thirty (30) days after receiving written notice thereof from BioLine, BioLine may terminate this Agreement immediately upon written notice to Licensors. Notwithstanding the foregoing, in the event that any breach is not susceptible of cure within the stated period and the breaching party uses diligent good faith efforts to cure such breach, the stated period will be extended by an additional thirty (30) days.

**13.3.2.2** In the event of an uncured material breach by Ramot and/or BIRAD as described in the foregoing paragraph, BioLine may elect not to terminate this Agreement but, instead, to sue Ramot and/or BIRAD, as the case may be, for damages arising from such breach, *provided however*, that in no event will BioLine seek damages against the breaching party in any such action which exceed amounts actually paid to Licensors under this Agreement.

#### 13.3.3. Bankruptcy.

**13.3.3.1** Either BioLine or Ramot may terminate this Agreement upon notice to the other if the other party becomes insolvent, is adjudged bankrupt, applies for judicial or extra-judicial settlement with its creditors, makes an assignment for the benefit of its creditors, voluntarily files for bankruptcy or has a receiver or trustee (or the like) in bankruptcy appointed by reason of its insolvency, or in the event an involuntary bankruptcy action is filed against the other party and not dismissed within ninety (90) days, or if the other party becomes the subject of liquidation or dissolution proceedings or otherwise discontinues business.

**13.3.3.2** Notwithstanding the foregoing, in the event a receiver or trustee (or the like) is appointed or BioLine has entered into a settlement with its creditors and BioLine is otherwise meeting its obligations pursuant to this Agreement, Ramot shall not be entitled to terminate this Agreement as contemplated under Section 13.3.3.1 during such period.

#### 13.4. Effect of Termination.

**13.4.1. Termination of Rights.** Upon termination by BioLine pursuant to Sections 13.3.1, 13.3.2 or 13.3.3 hereof or by Ramot pursuant to Sections 6.4, 13.3.2 or 13.3.3 hereof (except in the circumstances set out in Section 13.3.3.2) : (a) the rights and licenses granted to BioLine under Section 5 shall terminate; (b) all rights in and to the Licensor Technology shall revert to Licensors and BioLine shall not be entitled to make any further use whatsoever of the Licensor Technology nor shall BioLine develop, make, have made, use, offer to sell, sell, have sold, import, export, otherwise transfer physical possession of or otherwise transfer title to Licensed Products developed in whole or in part under the rights granted hereunder; and (c) any existing agreements that contain a sublicense of the Licensed Technology shall terminate to the extent of such sublicense;

provided, however, that, for each Sublicensee, upon termination of the sublicense agreement with such Sublicensee, Licensors shall be obligated, at the request of such Sublicensee, to enter into a new license agreement with such Sublicensee on substantially the same terms as those contained in such sublicense agreement, provided that such terms shall be amended, if necessary, to the extent required to ensure that such sublicense agreement does not impose any obligations or liabilities on Licensors which are not included in this Agreement.

**13.4.2.** Accruing Obligations. Termination of this Agreement shall not relieve the parties of obligations occurring prior to such termination, including obligations to pay amounts accruing hereunder up to the date of termination.

**13.4.3. Transfer of Regulatory Filings and Know How.** In the event BioLine terminates this Agreement pursuant to Section 13.3.1 or Ramot terminates this Agreement pursuant to Section 6.4, 13.3.2 or 13.3.3 (except in the circumstances set out in Section 13.3.3.2), BioLine shall promptly deliver and assign to Licensors (a) all documents and other materials filed by or on behalf of BioLine and its Affiliates with Regulatory Agencies in furtherance of applications for Regulatory Approval in the relevant country with respect to Licensed Products; and (b) all intellectual property, inventions, conceptions, materials, methods, processes, data, information, records, results, studies and analyses, discovered or acquired by, or on behalf of BioLine and its Affiliates which relate directly to actual or potential Licensed Products. The Licensors, the TAU Team and the BIU Team shall be entitled to freely use and to grant others the right to use all such materials, documents and know-how delivered pursuant to this 13.4.3.

**13.5.** Survival. The parties' respective rights, obligations and duties under Sections 9, 11.3, 12, 13, 14.2 and 14.4, as well as any rights, obligations and duties which by their nature extend beyond the expiration or termination of this Agreement, shall survive any expiration or termination of this Agreement.

#### 14. Miscellaneous.

**14.1. Entire Agreement.** This Agreement is the sole agreement with respect to the subject matter hereof and except as expressly set forth herein, supersedes all other agreements and understandings between the parties with respect to same.

**14.2. Publicity Restrictions.** Subject to Section 9.1.4, BioLine and its Affiliates and Sublicensees shall not use the name of Ramot, BIRAD, TAU, BIU or any of their governors, officers, faculty, students, employees, or agents, or any adaptation of such names, in any promotional material or other public announcement or disclosure relating to the subject matter of this Agreement or in connection with the marketing or sale of any Licensed Products, without the prior written consent of Licensors. Subject to Section 9.1.4, Ramot, BIRAD, TAU, BIU shall not use the name of BioLine and its Affiliates and Sublicensees or any of their employees, directors, stockholders and/or representatives or any adaptation of such names, in any promotional material or other public announcement or disclosure relating to the subject matter of this Agreement, without the prior written consent of BioLine.

**14.3. Notices.** Unless otherwise specifically provided, all notices required or permitted by this Agreement shall be in writing and may be delivered personally, or may be sent by facsimile or certified mail, return receipt requested, to the following addresses, unless the parties are subsequently notified of any change of address in accordance with this Section 14.3:

If to BioLine:	BioLineRx Ltd. 19 Hartum Street P.O. Box 45158 Jerusalem 91450 Israel Attn: CEO Fax: 972-2-548-9101
With a copy (which shall not constitute notice) to:	Yigal Arnon & Co., Law Offices 22 Rivlin Street Jerusalem, 94263 Israel Attn: Barry Levenfeld Fax: 972-2-623-9236
If to Ramot:	Ramot at Tel Aviv University Ltd. P.O. Box 39296 Tel Aviv 61392 Israel Attn: CEO Fax: 972-3-640-5064
If to BIRAD:	Bar-Ilan Research and Development Company Ltd. Bar-Ilan University Ramat Gan, 52900 Israel Attn: CEO Fax: 972-3-5356088

Any notice shall be deemed to have been received as follows: (i) by personal delivery, upon receipt; (ii) by facsimile, one business day after transmission or dispatch; (iii) by airmail, three (3) business days after delivery to the postal authorities by the party serving notice. If notice is sent by facsimile, a confirming copy of the same shall be sent by mail to the same address.

**14.4. Governing Law and Jurisdiction.** This Agreement shall be governed by and construed in accordance with the laws of the State of Israel, without regard to the application of principles of conflicts of law, except for matters of patent law, which, other than for matters of inventorship on patents, shall be governed by the patent laws of the relevant country of the patent. The parties hereby consent to personal jurisdiction in Israel and agree that any lawsuit they file to enforce their respective rights under this Agreement shall be brought in the competent court in Tel Aviv, Israel.

**14.5. Binding Effect.** This Agreement shall be binding upon and inure to the benefit of the parties and their respective legal representatives, successors and permitted assigns.

14.6. Headings. Section and subsection headings are inserted for convenience of reference only and do not form a part of this Agreement.

14.7. Counterparts. This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed an original.

**14.8. Amendment; Waiver.** This Agreement may be amended, modified, superseded or canceled, and any of the terms may be waived, only by a written instrument executed by each party or, in the case of waiver, by the party waiving compliance. The delay or failure of any party at any time or times to require performance of any provisions hereof shall in no manner affect the rights at a later time to enforce the same. No waiver by either party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

**14.9.** No Agency or Partnership. Nothing contained in this Agreement shall give any party the right to bind another, or be deemed to constitute either parties as agents for each other or as partners with each other or any third party.

**14.10.** Assignment and Successors. This Agreement may not be assigned by either party without the consent of the other, which consent shall not be unreasonably withheld, except that each party may, without such consent, assign this Agreement and the rights, obligations and interests of such party, in whole or in part, to any of its Affiliates, to any purchaser of all or substantially all of its assets or research to which the subject matter of this Agreement relates, or to any successor corporation resulting from any merger or consolidation of such party with or into such corporation.

**14.11.** Force Majeure. Neither party will be responsible for delays resulting from causes beyond the reasonable control of such party, including without limitation fire, explosion, flood, war, strike, or riot, provided that the nonperforming party uses commercially reasonable efforts to avoid or remove such causes of nonperformance and continues performance under this Agreement with reasonable dispatch whenever such causes are removed.

**14.12. Interpretation.** The parties hereto acknowledge and agree that: (i) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting party shall not be employed in the interpretation of this Agreement; and (iii) the terms and provisions of this Agreement shall be construed fairly as to both parties hereto and not in favor of or against either party, regardless of which party was generally responsible for the preparation of this Agreement.

**14.13. Severability.** If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the parties that the remainder of this Agreement shall not be affected.

### [REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

Ramot at Tel Aviv University Ltd.		BioLineRx Ltd.		
By:	/s/ Isaac T. Kohlberg	By:	/s/ Morris Laster	
Name:	Isaac T. Kohlberg	Name:	Morris Laster	
Title:	Chief Executive Officer	Title:	CEO	
	n Research and Development ny Ltd.			
By:	/s/ Gabriel Kenan			
Name:	Gabriel Kenan			
Title:	CEO			
We, the undersigned, hereby confirm that we have read the Agreement, that its contents are acceptable to us and that we will act in accordance with its terms.				
/s/ Irit C Dr. Irit			a Rephaeli	

/s/ Abraham Weizman Professor Abraham Weizman /s/ Abraham Nudelman Professor Abraham Nudelman

# Exhibit 1.4

# BIRAD Research Plan

Year 1

Objectives						
Objectives Objective #	Description	End- point				
1	[***]	[***]				
2	[***]	[***]				
3	[***]	[***]				
4	[***]	[***]				
5	[***]	[***]				

# **Description of objectives**

1. [\*\*\*] 2. [\*\*\*].

3. [\*\*\*]

4. [\*\*\*] 5. [\*\*\*]

# Year 2

Commencing January 1, 2005, the parties will meet to discuss and agree upon the BIRAD Research Plan for the second year of the research period.

# [\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

# Exhibit 1.11

Development Plan

[\*\*\*]

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

# Exhibit 1.20(a)

# License Patent Rights

National Phase Applications, submitted March 27, 2004:

<u>Country</u>	Ramot file	<u>Attorney</u>
ISRAEL	[***]	[***]
AUSTRALIA	[***]	[***]
EUROPE	[***]	[***]
JAPAN	[***]	[***]
CANADA	[***]	[***]
CHINA	[***]	[***]
SOUTH KOREA	[***]	[***]
INDIA	[***]	[***]
MEXICO	[***]	[***]

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

# Exhibit 1.21

# Licensed Product

A compound having the general formula:

[\*\*\*]

wherein,

[\*\*\*]

# Exhibit 1.31

# **Ramot Research Plan**

# Year 1

Objectives				
Objective	Description	End- point		
#				
1	[***]	[***]		
2	[***]	[***]		
3	[***]	[***]		
4	[***]	[***]		
5	[***]	[***]		
6	[***]	[***]		

# **Description of objectives**

1. [\*\*\*]

2. [\*\*\*].

3. [\*\*\*]

4. [\*\*\*]

5. [\*\*\*]

# <u>Year 2</u>

Commencing January 1, 2005, the parties will meet to discuss and agree upon the Ramot Research Plan for the second year of the research period.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

# Exhibit 2.2.2

# **BIRAD Payment Schedule**

Due Dates for Payment	\$
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

# Exhibit 4.3

# List of National Phase Countries

# Exhibit 6.1.1

# Milestones

[\*\*\*]

#### Exhibit 9.1.2.2(a)

#### **TAU Team Agreement**

#### **Team Agreement**

April 15, 2004

Dear Professor Avraham Weizman (the "Principal Investigator")

#### Re: Team Agreement

This letter agreement (this "Letter") is addressed to you and the persons listed in Exhibit A to this Letter (each a "Researcher" and collectively, the "Researchers"). Exhibit A may be amended by the addition of new Researchers as described below. You and the Researchers are referred to collectively in this Letter as the "Team Members".

The Team Members are or were faculty members, post-doctoral fellows, students or technicians performing research at Felsenstein Medical Research Center of Tel Aviv University ("FMRC"). In such capacity, they have performed research at FMRC relating to conjugated anti-psychotic drugs and the use thereof (as further described in Exhibit B to this Agreement, the "Project") and/or are members of a team that will perform further research at FMRC relating to the Project under the supervision of the Principal Investigator.

By operation of law or under the terms of their employment or other relationships with Clalit Health Services, Tel Aviv University ("TAU") or Ramot, and according to agreements between Clalit Health Services and TAU and between TAU and Ramot, all rights, title and interest in and to any *and* all inventions and other results arrived at by the Team Members as a result of their relationship with TAU are owned by Ramot. This includes all intellectual property, inventions, know-how, technology, methods, data and other results directly relating to the Project arrived at prior to the date of this Agreement during the course of research and development at FMRC (the "Existing Project Technology").

Ramot and BioLineRX Ltd. ("BioLine") have entered into a research and license agreement (the "Research and License Agreement") pursuant to which: (1) Ramot granted BioLine a license with respect to certain patent and other rights relating to the Existing Project Technology, (2) BioLine agreed to fund further research relating to the Project at FMRC by Team Members; and (3) Ramot agreed to cause the performance of such research by Team Members and to grant BioLine a license with respect to the results arrived at in the performance of such research.

The purpose of this Letter is to set forth the rights and obligations of the Team Members with respect to the Project and the further research relating to the Project to be performed by some or all of the Team Members. Please read this Letter carefully and if you agree with its contents sign in the appropriate place next to your name below.

#### Sponsored Research.

(a) The Principal Investigator agrees to supervise and cause the performance at FMRC of further research relating to the Project in accordance with the research program included in Exhibit C to this Letter (as may be amended from time to time by the mutual agreement of Ramot and BioLine, after consultation with the Principal Investigator) and the budget included in Exhibit C to this Letter (as may be amended from time to time by the mutual agreement of Ramot and BioLine, after consultation with the Principal Investigator). Such research is referred to in this Letter as the "Sponsored Research."

#### (b) The Principal Investigator will keep BioLine reasonably informed concerning the Sponsored Research, its progress and its results.

2. Intellectual Property Rights.

(a) Each of the Team Members acknowledges, confirms and agrees that Ramot is and shall be the sole owner of all rights, title and interest in and to any and all Project Technology and any and all intellectual property rights relating to the Project Technology. "Project Technology" means the Existing Project Technology and any and all inventions, products, materials, methods, processes, techniques, know-how, data, information, discoveries and other results of whatever nature arrived at in the course of the performance of the Sponsored Research, whether at FMRC or elsewhere.

(b) Each of the Team Members agrees to sign and deliver to Ramot any documents, and to take any actions, that Ramot believes are needed or desirable in order to best confirm Ramot's title in the Project Technology.

(c) The Team Members acknowledge that all patent applications relating to Project Technology, to the extent they cover inventions made by Team Members, will be filed in the name of Ramot, except in cases where Ramot believes that it is necessary that the patent applications be filed in the name of Team Members and then assigned to Ramot. Each of the Team Members agrees, at Ramot's request, to assist Ramot to file and obtain, and if needed to enforce, any patent or patent application relating to the Project Technology in any country requested by Ramot. Such assistance may include signing, verifying and delivering to Ramot such documents, and performing such other acts (including appearances as a witness), as Ramot may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such patents and patent applications and confirming their assignment to Ramot.

(d) In the event Ramot is unable for any reason, after reasonable effort, to secure a Team Member's signature on any document needed in connection with the actions specified in this clause 2, such Team Member hereby irrevocably designates and appoints Ramot and its duly authorized officers and agents as such Team Member's agent and attorney in fact, which appointment is coupled with an interest, to act for and in such Team Member's behalf to sign, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of this clause 2 with the same legal force and effect as if executed by such Team Member.

#### 3. Confidentiality and Publications.

(a) Each Team Member undertakes to keep confidential and not to disclose or use (other than for the furtherance of the Project) any Project Technology or BioLine Confidential Information to any person or entity other than a fellow Team Member, an employee of Ramot, or an employee, officer or director of BioLine, except and to the extent that s/he is instructed or authorized to do so by Ramot. This obligation of confidentiality does not apply to any portion of the Project Technology that is in the public domain (other than through the fault of such Team Member), nor does it apply to information included in scientific publications that have been approved by Ramot prior to publication. "BioLine Confidential Information" means any scientific, technical, trade or business information relating to the Sponsored Research designated as confidential or which otherwise should reasonably be construed under the circumstances as being confidential disclosed by or on behalf of BioLine to a Team Member, except to the extent such information: (i) was known to such Team Member at the time it was disclosed, other than by previous disclosure by or on behalf of BioLine, as evidenced by such Team Member's written records at the time of disclosure; (ii) is at the time of disclosure or later becomes publicly known under circumstances involving no breach of this Letter; (iii) is lawfully and in good faith made available to the Team Member by a third party who is not subject to obligations of confidentiality to BioLine or Ramot with respect to such information; or (iv) is independently developed by the Team Member without the use of or reference to BioLine Confidential Information, as demonstrated by documentary evidence.

(b) In general, Ramot will endeavor to assist the Team Members in facilitating publications relating to Project Technology and Ramot agrees not to unreasonably withhold its approval of publications, except to the extent described in this paragraph. In order to permit Ramot to comply with its obligations to BioLine and the opportunity to properly protect patent and proprietary rights relating to information included in such proposed publications, the Team Members agree to provide Ramot with a copy of each proposed publication at least forty (40) days in advance of the contemplated submission for publication to permit Ramot to review such submission to determine whether the publication or presentation contains subject matter for which patent protection should be sought prior to publication or presentation. Ramot will review, and shall allow BioLine to review, such proposed publication. If Ramot informs the Principal Investigator within thirty (30) days of the receipt of such proposed publication, that it wishes to seek protection with respect to material included within such proposed publication, then the Team Members will delay the submission of the publication or presentation for a further period of up to sixty (60) days (or longer if Ramot notifies the Team Members that such additional period is required in order to make the necessary patent filings) to enable Ramot to make the necessary patent filings.

(c) Each Team Member's obligations under this clause 3 shall continue in full force and effect during the term such Team Member is involved with the Sponsored Research and for a period of seven (7) years after the termination of such Team Member's involvement with the Sponsored Research.

#### 4. Distributions.

(a) Those of the Team Members who are inventors of technologies included in patents relating to the Project Technology (together, the "Inventors") will be entitled, together, to receive from the proceeds received by Ramot from the commercialization of Project Technologies the amounts determined in accordance with the rules and regulations in effect at TAU, from time to time, relating to the allocation of the proceeds from the commercialization by Ramot of inventions made by them. The total distributions received by all Team Members according to this clause are referred to in this Agreement as the "Distributions".

(b) The Distributions shall be allocated among the Inventors in accordance with the percentages set forth in Exhibit C hereto. The Team Members understand that this allocation of the Distributions among the Inventors is based on the contribution of each Inventor to the inventions included in the Existing Technology.

(c) Each of the Team Members agrees that if, in the Principal Investigator's judgment, a change in the Sponsored Research, the composition of the research team or the respective contributions of the Inventors to the Project Technology being commercialized justifies a change in the allocation of the Distributions among the Inventors, the Principal Investigator will decide, at his sole discretion, on an amended allocation of the Distributions. Such change may include: (i) additions of persons to the list of Inventors entitled to a share of the Distributions; (ii) deletion of certain persons from the list of Inventors entitled to Distributions an Inventor is entitled to; and/or (iv) any other change deemed by the Principal Investigator to be appropriate, in his absolute discretion. (d) Ay change made pursuant to clause 4(c) will only affect Distributions paid after the date of the relevant change. It will not affect Distributions distributed to individual Inventors prior to the relevant change.

(e) Each of the Team Members agrees that, if a Team Member disputes a decision made by the Principal Investigator pursuant to this clause 4, or if there is more than one Principal Investigator and they are unable to reach agreement between them regarding the allocation of Distributions among Inventors pursuant to this clause 4, then the matter will be finally resolved by the Vice President and Dean for Research of TAU followed by confirmation of such determination by the President of TAU.

5. No Other Consideration. Notwithstanding anything to the contrary in the terms of employment of the Team Members, the Team Members agree that they will not be entitled to any consideration or benefits of any nature in connection with or arising out of the commercialization of Project Technology, other than as specifically set forth in clause 4 above with respect to Inventors.

6. Taxes. Each Inventor will bear and pay any taxes imposed on such Team Member with respect to his/her share of Distributions. Ramot and TAU will be entitled to withhold, deduct or pay any withholding taxes and/or any other deductions or payments that Ramot or TAU may be required under law to withhold, deduct or pay with respect to any Distributions received by any Team Member.

7. Execution by New Team Members. The Principal Investigator undertakes to notify Ramot and TAU immediately of any new faculty member, postdoctoral fellow, student or other researcher who is to participate in the performance of the Sponsored Research. After consultation with the Principal Investigator, Ramot will decide whether such new researcher should sign this Letter as a Team Member. If Ramot determines that such new researcher should sign this Letter, the Principal Investigator will cause such new researcher to sign this Letter prior to performing Sponsored Research.

If the terms and provisions of this Letter are acceptable to you, please indicate your acceptance by signing in the space indicated below (if you are the Principal Investigator) or on Exhibit A (if you are a Researcher).

Sincerely,

Ramot at Tel Aviv University Ltd.	Tel Aviv University
Ву:	Ву:
Name:	Name:
Title:	Title:

I have read this Letter and I understand its contents. I hereby agree to and accept the terms and conditions of this Letter.

Principal Investigator

#### Exhibit 9.1.2.2(b)

#### **BIU Team Agreement**

#### **Team Agreement**

April 15, 2004

Dear Professor Abraham Nudelman (the "Principal Investigator")

#### Re: Team Agreement Relating to Project

This letter agreement (this "Letter") is addressed to you and the persons listed in Exhibit A to this Letter (each a "Researcher" and collectively, the "Researchers"). Exhibit A may be amended by the addition of new Researchers as described below. You and the Researchers are referred to collectively in this Letter as the "Team Members".

The Team Members are or were faculty members, post-doctoral fellows, students or technicians performing research at Bar-Ilan University ("Bar-Ilan"). In such capacity, they have performed research at Bar-Ilan relating to conjugated anti-psychotic drugs and the use thereof (as further described in Exhibit B to this Agreement, the "Project") and/or are members of a team that will perform further research at Bar-Ilan relating to the Project under the supervision of the Principal Investigator.

By operation of law or under the terms of their employment or other relationships with Bar-Ilan or Bar-Ilan Research and Development Company Ltd. ("BIRAD"), and according to agreements between Bar-Ilan and BIRAD, all rights, title and interest in and to any and all inventions and other results arrived at by the Team Members as a result of their relationship with Bar-Ilan are owned by BIRAD. This includes all intellectual property, inventions, know-how, technology, methods, data and other results directly relating to the Project arrived at prior to the date of this Agreement during the course of research and development at Bar-Ilan (the "Existing Project Technology").

BIRAD, Ramot at Tel Aviv University Ltd. ("Ramot") and BioLineRX Ltd. ("BioLine") have entered into a research and license agreement (the "Research and License Agreement") pursuant to which: (1) BIRAD granted BioLine a license with respect to certain patent and other rights owned by BIRAD relating to the Existing Project Technology, (2) BioLine agreed to fund further research relating to the Project at Bar-Ilan by Team Members ; and (3) BIRAD agreed to cause the performance of such research by Team Members and to grant BioLine a license with respect to the results arrived at in the performance of such research.

The purpose of this Letter is to set forth the rights and obligations of the Team Members with respect to the Project and the further research relating to the Project to be performed by some or all of the Team Members. Please read this Letter carefully and if you agree with its contents sign in the appropriate place next to your name below.



#### 1. Sponsored Research.

(a) The Principal Investigator agrees to supervise and cause the performance at Bar-Ilan of further research relating to the Project in accordance with the research program included in Exhibit C to this Letter (as may be amended from time to time by the mutual agreement of BIRAD and BioLine, after consultation with the Principal Investigator) and the budget included in Exhibit C to this Letter (as may be amended from time to time by the mutual agreement of BIRAD and BioLine, after consultation with the Principal Investigator) and the budget included in Exhibit C to this Letter (as may be amended from time to time by the mutual agreement of BIRAD and BioLine, after consultation with the Principal Investigator ). Such research is referred to in this Letter as the "Sponsored Research."

(b) The Principal Investigator will keep BioLine reasonably informed concerning the Sponsored Research, its progress and its results.

#### 2. Intellectual Property Rights.

(a) Each of the Team Members acknowledges, confirms and agrees that BIRAD is and shall be the sole owner of all rights, title and interest in and to any and all Project Technology and any and all intellectual property rights relating to the Project Technology. "Project Technology" means the Existing Project Technology and any and all inventions, products, materials, methods, processes, techniques, know-how, data, information, discoveries and other results of whatever nature arrived at in the course of the performance of the Sponsored Research, whether at Bar-Ilan or elsewhere.

(b) Each of the Team Members agrees to sign and deliver to BIRAD any documents, and to take any actions, that BIRAD believes are needed or desirable in order to best confirm BIRAD's title in the Project Technology.

(c) The Team Members acknowledge that all patent applications relating to Project Technology, to the extent they cover inventions made by Team Members, will be filed in the name of BIRAD, except in cases where BIRAD believes that it is necessary that the patent applications be filed in the name of Team Members and then assigned to BIRAD. Each of the Team Members agrees, at BIRAD's request, to assist BIRAD to file and obtain, and if needed to enforce, any patent or patent application relating to the Project Technology in any country requested by BIRAD. Such assistance may include signing, verifying and delivering to BIRAD such documents, and performing such other acts (including appearances as a witness), as BIRAD may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such patents and patent applications and confirming their assignment to BIRAD.

(d) In the event BIRAD is unable for any reason, after reasonable effort, to secure a Team Member's signature on any document needed in connection with the actions specified in this clause 2, such Team Member hereby irrevocably designates and appoints BIRAD and its duly authorized officers and agents as such Team Member's agent and attorney in fact, which appointment is coupled with an interest, to act for and in such Team Member's behalf to sign, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of this clause 2 with the same legal force and effect as if executed by such Team Member.

#### 3. Confidentiality and Publications.

(a) Each Team Member undertakes to keep confidential and not to disclose or use (other than for the furtherance of the Project) any Project Technology or BioLine Confidential Information to any person or entity other than a fellow Team Member, an employee of BIRAD, or an employee, officer or director of BioLine, except and to the extent that s/he is instructed or authorized to do so by BIRAD. This obligation of confidentiality does not apply to any portion of the Project Technology that is in the public domain (other than through the fault of such Team Member), nor does it apply to information included in scientific publications that have been approved by BIRAD prior to publication. "BioLine Confidential Information" means any scientific, technical, trade or business information relating to the Sponsored Research designated as confidential or which otherwise should reasonably be construed under the circumstances as being confidential disclosed by or on behalf of BioLine to a Team Member, except to the extent such information: (i) was known to such Team Member at the time it was disclosed, other than by previous disclosure by or on behalf of BioLine, as evidenced by such Team Member's written records at the time of disclosure; (ii) is at the time of disclosure or later becomes publicly known under circumstances involving no breach of this Letter; (iii) is lawfully and in good faith made available to the Team Member by a third party who is not subject to obligations of confidentiality to BioLine or BIRAD with respect to such information; or (iv) is independently developed by the Team Member without the use of or reference to BioLine Confidential Information, as demonstrated by documentary evidence.

(b) In general, BIRAD will endeavor to assist the Team Members in facilitating publications relating to Project Technology and BIRAD agrees not to unreasonably withhold its approval of publications, except to the extent described in this paragraph. In order to permit BIRAD to comply with its obligations to BioLine and the opportunity to properly protect patent and proprietary rights relating to information included in such proposed publications, the Team Members agree to provide BIRAD with a copy of each proposed publication at least forty (40) days in advance of the contemplated submission for publication to permit BIRAD to review such submission to determine whether the publication or presentation contains subject matter for which patent protection should be sought prior to publication or presentation. BIRAD will review, and shall allow BioLine to review, such proposed publication. If BIRAD informs the Principal Investigator within thirty (30) days of the receipt of such proposed publication, that it wishes to seek protection with respect to material included within such proposed publication, then the Team Members will delay the submission of the publication or presentation for a further period of up to sixty (60) days (or longer if BIRAD notifies the Team Members that such additional period is required in order to make the necessary patent filings) to enable BIRAD to make the necessary patent filings.

(c) Each Team Member's obligations under this clause 3 shall continue in full force and effect during the term such Team Member is involved with the Sponsored Research and for a period of seven (7) years after the termination of such Team Member's involvement with the Sponsored Research.

#### 4. Distributions.

(a) Those of the Team Members who are inventors of technologies included in patents relating to the Project Technology (together, the "Inventors") will be entitled, together, to receive from the proceeds received by BIRAD from the commercialization of Project Technologies the amounts determined in accordance with the rules and regulations in effect at Bar-Ilan, from time to time, relating to the allocation of the proceeds from the commercialization by BIRAD of inventions made by them. The total distributions received by all Team Members according to this clause are referred to in this Agreement as the "Distributions".

(b) The Distributions shall be allocated among the Inventors in accordance with the percentages set forth in Exhibit C hereto. The Team Members understand that this allocation of the Distributions among the Inventors is based on the contribution of each Inventor to the inventions included in the Existing Technology.



(c) Each of the Team Members agrees that if, in the Principal Investigator 's judgment, a change in the Sponsored Research; the composition of the research team or the respective contributions of the Inventors to the Project Technology being commercialized justifies a change in the allocation of the Distributions among the Inventors, the Principal Investigator will decide, at his sole discretion, on an amended allocation of the Distributions. Such change may include: (i) additions of persons to the list of inventors entitled to a share of the Distributions; (ii) deletion of certain persons from the list of Inventors entitled to Distributions an Inventor is entitled to; and/or (iv) any other change deemed by the Principal Investigator to be appropriate, in his absolute discretion.

(d) Any change made pursuant to clause 4(c) will only affect Distributions paid after the date of the relevant change. It will not affect Distributions distributed to individual Inventors prior to the relevant change.

(e) Each of the Team Members agrees that, if a Team Member disputes a decision made by the Principal Investigator pursuant to this clause 4, or if there is more than one Principal Investigator and they are unable to reach agreement between them regarding the allocation of Distributions among Inventors pursuant to this clause 4, then the matter will be finally resolved by the Vice President and Dean for Research of Bar-Ilan followed by confirmation of such determination by the President of Bar-Ilan.

5. No Other Consideration. Notwithstanding anything to the contrary in the terms of employment of the Team Members, the Team Members agree that they will not be entitled to any consideration or benefits of any nature in connection with or arising out of the commercialization of Project Technology, other than as specifically set forth in clause 4 above with respect to Inventors.

6. Taxes. Each Inventor will bear and pay any taxes imposed on such Team Member with respect to his/her share of Distributions. BIRAD and Bar-Ilan will be entitled to withhold, deduct or pay any withholding taxes and/or any other deductions or payments that BIRAD or Bar-Ilan may be required under law to withhold, deduct or pay with respect to any Distributions received by any Team Member.

7. Execution by New Team Members. The Principal Investigator undertakes to notify BIRAD and Bar-Ilan immediately of any new faculty member, postdoctoral fellow, student or other researcher who is to participate in the performance of the Sponsored Research. After consultation with the Principal Investigator, BIRAD will decide whether such new researcher should, sign this Letter as a Team Member. If BIRAD determines that such new researcher should sign this Letter, the Principal Investigator will cause such new researcher to sign this Letter prior to performing Sponsored Research.

If the terms and provisions of this Letter are acceptable to you, please indicate your acceptance by signing in the space indicated below (if you are the Principal Investigator) or on Exhibit A (if you are a Researcher).

Bar-Ilan Research and Development Company Ltd.	Bar-Ilan University
Ву:	Ву:
Name:	Name:
Title:	Title:

I have read this Letter and I understand its contents. I hereby agree to and accept the terms and conditions of this Letter.

BioLineRx Ltd. Hartum Street P.O. Box 45158 Jerusalem, 91450 Israel Attn: CEO

Dear Sirs,

Re: <u>First Amendment of Research and License Agreement, Dated April 15, 2004, by and Among BioLineRX Ltd., Ramot at Tel Aviv University,</u> <u>Ltd and Bar-Ilan Research and Development Company Ltd. the "Agreement"</u>)

You have brought to our attention the fact that Section 9.1.1 of the Agreement (Licensor Confidential Information) has created a problem with respect to your ability to enter into agreements with potential contractors/collaborators and to attract investors. Specifically, the provision states that your obligations of confidentiality and non-use (other than for the purposes of the Agreement) remain in effect during the term of the agreement, and for five (5) years thereafter. As you have explained to us, potential contractors/collaborators are unwilling to be bound by such confidentiality and non-use obligations with respect to the Confidential Information (as defined in the Agreement) for such undefined term. Therefore, in order to enable you to continue to develop Licensed Product (as defined in the Agreement) and to exercise your rights and fulfill your obligations under the Agreement, we hereby agree to amend the agreement as follows, effective immediately:

The following shall be inserted at the end of Section 9.1.1:

"Notwithstanding anything to the contrary in this Section 9.1.1, Bioline may disclose Licensor Confidential Information to actual and potential business partners, collaborators, investors, contractors, service providers and consultants, provided, in each case, that such recipient of Confidential Information first enters into a legally binding agreement with BioLine which imposes confidentiality and non-use obligations with respect to Confidential Information comparable to those set forth in this Agreement for a period of least five (5) from the date of disclosure of Licensor Confidential Information to such recipient."

All other provisions of the Agreement shall remain unchanged.

Please indicate your agreement to the above amendment to the Agreement by signing below.

		Sincerely,
Ramot	at Tel Aviv University Ltd.	Bar-Ilan Research and Development Company Ltd.
By:	/s/ ISAAC KOHLBERG	By: /s/ GABRIEL KENAN
Name:	ISAAC KOHLBERG	Name: GABRIEL KENAN
Title:	CEO	Title: CEO
Agreed	l to and Accepted:	
BioLine	eRx Ltd.	
By:	/s/ Yuri Shoshan /s/ Morris Laster	
Name:	Yuri Shoshan Morris Laster	
Title:	VP Finance CEO	

#### AMENDMENT AGREEMENT

THIS AMENDMENT AGREEMENT, dated as of the 20th day of December, 2005, (the "Effective Date"), is entered into by and between BioLineRx Ltd. ("BioLine"), Bar-Ilan Research and Development Company Ltd. ("BIRAD") and Ramot at Tel Aviv University Ltd. ("Ramot", and together with BIRAD, the "Licensors").

WHEREAS, BioLine and the Licensors entered into that certain Research and License Agreement dated as of April 15, 2004 (the "**Research and License Agreement**"); and

WHEREAS, the parties desire to amend the Research and License Agreement as set out herein;

NOW, THEREFORE, the parties agree as follows:

- 1. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Research and License Agreement.
- 2. Section 13.4.3 of the Resarch and License Agreement shall be deleted in its entirety and replaced with the following:

"13.4.3. Transfer of Regulatory Filings and Know How. In the event BioLine terminates this Agreement pursuant to Section 13.3.1 or Ramot terminates this Agreement pursuant to Section 6.4, 13.3.2 or 13.3.3 (except in the circumstances set out in Section 13.3.3.2), BioLine shall promptly deliver and assign to Licensors (a) all documents and other materials filed by or on behalf of BioLine and its Affiliates with Regulatory Agencies in furtherance of applications for Regulatory Approval in the relevant country with respect to Licensed Products; and (b) all intellectual property, inventions, conceptions, compositions, materials, methods, processes, data, information, records, results, studies and analyses, discovered or acquired by, or on behalf of BioLine and its Affiliates which relate directly to actual or potential Licensed Products; <u>provided</u>, <u>however</u>, that to the extent that any of the items set forth in clauses (a) or (b) were developed using funds granted by the Office of Chief Scientist of the Israel Ministry of Industry, Trade and Labor (the "OCS"), such items are and remain subject to the rules and regulations of the OCS, including without limitation, the Law for the Encouragement of Industrial Research & Development, 1984. The Licensors, the TAU Team and the BIU Team shall be entitled to freely use and to grant others the right to use all such materials, documents and know-how delivered pursuant to this 13.4.3."

3. Except as amended pursuant to this Amendment Agreement, the terms of the Research and License Agreement shall remain in full force and effect.

[Remainder of page intentionally left blank. Signature page follows.]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

Ramot at Tel Aviv University Ltd.	BioLineRx Ltd.		
By: /s/ Ze'ev Weinfeld, Ph.D.	By: /s/ Yuri Shoshan		
Name: Ze'ev Weinfeld, Ph.D.	Name: Yuri Shoshan		
Title: Executive Vice President Business Development	Title: Vice President Finance and Corporate Development		
Bar-Ilan Research and Development Company Ltd.			
By: /s/ Gabriel Kenan			

Name:Gabriel Kenan

Title: CEO

#### AMENDMENT AGREEMENT

THIS AMENDMENT AGREEMENT, dated as of the 7th day of March, 2006, (the "Effective Date"), is entered into by and between BioLineRx Ltd. ("BioLine"), Bar-Ilan Research and Development Company Ltd. ("BIRAD") and Ramot at Tel Aviv University Ltd. ("Ramot", and together with BIRAD, the "Licensors").

WHEREAS, BioLine and the Licensors entered into that certain Research and License Agreement dated as of April 15, 2004 (the "Research and License Agreement"); and

WHEREAS, BioLine and the Licensors entered into an amendment agreement dated June 2004 (the "First Amendment Agreement") to amend the Research and License Agreement; and

WHEREAS, BioLine and the Licensors desire to further amend the Research and License Agreement as set out herein;

NOW, THEREFORE, the parties agree as follows:

1. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Research and License Agreement.

2. Section 1.21 of the Resarch and License Agreement shall be deleted in its entirety and replaced with the following:

"1.21 "Licensed Product" shall mean any of the following:

(i) any therapeutic product that comprises, contains or incorporates Licensor Technology; or
(ii) Any therapeutic product that comprises, contains, or incorporates any compound that is covered by a Valid Patent Claim under the Joint Patent Rights.

3. The following new Section 1.41 shall be added following Section 1.40:

"1.41 "Valid Patent Claim " shall mean a claim of a Licensed Patent Right for as long as such claim shall not have expired or been held invalid in a final non appealable court judgment or patent office decision in the relevant jurisdiction, or an appeal for it has not been filed within the time allowed for an appeal.

4. The following shall be added at the end of the last sentence of section 5.1:

"..., and *subject further*, to the rights of employees, students and other researchers of TAU and BIU to practice and utilize such rights and licenses solely for academic research purposes within TAU and BIU (the "Academic Research"). Notwithstanding the foregoing, any *in vivo* experimentation that may be included within the scope of Academic Research that is conducted by, or on behalf of Ramot or BIRAD, shall require the prior written approval of BioLine if and to the extent that such research involves *in vivo* experimentation of compounds that are currently being developed as Licensed Products by BioLine, such approval not to be unreasonably delayed or withheld. For the removal of doubt, Ramot, Tel Aviv University, BIRAD and BIU shall not obtain funding for Academic Research from any party on terms that (i) give such party any rights to the Licensed Technology that are inconsistent with the rights granted to BioLine hereunder, or (ii) limit in any manner the scope or terms of the license and rights granted to BioLine hereunder.

5. Except as amended pursuant to this Amendment Agreement, the terms of the Research and License Agreement and the First Amendment Agreement shall remain in full force and effect.

[Remainder of page intentionally left blank Signature page follows.]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

Ramot at Tel Aviv Univ ty Ltd. By: /s/ Ze'ev Weinfeld, Ph.D. Name: Ze'ev Weinfeld, Ph.D. Title: Executive Vice President, Business Development

BiolineRx Ltd. By: /s/ Yuri Shoshan Name: Yuri Shoshan Title: Vice President, Finance and Corporate Development

Bar-Ilan Research and Development By: /s/ Gabriel Kenan Name: Gabriel Kenan Title: C.E.O. Bar-Ilan Research & Development Company Ltd.

We, the undersigned, hereby confirm that we have read the Amendment Agreement, that its contents are acceptable to us and that we will act in accordance with its terms.

/s/ lrit Gil-Ad Dr.lrit Gil-Ad

/s/ Abraham Weizman Professor Abraham Weizman

/s/ Ada Rephaeli Dr. Ada Rephaeli

/s/ Abraham Nudelman

Professor Abraham Nudelman

### CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. ASTERISKS DENOTE OMISSIONS.

#### ASSIGNMENT AGREEMENT

This Assignment Agreement, dated as of the 2 day of July, 2006, (the "Effective Date"), is entered into by and between BioLineRx Ltd. ("BioLine"), BioLine Innovations Jerusalem, LP ("BIJ"), Bar-Ilan Research and Development Company Ltd. ("BIRAD") and Ramot at Tel Aviv University Ltd. ("Ramot", and together with BIRAD, the "Licensors").

WHEREAS, BioLine and the Licensors entered into that certain Research and License Agreement dated as of April 15, 2004 (the "Research and License Agreement"); and

WHEREAS, BioLine and the Licensors entered into an amendment agreement dated as od December, 2005 (the "First Amendment Agreement") to amend the Research and License Agreement; and

WHEREAS, BioLine and the Licensors entered into an amendment agreement dated the 7th day of March, 2006 (the "**Second Amendment Agreement**") to further amend the Research and License Agreement (the Research and License Agreement as amended by the First Amendment Agreement and the Second Amendment Agreement shall be hereinafter referred to as the "**Agreement**"); and

WHEREAS, certain Research Results have been generated in the course of performing the Agreement for which patent protection is currently being sought, as more particularly detailed in <u>Exhibit A</u> attached hereto (hereinafter referred to as the "**Selected Compounds**"); and

WHEREAS, the Selected Compound forms part of the Licensed Technology licensed to BioLine pursuant to the Agreement; and

WHEREAS, BioLine desires to assign all of its rights and obligations under Agreement with respect to the Selected Compounds to BIJ according to Section 14.10 of the Agreement; and

WHEREAS, BioLine and the Licensors have agreed to certain additional arrangements in respect of such assignment as set out herein;

NOW, THEREFORE, the parties agree as follows:

1. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Agreement.

2. The Licensors hereby acknowledge and agree to the assignment of BioLine's rights and obligations under the Agreement with respect to the Assigned Technology to BIJ effective as of the date hereof.

3. Without limiting the generality of the foregoing, the parties hereby acknowledge and agree that (i) all rights, title and interest in and to the Selected Compounds shall be retained by the owners thereof as determined in accordance with Section 3 of the Agreement and, following the assignment of BioLine's rights under the Agreement with respect to the Selected Compounds as contemplated in Section 2 above, the exclusive license granted to BioLine with respect to the Selected Compounds pursuant to the Agreement shall be assigned to BIJ; and (ii) all rights, title and interest in and to the Development Results shall be owned solely and exclusively by BIJ. For the purpose hereof, the term "**Development Results**" shall mean all intellectual property, inventions, conceptions, compositions, materials, methods, processes, data, information, filings, records, results, studies and analyses, and other results and information of any kind relating to the Selected Compounds generated, discovered or acquired solely by employees, subcontractors or consultants of BIJ (other than members of the TAU Team, as defined in the Agreement) in the continued development and commercialization of the Selected Compounds. For purpose of clarity and without derogating from the generality of the foregoing, procedures and experiments developed by BIJ in the course of such development, including methods of chemical synthesis, drug administration modes, efficacy studies in animal models, formulations, toxicology, safety, pharmacology, stability, clinical studies and production and the results of all the foregoing shall be considered "Development Results".

4. BIJ may apply for grants and other funding from the Biotech Incubators Program of the Office of the Chief Scientist of the Israeli Ministry of Industry and Trade (the "**OCS**") for the continued development of the Selected Compounds. If BIJ receives such grants, the development and commercialization of the Selected Compounds will become subject to the applicable laws and regulations governing such grants including, without limitation, the Law for the Encouragement of Industrial Research and Development, 5744-1984 as amended or supplemented from time to time and all regulations promulgated thereunder, the rules and regulations of the OCS and the relevant directives of the Director General of the Ministry of Trade, Industry and Employment (including Directive 8.4), and the rules and regulations of the Incubator Program of the OCS (together, the "**Applicable Law**"). Except as set forth in Section 5 below, BIJ alone shall be responsible for meeting the the requirements of the Applicable Law with respect to the Development Results.

5. In the event the Agreement is terminated for any of the reasons set out in 13.4.3 of the Agreement, BIJ shall transfer and assign to the Licensors all Development Results and all rights, title and interest therein and thereto; *subject, however*, to any conditions governing such transfer and assignment set out in the Applicable Law (collectively, the "**Grant Transfer Conditions**"), in which case BIJ will not be required to transfer and assign the Development Results as contemplated above *unless and until* the Licensors either (i) agree in writing to assume all obligations required by the Grant Transfer Conditions, or (ii) reach another arrangement with the OCS which absolves BioLine and BIJ of any liability to such grantors with respect to the transfer and/or assignment of the Development Results.

6. Except as otherwise provided herein , the terms of the Agreement shall remain in full force and effect.

[Remainder of page intentionally left blank. Signature page follows.]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

Ramot at Tel Aviv University Ltd. By: /s/ Ze'ev Weinfeld, Ph.D. Name: Ze'ev Weinfeld, Ph.D. Title: Executive Vice President, Business Development

#### **Bar-Ilan Research and Development**

**Company Ltd.** By: /s/ Gabriel Kenan Name: Gabriel Kenan Title: C.E.O., Bar-Ilan Research & Development Company Ltd

# BioLineRx Ltd.

By: /s/ Yuri Shoshan Name: Yuri Shoshan Title: Vice President, Finance and Corporate Development

#### **BioLine Innovations Jerusalem, LP**

By: /s/ Kinneret Savitsky Name: Kinneret Savitsky Title: Director, BioLine Innovations Jerusalem, LP

### TRANSLATION FROM HEBREW

#### State of Israel Ministry of Industry and Trade, Office of the Chief Scientist Technological Innovation Incubator Program Administration

Date: August 18, 2005

# **Registered**

To: Kinneret Savitsky BioLine

Dear Sir or Madam,

Re: <u>Agreement to Establish a Center run as an Incubator:</u> File: 35583

Enclosed please find an agreement/amendment to an agreement for the operation of a technological innovation center as an incubator, signed by all parties.

Please confirm the receipt of this agreement in writing.

Sincerely, <Signature> Rina Pridor Director, Technological Innovation Incubator Program

Rubber stamp: Received: 8-28-2005

Drawn up and signed in Jerusalem on \_\_\_\_\_

#### Between

The Government of Israel, on behalf of the State of Israel, represented by the Chief Scientist and the Controller of the Ministry of Industry, Trade, and Employment (hereinafter "the State");

#### And

The BioLine Innovations Jerusalem Limited Partnership Biotechnology Incubator, corporate No. 550218853

by Yuri Shoshan, ID No. 321101347

and Morris Laster, ID No. 069455137

Its authorized signatories (hereinafter "the Incubator");

#### Whereas

The Incubator is a center for biotechnological research and development run as an incubator, as designated in the operating plan attached to this agreement, marked Appendix A;

#### And whereas

The Incubator commits itself to operate as a Type-2 Incubator, pursuant to the Guidelines issued by the director general of the Ministry of Industry and Trade, No. 8.4 (hereinafter "the director general's Guidelines"), the provisions of this agreement, the operating plan, the certificate of approval, and the statement of commitment to the entire project and the directives of the Biotechnology Incubator Committee (all of them together: "the Provisions");

#### And whereas

The State is interested in the operation of the incubator as a physical, organizational, professional, marketing, and business framework for research and development projects in the field of biotechnology with commercial purposes, and all of this, as detailed in the present agreement;

Now therefore be it stated, agreed, and stipulated by the parties as follows:

1.

- 1.1 The preamble to this agreement and its appendices are integral parts thereof.
- 1.2 All definitions not stated in this agreement are to be understood as defined in the director general's Guidelines.
- 2. The representative of the State for the purposes of this agreement is the Chief Scientist of the Ministry of Industry and Trade (hereinafter "the Chief Scientist") or his representative.
- 3. The purpose of this agreement is to govern the State's support for the operation of the incubator, which will provide a physical, organizational, professional, marketing, and business framework for research and development projects in the field of biotechnology with commercial purposes (hereinafter "the Incubator Project" or "the Incubator Projects").

- 4. The term of this agreement shall be a period of six years, beginning on January 1, 2005, and concluding on December 31, 2010 (hereinafter "the Term of the Agreement"). The Incubator will be entitled to submit, after the lapse of 48 months from the beginning of the Term of the Agreement, a request to extend the Term of the Agreement by three additional years. Should such a request be submitted, the Biotechnology Incubators Committee, as defined below, is entitled to reject it or approve it, to stipulate conditions, or to introduced amendments to this agreement or to set a shorter extension period. The Biotechnology Incubators Committee shall notify the Incubator in writing of its decision on the request for an extension within 90 days. Should the extension of the Term of the Agreement be approved, the Incubator shall be entitled to sign the extension document within 30 days of receiving notification from the committee.
- 5. Definitions
  - 5.1 State Loan: The loan approved by the Biotechnology Incubators Committee for the Incubator for a project for its implementation, pursuant to the Certificate of Approval for the implementation of that project and in keeping with the Provisions.
  - 5.2 Project agreement: an agreement between a Type-1 Biotechnology Incubator and the Project Company, as defined below.
  - 5.3 The Biotechnology Incubators Committee: as defined in section 2.4 of the director general's Guidelines (hereinafter "the Committee").
  - 5.4 Franchise holder: as defined in section 2.4 of the director general's Guidelines.
  - 5.5 Project company: as defined in section 2.5 of the director general's Guidelines.
  - 5.6 Type-1 Biotechnology Incubator: as defined in section 2.3.1 of the director general's Guidelines.
  - 5.7 Type-2 Biotechnology Incubator: as defined in section 2.3.2 of the director general's Guidelines.
  - 5.8 Incubator: a type-1 or type-2 Biotechnology Incubator as defined above.
  - 5.9 Entrepreneur: as defined in section 2.2 of the director general's Guidelines.
  - 5.10 Certificate of Approval: A certificate signed by the Chief Scientist, stipulating the conditions of implementation of the R&D work by every Project Company and/or Project that is housed in the Incubator, and governing the issuing of state loans to the Incubator and/or the Project Company and/or the Project.
  - 5.11 Encumbered Project Assets: As defined in section 5.14 of the director general's Guidelines.
  - 5.12 Incubator Project: As defined in section 2.6 of the director general's Guidelines.
  - 5.13 Intellectual Property: The expertise and experience accumulated by the Incubator and/or the Project Company and/or anyone acting on their behalf, the trade secrets that are relevant, directly and/or indirectly, to the operation of the Incubator and/or the Project Company and/or the Project, as well as the patents, copyrights, trademarks, trade names, trade secrets, inventions, samples, processes, computer programs, technical data, any agreement and/or license for implementing the project in any stage whatsoever, specific trials on an animal model, synthesis of compounds, preclinical trials and their outcomes, and any other intangible rights, whether registered or not registered, associated with the operation of the Incubator and/or the Project.

- 5.14 Interest: As per the interest rate set in the Award of Interest and Linkage Law 5721-1961.
- 5.15 Operating plan: the plan for operating the incubator submitted to and approved by the Committee and/or as it may be updated from time to time with the approval of the Committee, including the operating budget of the Incubator, all as stipulated in Appendix A.
- 5.16 Project Implementation: As defined in the Certificate of Approval for that Project and pursuant to the director general's Guidelines.
- 5.17 Allowed Overhead: A payment by a Project Company and/or Project to the Incubator on account of outlays for project overhead, in a total amount not to exceed 20% (twenty percent) of the labor costs in the approved budget of that Project Company and/or Project.
- 6. The Incubator hereby affirms as follows:
  - 6.1 That it is organized and registered as an Israeli for-profit corporation whose goal is the successful operation of the Incubator. The details of its incorporation, including its certificate of incorporation and an up-to-date report from the Office of the Registrar of Companies, its bylaws, founders' agreement, and statement of signatory rights certified by the Incubator's attorney are attached to the present agreement as Appendix B.
  - 6.2 That, no later than the end of three months from the date of signing of this agreement, the Incubator will operate and be the owner or have leasehold rights of an appropriate structure approved in advance by the Committee for the housing and implementation of at least eight projects with approximately five employees per project. The structure will also include the infrastructure appropriate for the operation of a central equipment lab, as detailed in section 7.6 of the present agreement (hereinafter "the Structure"). Any change in the identity and/or nature of the leasehold shall require the advance approval of the Incubators Committee.
  - 6.3 That it has the expertise, experience, and professional and economic capacity to manage the incubator pursuant to this agreement and the Provisions, and to provide the Project or Projects with a physical, organizational, professional, marketing, and business environment for conducting research and development in the field of biotechnology for commercial purposes.
  - 6.4 That it has access to first-class consulting services, including in the following fields: legal counsel, patents, quality control, regulatory affairs and clinical trials, information management, and bookkeeping and financial advice.
- 7. The Incubator undertakes:
  - 7.1 To prepare the structure and make it suitable for the needs of running the Project or Projects, as may be required.
  - 7.2 To manage the incubator, with all its functions, by means of an administrative staff, in a professional manner, in keeping with the Provisions and to faithfully satisfy all provisions that may be in force at that time.
  - 7.3 To employ a fulltime general manager for the incubator, with the appropriate skills (hereinafter "General Manager").

- To employ a fulltime administrative director for the incubator, as well as a secretarial and bookkeeping staff with the appropriate skills, 7.4 proportional to the scale of the incubator's activities.
- 7.5 To employ, in addition to the above, one assistant manager with the professional and business skills appropriate for the field for every three projects being carried out in the incubator, starting from the first project.
- 7.6 To establish and operate a central lab for all the projects (hereinafter "the Lab").
  - 7.6.1 To employ a fulltime manager or operator of the central Lab, with the appropriate skills. During its first year of activity the Incubator is entitled to satisfy this obligation by means of an outside contractor that runs the Lab and/or to employ a part-time manager only.
  - 7.6.2 To set up and operate the Lab no later than the end of the first year of the Incubator's activity, as per the requirements included in section 4.2 of the director general's Guidelines.
- 7.7 To train the project managers to work according to quality principles.
- 7.8 To operate the Incubator for at least six years and to invest in its operation an annual sum of not less than NIS 2,700,000 (two million seven hundred thousand) for each year of operation (as defined below) for the Term of the Agreement (hereinafter the "Total Investment"). The Total Investment will be linked to the Consumer Price Index published in February 2004. The Total Investment will be updated once at the start of each year as a function of the rise in the index from February 2004 to January of that year (hereinafter the "Updated Total Investment"). It is stipulated that should the cumulative change in the index be negative, the Total Investment will not be decreased. To eliminate any doubt, the Total Investment shall be in addition to the supplementary financing required for each Incubator project and for the Allowed Overhead as part of the Project's approved budget project, and in addition to financing equipment for the Lab and its maintenance, as stipulated in section 7.6 above.
- 7.9 Bank Guarantee
  - 7.9.1 To guarantee the Incubator's undertakings under the present agreement, the Incubator and/or its controlling party will convey a linked bank guarantee payable to the State in the amount of NIS 8,100,000 (eight million one-hundred thousand), linked to the Consumer Price Index published in February 2004, which will remain in force until the passage of three months after the Term of the Agreement, in the form attached to the present agreement as Appendix C.
  - 7.9.2 It is stipulated and agreed that after the lapse two years from the start of the Term of the Agreement, the amount of the bank guarantee to the State will be reduced on account of any reported outlays approved by the Chief Scientist and included in the approved budget of the Incubator. This reduction will be at the rate of 50% (fifty percent) of the outlays reported as above, which will not be less than NIS 500,000 (five hundred thousand), but the sum of the Guarantee will not fall, in any case and at any time, to less than NIS 1,500,000 (one million five-hundred thousand), and as specified in Appendix C to the present agreement.
- Not to charge any fee to the Project Company and/or an Incubator Project for the operation or use of equipment in the Lab and/or any other 7.10 expenditure associated with the Lab or for the personnel to run it, beyond the Allowed Overhead, except for payments for materials and consumables that may be required to conduct the project.

- 7.11 To obtain the Committee's approval for any transfer of controlling interest in the Incubator. For this purpose "Control" is as defined in the Securities Law 5722-1968.
- 7.12 To manage the State Loan to the project in a professional manner, pursuant to the Provisions. Any outstanding balance of the State Loan that has not yet been made available to the Project Company and/or Project, for any reason whatsoever, shall be invested exclusively in interest-bearing bank deposits or government securities.
- 7.13 To use the State Loan for projects exclusively to support projects under the present agreement.
- 7.14 To maintain proper audited books of all of the Incubator's activities, as per all laws and regulations, and in keeping with Generally Accepted Accounting Principles, to permit examination by the Chief Scientist or his representative at any time.
- 7.15 To submit a report summarizing the activities of the incubator for that period to the Office of the Chief Scientist, every six months after the start of the Term of the Agreement.
- 7.16 To submit to the Office of the Chief Scientist an annual trial balance for all of the Incubator's financial activities, for each six months of activity. This shall include details of all moneys paid out on account of the State Loan and all moneys spent by the Incubator, for each six months of activity.
- 7.17 To submit to the Office of the Chief Scientist for every calendar year running from January 1 through December 31<sup>st</sup> (hereinafter the "Fiscal Year"), starting on the date of the signing of this agreement, a financial statement approved by an accountant that covers all of the Incubator's financial activities and that includes full information about all moneys paid out on account of the State Loan to Projects and all moneys spent by the Incubator, for the entire Fiscal Year (hereinafter "Yearly Financial Statement"), no later than 90 days after the end of the Fiscal Year.
- 7.18 To submit the aforesaid reports and statements, pursuant to the Chief Scientist's regulations for financial statements and technical reports, on the forms that may be specified by the Chief Scientist and as may be modified from time to time.
- 7.19 To identify, study, and select appropriate project or projects to be run as part of the Incubator. The selection of project or projects and their acceptance for the Incubator shall be at the Incubator's discretion, in keeping with the list of criteria for the approval of projects attached to the present agreement and labeled Appendix D.
- 7.20 To help project developers identify, interview, and hire appropriate researchers for the projects.
- 7.21 To provide the projects with administrative services, including secretarial services, maintenance, purchasing, bookkeeping, and computer infrastructure and services, as required for the efficient and effective operation of each project, all in keeping with the project agreement and in keeping with the terms that may be agreed upon between the Incubator and the Project Company and/or the Project.

- 7.22 To provide the Projects with professional assistance and guidance so that they can carry out their R&D efficiently and professionally.
- 7.23 For each Project that has received a Certificate of Approval, to make available supplemental financial resources, in addition to the State Loan, as required for carrying out the R&D work on the Projects (the "Supplementary Financing").
- 7.24 To assist the Projects in registering and/organizing as commercial entities, if necessary, to draw up a business plan, to organize for marketing and raising capital for the further successful operation of the Project and its development as a commercial venture.
- 7.25 To manage, faithfully and separately for each project, the budget of that Project, including the State Loan for the Project transferred to the Incubator for implementation of the project.
- 7.26 To conduct an administrative, financial, and professional audit of the implementation of each project and its progress as per the Project plan, and to fulfill all of the obligations incumbent on the Incubator under Certificates of Approval.
- 7.27 Services supplied to Projects
  - 7.27.1 To provide the Projects with access to consulting and oversight services in the following domains: bookkeeping and auditing, legal counsel, patents, quality control, information management, regulatory affairs and clinical trials, to be provided by service providers who are known to the Committee and/or substitutes approved by the Committee as being of acceptable scope and quality.
  - 7.27.2 Not to deviate from the Allowed Overhead permitted by the director general's Guidelines, with regard to the collection of payments from Projects in the Incubator for services provided to the Projects by the Incubator.
- 7.28 That the signatories below are authorized to bind it with regard to the present agreement.
- 7.29 Against the State Loans to be granted to the Incubator on account of the Projects, the Incubator will record to the benefit of the State a first-degree floating lien, as in the form attached as Appendix E, on all of the Incubator's assets, including restriction of the transfer and/or registration of rights in the technologies created by the Projects during the term of the Incubator, and all equipment that may be purchased for use by the Project. The Incubator shall be required to notify the Incubators Administration about the assets covered by the aforesaid lien, pursuant to the procedures of the Technological Innovations Incubator Program of the Office of the Chief Scientist. To eliminate all doubt, in no case shall the Incubator and/or Project Company be entitled to sell the equipment stated in the present section 7.29, or any part thereof, or to transfer it in any fashion whatsoever to a third party, or to create additional liens on it, without the written agreement of the State, until it has fully repaid the State Loans to the State. All revenues from realization of the lien and/or liens shall be divided pro rata between the State and other creditors, as per law and regulations.
- 7.30 That a Project will remain in the incubator only for the period of its implementation. The Incubator shall be entitled to appeal to the Committee and request an extension of the period. The Committee is entitled to approve the extension of the period at its exclusive discretion, as stipulated in the director general's Guidelines.

#### 7.31 Intellectual Property

- 7.31.1 For a Type-1 Biotechnology Incubator: That it will not own the intellectual property associated with the Projects and/or owned by the Project Companies and/or licensed by them and will have no call or claim on it. A Type-1 Biotechnology Incubator will guarantee that the intellectual property is in the exclusive ownership of the Project Company and that the Project Company and/or those acting on its behalf will not permit any use and/or transfer of the intellectual property to a third party.
- 7.31.2 For a Type-2 Biotechnology Incubator: That the intellectual property will be in its exclusive ownership and that it and/or anyone acting on its behalf will not permit the use and/or transfer of the intellectual property to a third party, except for the Project Company and/or pursuant to the provisions of section 12 below, and subject to section 7.1 in the director general's Guidelines.
- 7.31.3 That the agreement between the Project Companies and/or Type-2 Biotechnology Incubator with any third party includes, but not exclusively, university technology transfer companies and/or research institutes, in everything associated with the projects:
  - 7.31.3.1 With regard to intellectual property that existed prior to the Project, the Incubator will acquire ownership rights in the intellectual property or the grant of an exclusive and irrevocable use license from a third party to the Project Company and/or Type-2 Biotechnology Incubator.
  - 7.31.3.2 The aforesaid third party shall not be granted any rights in the intellectual property beyond those already possessed by said third party when the irrevocable use license was granted or acquisition of ownership rights to the intellectual property by the Project Company or the Type-2 Biotechnology Incubator and on account of which the Project Companies or Type-2 Biotechnology Incubator have received a use license.
  - 7.31.3.3 The aforesaid notwithstanding, in the case of Projects that have failed or have been terminated, an aforesaid third party shall be entitled to acquire rights in the intellectual property associated with the Project and/or created by it, subject to the Provisions and the approval of the Committee, if it agrees to assume all of the Incubator's obligations to the State with regard to the Project, and in particular section 7.1 of the director general's Guidelines.
- 7.31.4 Any transfer of knowledge to a third party is subject to the director general's Guidelines.
- 8. The State undertakes to act in accordance with the Provisions:
  - 8.1 To convey to the Incubator the State Loan for the Project on account of which the Certificate of Approval was issued, provided that the Incubator meets its full obligations pursuant to the Provisions.

- 8.2 To grant the Incubator a loan to purchase equipment for the central Lab, in an amount of up to 50% of the cost of the equipment, at the time of the purchase, with regard to purchases throughout the Term of the Agreement. The purchase of any item of equipment shall require the approval of Committee and said item will be covered by the lien on the assets of the Incubator as stated in section 7.19 above. When it is no longer in use the relative portion of its depreciated value or its market price on the date when it ceases to be in use, whichever is less, will be returned to the State and the lien in favor of the State removed from it.
- Shares of the Incubator Project Companies: The Incubator shall be entitled to acquire up to 70% of the share capital of each Project Company, pursuant to what the provisions of sections 5.11.6 through 5.11.8 of the director general's Guidelines.
- 10. Project Assets on which the State holds a lien:
- 11. As stated in section 7.29 above, against the State Loans granted to the Incubator on account of the Projects, the Incubator will record to the benefit of the State a first-degree floating lien on all assets of the incubator, including restriction of the transfer and/or registration of rights in the technologies created by the Projects during the term of the Incubator, and all equipment that may be purchased for use by the Project. The Incubator shall be required to notify the Incubators Administration about the assets covered by the aforesaid lien, pursuant to the procedures of the Technological Innovations Incubator Program of the Office of the Chief Scientist. In addition the Incubator undertakes to transfer the lien to the shares of the Project Companies when they are established, pursuant to section 5.14.1 of the director general's Guidelines. For additional allocations of shares:
  - 11.1 The initial allocation of shares in the Project Company as stated in section 9 above shall be of the same category. Subject to this, it shall be possible to allocate shares of different categories in the Project Company.
  - 11.2 The allocation of a category of shares to the Incubator and/or to a party associated with the Incubator of any type that bears rights other than those of the encumbered shares shall be possible only in the following conditions:
    - 11.2.1 Should the said allocation of shares be in the context of the inclusion of the Incubator and/or some party associated with the Incubator to a third-party investment in the Project Company, on terms worked out by said third party and the Project Company in an arms-length agreement, and the Incubator or party associated with the Incubator makes less than 50% of the investment in the Project Company in that round of investment, the Incubator will notify the Committee as to the existence of the agreement within seven (7) days of the signing of said agreement.
    - 11.2.2 In any other case, an allocation of shares shall be made only after written approval has been obtained from the Committee.
      "Party associated with the Incubator": an individual or corporation with a controlling interest in the Incubator or one in which the Incubator or controlling party in the Incubator holds more than 25% of its shares, directly or indirectly.
      "Third party": A party that neither the Incubator nor a party associated with the Incubator.
      "Control": a defined in the Securities Law 5728 1968
      - "Control": as defined in the Securities Law 5728-1968.
  - 11.3 No additional allocation of shares shall be made other than against cash, except with the approval of the Committee.

# 12. Sales of encumbered Project assets

- 12.1 The Incubator shall be entitled to sell encumbered assets of the Project that are in its possession at any time, at its exclusive discretion, on sole condition that when encumbered project assets are sold the Incubator makes use of the proceeds of the sale as follows:
  - 12.1.1 A Type-1 Biotechnology Incubator and/or its shareholder shall be entitled to sell their shares in the Project Company, including the encumbered assets of the Project, at any time and at their exclusive discretion, on condition that at least 25% of the proceeds of any sale be transferred by the Incubator and/or its shareholders to the State, against repayment of the State Loans to the Project, as per section 13 below.
  - 12.1.2 A Type-2 Biotechnology Incubator and/or its shareholders shall be entitled to sell their shares in the Project Company, including the encumbered assets of the Project, at any time and at their exclusive discretion, on condition that at least 25% of the proceeds of any sale be transferred by the Incubator and/or its shareholders to the State, against repayment of the State Loans to the Project, as per section 13 below.
  - 12.1.3 In any case of a sale of the technology in full and/or grant of an exclusive use license in any of the intellectual property assets, the State Loan given to the Incubator Project shall be repaid in full.
- 12.1.4 Should the technology be split up so as to grant more than one use license, an amount equivalent to 25% of the proceeds for each license. 12.2 In any case, the total of all moneys transferred to the State on account of sales as stated in the present section shall not exceed the total of the State
- Loan to the Incubator for that Project Company and/or Project, plus interest and linkage to the Consumer Price Index, as stated in section 13.
   For a Project Company: After full repayment of the balance of the State Loan, plus interest, the remaining proceeds of the sales of the Incubator's
- shares in that Project Company shall be full owned by the Incubator and the State shall have no claim or demand on it. For an Incubator Project: After full repayment of the balance of the State Loan, as stipulated in section 13 below, with regard to a particular project, the encumbered Project assets for that Project will be removed from the lien, in accordance with the procedures of the Technology Innovation Incubators Program of the Office of the Chief Scientist, and the State shall have no claim or demand on them. The State will give its approval in
- the form attached as Appendix F.12.4 The grant of an option to acquire the base shares to be transferred by the Incubator to employees of that Incubator Project shall not be considered to be a sale for the purposes of the present section.
- 12.5 The lien on encumbered project assets, in whole or in part, shall be removed immediately after payment to the State in keeping with section 13 below. If only part of the lien has been removed, the State's rights to receive the balance of the proceeds pursuant to this section must be retained, subject to the Provisions and to section 7.31 above.
- 13. Repayment of the State Loan to the Project:

- 13.1 The Incubator may repay the State Loan to the Project in cash, on the following terms:
- During the term of implementation of the Incubator Project, repayment shall be in exchange for the nominal value of the State Loan, plus interest. 13.2
- During the first two years after the end of the term of the Incubator Project the terms of section 13.2 shall remain in force, on condition that the 13.3 Incubator undertakes to continue to operate the Project Company and/or the Project on a similar scale.
- 13.4 For the next three years, the terms of section 13.2 shall remain on force, on condition that the Incubator undertakes to continue to operate the Project Company and/or the Project on a similar scale, but the interest on the State Loan in these years shall be doubled.
- 13.5 The state will remove the lien from the encumbered Project assets in an amount proportional to the fraction of the State Loan that has been repaid. In addition, the State will remove the lien from the relative part of the encumbered Project assets in an amount proportional to whatever sums have not been transferred to the Project and have been returned to the State. The removal of the lien shall be according to the procedures of the Technological Innovations Incubator Program of the Office of the Chief Scientist.
- Should the Incubator breach its undertakings under the Provisions, or some of them, and without derogating from other remedies available to the 13.6 State under this agreement or by law, the Incubator shall repay to the State, immediately upon its first demand and no later than 30 days thereafter, all sums it has received on account of the State Loan for the Projects and that have not yet been transferred to the Project Company and/or the Project and/or moneys that have been transferred to the Project Company and/or the Project that deviate from the terms of the Certificate of Approval, plus linkage differentials and interest, in the meaning of the Award of Interest and Linkage Law 5721-1961.
- 13.7 If the Incubator received a State Loan for Projects, but a liquidation order or bankruptcy order has been issued against it, or it has decided on its voluntary liquidation, before all of its obligation under the present agreement and/or the directives and/or the Certificate of Approval and/or the statement of commitment have been fulfilled, it will be considered as if it had undertaken to pay back the State Loan, including everything purchased using the moneys of said State Loan, before the liquidation order or bankruptcy order was issued or before the decision was taken.
- 14. Realization of liens
  - The State will be entitled to realize its liens on encumbered project assets to repay the balance of the State Loan for that Project:
    - 14.1.1 At the expiration of 8 years from the issuance of the Certificate of Approval for that Project, and after 30 days have lapsed from notification to the Incubator of its intention to do so; or
    - At any earlier date should an order of liquidation or order of bankruptcy be issued against the Incubator or Project Company or should the 14.1.2 latter decide on voluntary liquidation; or

- 14.1.3 Should the incubator breach its undertakings pursuant to the present agreement and/or the Provisions and/or the Certificate of Approval regarding that project, in some fundamental breach.
- 15. The incubator shall not be entitled to transfer any rights or obligations under the present agreement to another party.
  - 15.1 The aforesaid in section 15 notwithstanding, the Incubator shall be entitled to transfer and/or to assign its right to repayment of the State Loan to any third party, as stated in section 13 above. However, nothing in this shall be deemed to release the Incubator from any of its obligations under the present agreement. The Incubator undertakes to notify the State in writing immediately upon any assignment or transfer as stated.
  - 15.2 The agreement by any parties to deviate from any conditions whatsoever of the present agreement, in a specific case or in a series of cases, shall not serve as a precedent and nothing shall be inferred from it for any other cases in the future.
  - 15.3 Should either of the parties fail to enforce or enforce tardily any right whatsoever granted it pursuant to the present agreement under law, in any case or in a series of cases, this shall not be seen as a waiver of said right or of any other rights whatsoever.
- 16. Any notice or warning related to any matter that derives from the present agreement shall be sent by one party to the other by registered mail, to the addresses indicated below, and will be considered to have been received by the addressee within 72 hours of the posting of the letter that includes the notice or warning.

The State: Incubators Administration, Office of the Chief Scientist, Ministry of Industry and Trade, POB 50031, 61500 Tel Aviv The incubator:

- 17. All of the conditions of sections 4, 6, 7, 10, 11, and 12, are fundamental conditions. The breach of any one or more of them is fundamental breach under the Law of Contracts (Remedies for Breach of Contracts) 5731-1970. The present section is to be amended in accordance with the final draft.
- 18. The incubator will have the present agreement stamped and will be responsible for the stamp tax.

In witness whereof the parties have affixed their signatures on the date stated at the beginning of this agreement.

The State:

<rubber stamp and signature> Raanan Dinur, director general

<Signature> The Chief Scientist

<Signature> the Controller

Rubber stamp: BioLine Innovations Jerusalem Limited Partnership By its General Partner, BioLine Innovations Jerusalem Ltd.

Rubber stamp: BioLine Innovations Jerusalem Limited Partnership By its General Partner, BioLine Innovations Jerusalem Ltd. /s/ Yuri Shoshan Name of signatory: Yuri Shoshan

Version: January 26, 2005

Jerusalem, January 16, 2005 Ref. 9218

To: Ms. Rina Pridor Technological Incubators Administration Hamered 29, Tel Aviv

Dear Madam,

Re: Confirmation of Authorized Signatories, BioLine Innovations Jerusalem, Limited Partnership

As the attorneys of BioLine Innovations Jerusalem Limited Partnership (hereinafter "the Incubator"), I hereby affirm that, in keeping with the limited partnership agreement of the Incubator, dated December 23, 2004, the general partner of the Incubator is BioLine Innovations Jerusalem, Ltd. (hereinafter: "the General Partner"). In its capacity as general partner the General Partner will be exclusively responsible for managing all affairs of the Incubator, including that the signature of the General Partner shall bind the Incubator in every matter.

I hereby confirm that Morris Laster and Yuri Shoshan have been authorized by the General Partner to sign the agreement for the operation of a biotechnological incubator by and between the Incubator and the Government of Israel on behalf of the State of Israel, represented by the Chief Scientist and the Controller of the Ministry of Industry, Trade, and Employment. The signature of each of these parties, whether Morris Laster or Yuri Shoshan, on this agreement, without need for the company's seal or the printed name of the General Partner, binds the General Partner and thereby also binds the incubator in every matter. In addition I hereby verify the signatures of Morris Laster and Yuri Shoshan as follows:

Name	ID number	Signature
Morris Laster	069455137	/s/ Morris Laster
Yuri Shoshan	321101347	/s/ Yuri Shoshan

Sincerely yours, /s/ Barry Levenfeld

Barry Levenfeld, attorney-at-law

# **Appendix A: Operating Plan**

# Office of the Chief Scientist, Technological Incubators Administration Approved Chief Scientist Budget for an Incubator as a Pilot

Name of incubator: BioLine Innovations Jerusalem Date: Name of incubator corporation: File No.: 35583

Implementation period (for six years): From Jan. 1, 2005 to Dec. 31, 2010–04–22

A	Personnel costs											Total cost, first	Total cost, 2nd	Total cost, 3rd	Total cost, 4th	Total cost, 5th	Total cost, 6th	Total Budget for 6
	Surname	Given name	Position	NIS per month	FTE (%)	Months employed (1 <sup>st</sup> year)	Months employed (2 <sup>nd</sup> year)	Months employed (3 <sup>rd</sup> year)	Months employed (4 <sup>th</sup> year)	Months employed (5 <sup>th</sup> year)	Months employed (6 <sup>th</sup> year)	year	year	year	year	year	year	years
1	Savitsky	Kinneret	CEO		100%	12	12	12	12	12	12							
2	Ron	Hannah	VP		100%	12	12	12	12	12	12							
3	Kelper	Leah	VP		100%	12	12	12	12	12	12							
4	To be determined				100%		12	12	12	12	12							
5	Binyamin	Eran	Lab director		100%	12	12	12	12	12	12							
6	Levin	Chen	Adm. Director		100%	12	12	12	12	12	12							
7	Yunai	Lilach	Secretary		100%	12	12	12	12	12	12							
8			2															
9																		
										Reserve for inflation	3%							
В	Subcontractors: Company and service										Total Personnel							
1	Payments to members of advisory scientific council																	

2	Legal counsel	
3	PR	
4	Regulatory counsel	
5	Payments to medical	
	experts	
6	Bookkeeping and	
	accountant	
7	Intellectual property	
	counsel	
8	Program support	
С	Equipment –	Total Services
	Item/Type	
1	Office equipment	
2	Computer and network	
	network	
3	Software	
4	Setting up central	
	lab	
5	Setting up offices Office furniture	
6	Office furniture	
D	Miscellaneous	Total
		equipment
1	Rent and upkeep Municipal services	
2	Municipal services	
3	Communications	
4	Vehicles for	
	executives	
5	Upkeep of central	
C	lab	
6	Subscriptions to	
	journals and databases	
F		Total
Е	Marketing	Total miscellaneous
		miscenaneous

1	Attendance at	
	conferences	
2	Sponsorship of	
	conferences	
3	Travel	
4	Producing marketing	
	materials	
		Total
		marketing
	Signatures	Total
		Budget
	<rubber stamp=""></rubber>	Total
		grant to
		set up lab
	(illegible)	??? less
	Incubator director	grant to
		set up lab

# Appendix B: Incorporation Data of the Company:

BioLine Innovations Jerusalem is a limited partnership, fully controlled (100%) by BioLineRx Ltd. The general partner is BioLine Innovations Jerusalem, a limited corporation established by BioLineRx Ltd. The limited partner is BioLineRx Ltd.

# Data of the shareholders in the Incubator (clause 6.1)

Below is a list of the shareholders in BioLineRx Ltd.:

Shareholder's name	Place of incorporation/ citizenship	Address	Number of shares	Percent of holdings
Teva Pharmaceutical Industries	Israel	P.O. Box 3190, 5 Basel St., Petach Tikva	3,000,000	18.83%
Giza Venture Capital	Israel	40 Einstein St., Ramat Aviv Tower, P.O. Box 17672, Tel Aviv	3,000,000	18.83%
Pitango Venture Capital	Israel	11 HaMenofim St., Herzliyya Pituach	3,000,000	18.83%
Hadasit Ltd.	Israel	P.O. Box 121000, Hadassah Ein Kerem, Jerusalem	2,000,000	12.55%
STAR Ventures	Israel/Germany	11 Galgalei HaPlada, 3rd floor, Herzliyya Pituach	1,500,000	9.41%
Yehuda Zisapel	Israel	24 Raoul Wallenberg St., building C, Tel Aviv	750,000	4.71%
Jerusalem Development Authority	Israel	Municipal Compound, 2 Safra Square, P.O. Box 32226, Jerusalem	400,000	2.51%
Options and shares to be distributed to employees			2,285,024	14.34%

# Appendix C: Bank Guarntee

Bank Guarantee 055892

Guarantee No. **741-097800/55-30**–0841-0002/4 Date: Oct. 20, 2004

To: State of Israel via the Office of the Chief Scientist Ministry of Industry and Trade

Dear Sir or Madame

1. With regard to the agreement between the State of Israel and BioLine Rx, Ltd. (hereinafter "the Guaranteed") (hereinafter "the Agreement") and pursuant to Guideline No. 8.4 (Technological Innovation Centers—Biotechnology Incubators) issued by the director general of the Ministry of Industry and Trade, and at the request of the Guaranteed, we hereby guarantee to you payment of any sum, up to the "Amount of the Guarantee" (as defined below), relevant at the date of your demand, on condition that the total amount of all payments made to you under the present guarantee not exceed the Amount of the Guarantee as at the relevant date.

The "Amount of the Guarantee" means the sum of NIS 8,100,0900.00 (eight million one hundred thousand sheqels) only; but at any time that we receive notification from you that the Incubator has made an approved outlay of at least NIS 500,000 ("Approved Outlay"), as at the date of the submission of said notification to us, the Amount of the Guarantee will be reduced by half the amount of the Approved Outlay. Notwithstanding, the Amount of the Guarantee will not be reduced, at any time or in any circumstances, to less than NIS 1,500,000 (one million and a half). The Amount of the Guarantee will be linked to the Consumer Price Index as published form time to time by the Central Bureau of Statistics and Economic Research, with the following linkage terms:

"The Base Index" for the purposes of the present guarantee will be the index for September 2004 published on or around the fifteenth of the following month, which is 100.6 points (based on 2002).

"The New Index" for the purpose of the present guarantee will be the most recently published index before receipt of your demand for payment under this guarantee.

Linkage differentials for the present guarantee will be calculated as follows: If the new index is higher than the base index, the linkage differential will be a sum equal to the ratio of the new index to the base index times the Amount of the Guarantee, divided by the base index. If the new index is lower than the base index, we will pay you the sum stated in your demand, up to the Amount of the Guarantee, with no linkage differentials.

2. The Amount of the Guarantee will be paid to you within 10 days of our receipt of your first demand in writing, and you shall be under no obligation to prove your demands, nor shall we assert against you any defense that might be available to the party requesting this guarantee with regard to the debt to you and without your being required to first demand request the Amount of the Guarantee from the Guaranteed.

- 3. This guarantee will remain in force until Dec. 31, 2004. After that time it will be null and void.
- 4. 5. Any demand pursuant to the guarantee must be submitted to us at the following address: Kanfei Nesharim 22, Jerusalem.
- This guarantee cannot be transferred or assigned.

Sincerely yours, Bank Leumi le'Yisrael Givat Shaul Branch

<rubber stamp + /s/ Levana Arojas> Levana Arojas 3123 <rubber stamp + /s/ H. Barak > H. Barak 2732

Bank Guarantee 089947

Date: Dec. 16, 2004

Guarantee No. 741-097800/55-30-0841-0002/4

To: State of Israel via the Office of the Chief Scientist Ministry of Industry and Trade

Our guarantee to your credit, No. 741-097800/55-30-0841-0002/4

Date: Oct. 20, 2004 In the amount of 8,100,000.00 (eight million one hundred thousand new sheqels only) For: BioLine Rx Ltd. Valid through Dec. 31, 2004

We hereby extend the validity of the above guarantee until March 31, 2011.

Consequently, any demand pursuant to said guarantee must reach the undersigned branch, whose address is Jerusalem, Kanfei Nesharim 22, Givat Shaul, by said date, during the hours when the branch is open to the public for business.

A demand that arrives after said time will not be honored.

It is emphasized that a "written demand" as stated above does not include a demand sent to the bank by facsimile, telegram, or any other electronic medium and that such will not be considered to be a demand for the purposes of the present guarantee.

There are no changes to any other terms of the guarantee.

Sincerely yours, Bank Leumi le'Yisrael Givat Shaul Branch

<rubber stamp + /s/ Oshrit Bar-Gil> Oshrit Bar-Gil 5835 <rubber stamp + /s/ H. Barak> H. Barak 2732

# Appendix D: List of criteria for choosing projects

- 1. The project is for the development or improvement of a product or process which is intended for the global biotechnology market.
- 2. The product or process is technologically innovative.
- 3. A technical-economic and marketing examination has been performed and it shows that success is reasonably probable.
- 4. The duration of the project up until it is ready for the entry of an industrial partner or for raising capital for continued development and commercialization shall be up to three years.
- 5. All the of the project's budget finance sources have been settled and there are no other governmental source of development financing for the project and/or incubator other than the state loan.
- 6. The project has passed an initial feasibility test as part of the academic research or in any other framework. Initial feasibility testing will not be done as part of this program.
- 7. According to an examination, the project has the potential to achieve high returns. The maturity period for the project is long (approx. 10 years from the beginning of development until it reaches the market). The project is capable of raising external capital within 3 years. The technological risk of the project is high and the lion's share of the research and development shall be done as part of and in the framework of the incubator.

# Appendix E: Bond for a type 2 biotechnological incubator

Issued on the \_\_\_\_\_ day of the month of \_\_\_\_\_ in the year \_\_\_\_\_ by \_\_\_\_\_ (hereinafter "the Incubator")

with the State of Israel (hereinafter "the State") as the beneficiary

- Whereas to ensure the repayment of all sums that the Incubator owes and/or from time to time may owe the State for the State's loans to the Incubator to enable the execution of Incubator projects, and to ensure that the Incubator fulfills in full and on time its obligations to the State according to the agreement whereby it shall operate an industrial research and development entrepreneurial center under incubator conditions, an agreement between the Incubator and the State that was drawn up and signed on (date) \_\_\_\_\_\_ (hereinafter "**the Agreement**"), the Incubator hereby encumbers and mortgages all its assets through this bond, in a senior floating lien with the State as a beneficiary, and hereby assigns all its assets to the State through a floating lien.
- Whereas according to provision no. 8.4 of the director general of the Ministry of Industry and Trade issued on May 2, 2004 (hereinafter "**the Director General's Provision**") and according to the agreement the Incubator is and/or will be eligible to receive a loan (hereinafter "**the Loan**") from the State for a Project company and/or a project, as defined in the agreement, for purposes of executing the Project, as specified by law and as specified in the Director General's provisions;
- And whereas the State has approved the Incubator's request for funding, in keeping with the certificate of approval, as defined below, and in keeping with the agreement;
- And whereas as a condition of receiving the loan, the Incubator committed itself to encumbering the encumbered assets of the Project, as defined in clause 5.14 of the Director General's Provision, with the State as the beneficiary;

It is accordingly stipulated in the bond as follows:

- 1. The preamble to this bond (hereinafter "**the Bond**" or "**the Certificate of Encumbrance**") and the accompanying appendices are inseparable parts of the Bond.
- 2. In this Certificate of Encumbrance the following terms shall have the following meanings:
  - 2.1 <u>Approved plan:</u> The plan with all its conditions as it was approved by the Committee on Biotechnological Incubators (hereinafter: "**the Committee**") and for whose execution the Incubator has received and/or is eligible to receive a loan pursuant to the agreement.
  - 2.2 <u>Certificate of Approval</u>: A certificate to be signed by the Chief Scientist, for the purpose of funding an Incubator Project as defined in the agreement.
  - 2.3 **<u>Project:</u>** as defined in the agreement.
- 3. In every instance in which there is a contradiction between the provisions of this Bond and the provisions of the Agreement, the provisions of the Bond will override those of the Agreement. Notwithstanding, it is stipulated that the realization of the Bond and lifting of the lien on the assets will be subject to the provisions of the Agreement.

- 4. The section headings in this Bond are meant exclusively for ease of reading and are not to be used in its interpretation.
- 5. This Certificate of Encumbrance guarantees and shall guarantee the full and exact repayment of all sums of the loan and other sums that the Incubator is to repay to the State and, without derogating from the generality thereof, principal, interest, linkage differentials, guarantees, fees, expenses, realization expenses, legal expenses, and so forth.
- 6. As collateral for the full and exact repayment of all the guaranteed sums and by virtue of clauses 165–166 of the Companies Ordinance of 1983 (new version), and/or by virtue of any other legal provision the Incubator hereby encumbers the Incubator's assets with a senior floating lien. The lien applies to the Incubator's assets in both their current and any future states, including a restriction on the transfer and/or licensing of the rights to the technologies that were produced by the projects during their period in the Incubator; the lien also applies to any equipment that is purchased for use by the Project (hereinafter **"the Encumbered Property"**).
- 7. The Incubator hereby declares and confirms that there are no other attachments or liens or encumbrances or mortgages on the Encumbered Property or any part of it, or any undertaking to create any such lien or encumbrance or mortgage.
- 8. The Incubator hereby undertakes to ensure that the lien it has created through this Certificate of Encumbrance shall be recorded in the Register of Liens of the Registrar of Companies and/or the Registrar of Liens and/or in any other relevant register (hereinafter: **"the Registrar"**) within the legal time frame. The Incubator also agrees to sign at the State's request any document, letter, request, or similar document addressed to any agency for purposes of registering the lien in any register.
- 9. The Incubator agrees that the lien that is registered by the Registrar in the Register of Liens as stated above shall not be removed from the said Register of Liens until such time as the State provides it with a written declaration to the effect that it agrees to remove the lien.
- 10. The State shall be entitled to realize the lien, with itself as the beneficiary, without any need for the Incubator's consent. The State shall inform the Incubator of its intent to realize the lien thirty (30) days before doing so.
- 11. The Incubator undertakes to do the following:
  - 11.1 To insure the physical Encumbered Property beginning from the date this bond is signed and at all times at its full value as is the practice with physical property, against all risks for which similar physical assets are insured, with an insurance company registered in Israel that is legally authorized to sell insurance. The Incubator also undertakes to inform the said insurance company of any notice or instruction regarding the assignment of the rights accruing to the State from the insurance policies of which the State is the beneficiary, according to a formulation that is approved by the State. This formulation shall include among other provisions an irrevocable order to the said insurance company to pay all sums that the Incubator is or shall be entitled to collect on account of all or any part of the encumbered property exclusively to the State and/or to the State's designated recipient. In addition, the Incubator undertakes to submit to the State confirmation from the said insurance company that it has received the above-mentioned order and that it agrees to abide by it, and that it also undertakes to give the State notice by registered mail about any change or cancellation or expiration of any insurance policy at least thirty (30) days in advance. The Incubator undertakes not to introduce changes into any of its insurance policies without the State's approval. The Incubator also undertakes to extend the validity of its insurance policies from time to time as necessary throughout the period of the lien, even without any request or demand from the State.

- 11.2 To fulfill all the conditions of the insurance policies mentioned in clause 11.1 above and to comply with all their restrictions, and to submit copies of all the aforesaid policies to the State. In the event that the State asks the Incubator to introduce any revisions into the insurance policies the Incubator undertakes to make these revisions.
- 11.3 To preserve the physical Encumbered Property and to maintain it in good working condition, to use it carefully, and to inform the State immediately of any instance of substantive damage to and/or substantive malfunction of and/or substantive defect in the property, and to immediately repair any damage to and/or malfunction of and/or defect that occurs in the Encumbered Property for any reason, and to enable the State's or the Committee's representatives to check the condition of the Encumbered Property at any time.
- 11.4 Not to remove the physical Encumbered Property or any part of it from the premises of the Incubator building without the State's written agreement in advance, with the exception of the temporary removal of the Encumbered Property for the exclusive purpose of repairing it.
- 11.5 Not to sell, rent, give, transfer, and/or assign all or any part of the Encumbered Property to any third party whatsoever without receiving prior written consent from the State or pursuant to the provisions of the Agreement.
- 11.6 To immediately inform the State of the imposition of any attachment, the implementation of any action, the execution of any judgment, or the submission of a request for the appointment of a receiver for all or part of the Encumbered Property, and also to immediately notify any agency and/or third party that has imposed any such attachment or taken any such action. In addition, the Incubator undertakes to immediately perform at its own expense any action that may be required to rescind the attachment and/or revoke and/or cancel the action, as relevant.
- 11.7 The Incubator undertakes not to mortgage and/or encumber all or any part of the Encumbered Property to any third party with any other or additional lien and/or mortgage, whether prior, equal, subsequent, or junior, or any other encumbrance without receiving prior written permission from the State.
- 12. After the full balance of the State loan for a certain project has been repaid (as specified in clause 13 of the agreement), those assets of the Project that were encumbered with regard to the said project shall be removed from the scope of the lien, pursuant to clause 12.3 of the Agreement. The State undertakes to deduct the sum that corresponds to the lien from the relative portion of the State loan, in keeping with the procedures of the technological incubators program of the Chief Scientist's Office. In addition, the State shall deduct the sum that corresponds to the encumbered assets, in proportion to the sums that were not transferred to the Project and were returned to the State, or that were not transferred to projects that were shut down and/or that failed, in keeping with the procedures of the technological incubators program of the Chief Scientist's Office.
- 13. The Incubator hereby grants the State irrevocable power of attorney to carry out in its name, on its behalf, and at its expense any of the following activities: to file any suit against the insurance companies with regard to the insurance of all or part of the physical Encumbered Property, and to reach agreement with the insurance companies regarding the suits against them as the State sees fit, after notifying the Incubator, including agreements that constitute a compromise on or waiver of the Incubator's rights, all or in part, and to sign an arbitration agreement and collect the insurance monies. The State shall have the right to undertake any of the aforementioned actions whether the insurance policy was/will be taken out by the Incubator or in its name or whether it was/will be taken out by the State.

- 14. This lien shall in no way detract from any of the State's rights to collect the guaranteed sums, in whole or in part, in ways other than by realizing its rights according to this Bond, and the realization of the State's rights according to this Bond shall in no way detract from the State's right to collect from the Incubator the balance of the guaranteed sums that were not repaid by realization of the lien that is the subject of this bond.
- 15. The State shall be entitled to appoint a receiver and/or a liquidator and/or a special director and/or a trustee (**"the Receiver"**) for purposes of realizing the lien at its absolute and exclusive discretion, after it has given the Incubator prior warning of 30 days. In addition, if so requested the Incubator shall approve the fact of the appointment and/or the identity of the State's choice of appointees.
- 16. No waiver, discount, failure to take timely action, or extension granted by the State or on its behalf shall be considered a waiver of any sort of the State's rights under this Certificate of Encumbrance, and shall in no way impede the State or its representatives from filing suit or undertaking any other procedure. Any concession by the State regarding any previous breach by the Incubator or previous failure to fulfill one or more of its obligations under this Bond and/or under the Agreement shall not be considered to justify some other breach and shall not constitute a precedent and/or leave for the Incubator to commit another breach.
- 17. The books and accounts of the State and/or the Committee or the books and accounts of an organization or organizations that the State designates to pay out the loan (all or in part) to the Incubator shall be considered trustworthy by the Incubator and shall serve at any time as prima facie evidence against it with regard to sums the Incubator must repay and/or pay the State.
- 18. In order to remove all doubt, the Incubator hereby declares and confirms that none of the provisions of this Certificate of Encumbrance in any way detracts from any of the Incubator's obligations under the law or under any regulation that has been issued or rule that has been instituted in accordance with the law or according to any agreement that was made and/or shall be made between the State and the Incubator and/or according to any document that was and/or shall be signed by the Incubator with the State as the beneficiary.
- 19. The Incubator's address for the purposes of this Certificate of Encumbrance is the address of its office listed above.
- 20. All of the expenses involved in drawing up, signing, implementing, and realizing this Certificate of Encumbrance and everything connected with it shall be paid by the Incubator to the State at its first request, with interest.
- 21. The legal jurisdiction for this bond is hereby declared to be the competent court in the Jerusalem district; but the State shall be entitled to take legal action against the Incubator on all matters that pertain to this Certificate of Encumbrance in any other competent court as well.
- 22. No revision and/or update of any of the provisions of this bond shall be valid unless it is executed in writing and signed by both sides.

# In witness whereof we hereby affix our signatures:

The Incubator:						
By the authorized signatories:						
Name	Identity card no.	Position				
1						
2.						

# Appendix F: Format for confirmation/release of the Project [by the State of Israel]

Date:\_

To: BioLine Innovations Jerusalem Limited Partnership

Dear Sir or Madam:

# Re: Confirmation of repayment of the State loan for the "\_\_\_\_\_ project

In keeping with clause 12.3 of the agreement signed between us on \_\_\_\_\_\_ (hereinafter: **"the Incubator Agreement"**), we hereby confirm as follows:

- 1. The full amount of the State loan that was extended to you in connection with the project at issue (hereinafter: **"the Project"**) has been repaid in keeping with the conditions of the Incubator agreement.
- 2. Any lien that was placed with us as a beneficiary with regard to the Incubator agreement shall no longer apply to the Project and all the assets and rights connected with it.
- 3. As of the date of this letter, there shall no longer be any limitation—according to the Incubator Agreement and/or any lien that was placed with us as a beneficiary—on the Project and its assets and their transfer, sale, licensing and so forth, all subject to the restrictions that apply according to the Research and Development Law and subject to clause 7.1 of the director general's provisions.

Respectfully yours,

Director of the Incubators Project Office of the Chief Scientist The State of Israel

#### **Bridge Loan Agreement**

This Bridge Loan Agreement (this "Agreement") is entered into as of January 10, 2007 (the "Effective Date"), by and between BioLineRx Ltd., an Israeli company (the "Company"), and Pan Atlantic Investments Limited, a Barbados company (the "Lender").

- Whereas The Company is a company engaged in the development of innovative therapeutics; and
- Whereas The Company seeks to raise funds for its activities and is currently exploring a number of funding alternatives; and
- Whereas The Lender wishes to participate in the upcoming funding by way of loaning to the Company, and the Company wishes and agrees to receive from the Lender, a loan under the terms and conditions set forth herein below;

**NOW, THEREFORE**, in consideration of their mutual and respective undertakings and covenants herein contained, the parties hereto hereby agree as follows:

1. <u>Preamble, Exhibits and Headings</u>

The preamble to this Agreement and all Exhibits attached hereto form an integral part hereof. The headings appearing throughout this Agreement are used for convenience of reference, and are not to be used or referred to for the purpose of construing this Agreement or any provision thereof.

2. Loan of Funds

The Lender agrees and undertakes to loan to the Company the amount of US\$9,000,000 (nine million U.S. Dollars) (the "Loan Amount"), and the Company agrees to receive such loan from the Lender, in accordance with the terms and conditions set forth in this Agreement. Payment of the entire Loan Amount shall be made, in United States Dollars, by the Lender within 5 (five) business days from the date on which all the conditions listed in Section 9 below have been met, by way of a bank transfer, to the following bank account of the Company:

BioLineRx Ltd. Account No. 97800/55 Bank Leumi Branch #741 Givat Shaul, Jerusalem

The Loan Amount shall be automatically converted into an equity investment in the Company upon the occurrence of the first to occur of the events specified in Sections 3 and 4, and conversion of the Loan Amount pursuant to either of such Sections shall constitute full repayment of the Loan Amount.

- 3. Automatic Conversion upon a Private Placement
  - 3.1. In the event that the Company shall enter into an agreement for the investment in the Company of an amount of at least US\$8,000,000 (eight million U.S. Dollars) from current shareholders of the Company (or any affiliates thereof) (the "**Private Placement**"), then the Loan Amount shall be automatically converted into an equity investment, as part of, and on the same terms and conditions as, the Private Placement, <u>provided</u> however that the price per share paid by the Lender upon conversion of the Loan Amount shall be equal to the lower of (i) US\$1.34, or (ii) the agreed price per share of the Private Placement, and further <u>provided</u> that the shares to be issued to the Lender against conversion of the Loan Amount shall be subject to rights and preferences substantially similar to, but no worse than the rights and preferences attached to the Preferred A-1 Shares.

- 3.2. As part of the Private Placement, the Lender shall be party to all shareholders agreements, investors rights agreements, etc. which may apply to the shares issued as part of the Private Placement. It is further agreed that the definitive agreements of the Private Placement shall grant all investors in the Company customary registration rights, as shall be negotiated at that time.
- 3.3. Upon conversion of the Loan Amount into an equity investment, the Lender shall be entitled to appoint one (1) member to the Company's Board of Directors (the "**Board**"), so as long as the Lender and its Affiliates (any person or entity directly or indirectly, through one or more intermediary persons or entities, controls, is controlled by, or is under common control with the Lender) hold shares of the Company constituting at least 4% (four percent) of the Company's issued and outstanding share capital. This provision shall no longer be applicable when the Lender becomes a party to the Voting Agreement (as defined below).

#### 4. <u>Automatic Conversion upon a TASE IPO</u>

4.1. In the event that the Company shall offer to the public shares of the Company at the Tel Aviv Stock Exchange (a "TASE IPO"), then immediately prior to the closing of a TASE IPO that includes (i) an investment by current shareholders of the Company (or any affiliates of such shareholders) of at least US\$8,000,000 (eight million U.S. Dollars) (the "Qualifying Amount"); and (ii) aggregate net proceeds to the Company of at least US\$17,000,000 (seventeen million U.S. Dollars), and subject to approval of the Office of the Chief Scientist ("OCS"), to the extent required, the Loan Amount shall be automatically converted into an equity investment of a new class of Series B Redeemable Preferred Shares, par value NIS 0.01 each, of the Company (the "Preferred B Shares"), at a price per share paid by the Lender upon conversion of the Loan Amount of US\$1.34, but not more than the effective price per share of an Ordinary Share of the Company based on the pre-money company valuation of the company prior to the TASE IPO, and which Preferred B Shares shall automatically be converted into Ordinary Shares, at the same conversion ratio applicable at such time to the Preferred A-1 Shares.

In the event that current shareholders of the Company (or any affiliates of such shareholders) commit to submit offers to purchase at least the Qualifying Amount of securities offered for sale in the TASE IPO, but the underwriters require that such shareholders purchase less than the Qualifying Amount or the rules applying to the public offering result in such outcome, the Loan Amount shall be automatically converted as set forth in the above paragraph even though the actual amount invested by the current shareholders of the Company may be less than the Qualifying Amount.

4.2. As part of the TASE IPO, certain shareholders of the Company, including at least the Pitango Group entities, the Giza Group entities, and Hadasit (as such terms are defined in the Articles of Association of the Company (the "**Articles**") may enter into a voting agreement in substantially the form attached hereto as <u>Schedule A</u> (the "**Voting Agreement**"), in which case the Lender agrees to join as a party to such Voting Agreement.

— 3 —

- 4.3.
- In the event that OCS approval is required but not obtained, then the Lender may demand repayment of the entire Loan Amount together with interest at the rate of 6.0% (six percent) per annum from the proceeds of the TASE IPO.

## 5. <u>Repayment; Voluntary Conversion</u>

In the event that no Private Placement or TASE IPO shall occur prior to the end of 4 (four) months from the date of payment to the Company of the Loan Amount, then, upon the written demand of the Lender, the Company shall repay to the Lender the entire Loan Amount, together with interest at the rate of 6.0% (six percent) per annum. In the event that no such demand is made within 120 (one hundred and twenty) days (which period of time may be extended upon mutual written consent), or if the Lender earlier requests a conversion, then the Loan Amount shall be converted in accordance with the relevant provisions of Section 3.1 at a price per share of US\$1.34.

# 6. <u>Upgrade Right</u>

At any time as of the date of issuance of shares to the Lender pursuant to Section 3 or Section 5 (as applicable) and until such date on which the Company shall have raised an aggregate amount of US\$26,000,000 (twenty six million U.S. Dollars), taking into account the converted Loan Amount as well any and all funds which may raised pursuant to Section 3 and/or Section 4 (but including the financing round itself which results in the Company having raised at least US\$26,000,000), in the event that the Company shall issue any shares to any person or entity, in consideration for an equity investment in the Company ("**New Securities**"), the Lender shall have the right to have its holdings in the Company converted into the New Securities at the time of closing of the issuance of such New Securities, at the price per share equal to the lowest price per share paid for such New Securities by the other investors thus subjecting and entitling the Lender, as a shareholder of the Company, to all rights, preferences, obligations and restrictions generally applying to all the holders of the New Securities.

## 7. <u>Representations and Warranties of the Company</u>

Subject to the provisions of Exhibit 7 (the "Disclosure Schedule"), the Company hereby represents and warrants to the Lender, and acknowledges that the Lender is entering into this Agreement in reliance thereon, as follows:

- 7.1. <u>Organization</u>. The Company is duly organized and validly existing under the laws of Israel, and has full corporate power and authority to own, lease and operate its properties and assets and to conduct its business as now being conducted and as currently proposed to be conducted. The Company has all requisite power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby.
- 7.2. Share capital. The authorized share capital of the Company as of the Effective Date is NIS400,000 (four hundred thousand New Israeli Shekels), divided into 16,350,000 (sixteen million three hundred fifty thousand) Ordinary Shares, par value NIS 0.01 each, of the Company ("**Ordinary Shares**"), 13,650,000 (thirteen million six hundred fifty thousand) Series A Redeemable Preferred Shares, par value NIS 0.01 each, of the Company (the "**Preferred A Shares**"), and 10,000,000 (ten million) Series A-1 Redeemable Preferred Shares, par value NIS 0.01 each, of the Company (the "**Preferred A-1 Shares**"). A complete and correct list of the shareholders of the Company and their shareholdings as of the Effective Date is set forth in Section 7.2 of the Disclosure Schedule.

The Company is not under any current obligation to register for trading on any securities exchange any of its currently outstanding securities or any of its securities which may hereafter be issued.

- 7.3. <u>Ownership of Shares</u>. A complete and correct list of the shareholders of the Company on the Effective Date is set forth in Section 7.2 of the Disclosure Schedule. To the Company's knowledge, the individuals identified in Section 7.2 of the Disclosure Schedule as the shareholders of the Company are the lawful owners, beneficially and of record, of all of the issued and outstanding shares of share capital of the Company and of all rights thereto, free and clear of all liens, claims, charges, encumbrances, restrictions, rights, options to purchase, proxies, voting trust and other voting agreements, calls or commitments of every kind (except as specified in the Articles and the Shareholders Agreement dated September 26, 2005), and, to the Company's knowledge, none of the said individuals owns any other share, options or other rights to subscribe for, purchase or acquire any share capital of the Company from the Company or from each other.
- 7.4. <u>Financial Statements</u>. The Company has furnished the Lender with its audited financial statements for the annual period ended on December 31, 2005, as well as un-audited balance sheets of the Company for the period ended on September 30, 2006 (hereinafter collectively referred to as the "**Financial Statements**"). The Financial Statements are true and correct, in accordance with the books and records of the Company, and have been prepared in accordance with Israeli generally accepted accounting principles ("**GAAP**") consistently applied, and fairly and accurately present the financial condition of the Company as of such dates and the results of its operations for the periods then ended. The Company does not have any material liabilities, debts or obligations, whether accrued, absolute or contingent, pertaining to the time periods referred to in the Financial Statements, other than liabilities reflected or reserved against in the Financial Statements.

Since September 30, 2006, there has not been:

- (a) any material change in the assets, liabilities, condition (financial or otherwise) or business of the Company;
- (b) any damage, destruction or loss, whether or not covered by insurance, materially and adversely affecting the material assets, properties, conditions (financial or otherwise), operating results or business of the Company;
- (c) any waiver by the Company of a valuable right or of a material debt owed to it;
- (d) any satisfaction or discharge of any material lien, material claim or material encumbrance or payment of any material obligation by the Company, except in the ordinary course of business and that is not individually or in the aggregate adverse to the assets, properties, condition (financial or otherwise), operating results or business of the Company;
- (e) any material change or amendment to a material contract or material arrangement by which the Company or any of its assets or properties is bound or subject;

- (f) any loans made by the Company to its employees, officers, or directors, other than travel advances made in the ordinary course of business;
- (g) any sale, transfer or lease of, except in the ordinary course of business, or mortgage or pledge of imposition of lien on, any of the Company's material assets;
- (h) any change in the accounting methods or accounting principles or practices employed by the Company, except as required by applicable laws, rules, regulations and standards; or
- (i) to the Company's knowledge, any other event or condition of any character that would materially adversely affect the assets, properties, condition (financial or otherwise), operating results or business of the Company.
- 7.5. <u>Authorization; Approvals</u>. All corporate action on the part of the Company necessary for the authorization, execution, delivery, and performance of all of the Company's obligations under this Agreement has been taken. This Agreement, when executed and delivered by or on behalf of the Company, shall constitute the valid and legally binding obligation of the Company, legally enforceable against the Company in accordance with its terms. No consent, approval, order, license, permit, action by, or authorization of or designation, declaration, or filing with any governmental authority on the part of the Company is required that has not been obtained by the Company in connection with the valid execution, delivery and performance of this Agreement.
- 7.6. <u>Compliance with Other Instruments</u>. To the best of its knowledge, the Company is not in default (a) under the Articles, or under any material note, indenture, mortgage, lease, agreement, contract, purchase order or other instrument, document or agreement to which the Company is a party or (b) with respect to any Israeli law, statute, ordinance, regulation, order, writ, injunction, decree, or judgment of any court or any governmental authority, which default, in any such case, would adversely affect the Company's business, prospects, condition (financial or otherwise), affairs, operations or assets. To the best knowledge of the Company is a party.
- 7.7. <u>No Breach</u>. Neither the execution and delivery of this Agreement nor compliance by the Company with the terms and provisions hereof, will conflict with, or result in a breach or violation of, any of the terms, conditions and provisions of: (i) the Articles, (ii) to the Company's knowledge, any judgment, order, injunction, decree, or ruling of any court or governmental authority, (iii) any material agreement, contract, lease, license or commitment to which the Company is a party, or (iv) to the best of its knowledge, applicable law. Such execution, delivery and compliance will not (a) give to others any rights, including rights of termination, cancellation or acceleration, in or with respect to any agreement, contract or commitment referred to in this paragraph, or to any of the properties of the Company or (b) unless otherwise specified herein, otherwise require the consent or approval of any person, which consent or approval has not heretofore been obtained.

#### 7.8. Intellectual Property and Other Intangible Assets.

- 7.8.1. Unless otherwise stated in any of the agreements referred to in Section 7.8.1 of the Disclosure Schedule, the Company owns and has developed, or has obtained the right to use, free and clear of all liens, claims and restrictions, all patents, trademarks, service marks, trade names and copyrights, and applications, licenses and rights with respect to the foregoing, and all related trade secrets, including know-how, inventions, designs, processes, works of authorship, computer programs and technical data and information (collectively herein "**Intellectual Property**"), without, to the knowledge of the Company, infringing upon or violating any right, lien, or claim of others. Unless otherwise stated in the applicable agreements referred to in Section 7.8.1 of the Disclosure Schedule, the Company is not obligated or under any liability whatsoever to make any payments by way of royalties, fees or otherwise to any owner or licensee of, or other claimant to, any patent, trademark, service mark, trade name, copyright or other intangible asset, with respect to the use thereof or in connection with the conduct of its business as now conducted or as currently proposed to be conducted or otherwise.
- 7.8.2. Any and all Intellectual Property of any kind which has been developed, is currently being developed, or will be developed in the future, by any employee of the Company in the course of their employment by the Company shall be the property solely of the Company. The Company has taken security measures to protect the secrecy, confidentiality and value of all the Intellectual Property, which measures are reasonable and customary in the industry in which the Company operates. Each of the Company's employees have entered into written agreements with the Company, assigning to the Company all rights in intellectual property developed in the course of their employment by the Company and each of the Company's employees who, either alone or in concert with others, developed, invented, discovered, derived, programmed or designed the Intellectual Property have entered into a written agreement with the Company, the forms of which have been made available to the Lender.
- 7.8.3. The Company has not received any communications alleging that the Company has violated or by conducting its business as proposed, would violate, any of the patents, trademarks, service marks, trade names, copyrights or trade secrets or other proprietary rights of any other person or entity. To the Company's knowledge, none of the Company's employees is obligated under any contract (including licenses, covenants or commitments of any nature) or other agreement, or subject to any judgment, decree or order of any court or administrative agency, that would interfere with the use of such employee's best efforts to promote the interests of the Company. To the Company's business by the employees of the Company, nor the conduct of the Company's business as currently proposed to be conducted, will conflict with or result in a breach of the terms, conditions or provisions of, or constitute a default under, any contract, covenant or instrument under which any of such employees is now obligated.
- 7.9. <u>Litigation</u>. Except as set forth in Section 7.9 of the Disclosure Schedule, no action, proceeding or governmental inquiry or investigation is pending or, to the knowledge of the Company, threatened against the Company or any of its officers, directors, or employees (in their capacity as such), or against any of the Company's properties, before any court, arbitration board or tribunal or administrative or other governmental agency, nor, to the knowledge of the Company, is there is any basis for the foregoing. To its knowledge, the Company is not a party to or subject to the provisions of any order, writ, injunction, judgment or decree of any court or governmental agency or instrumentality. There is no action, suit, proceeding or investigation by the Company currently pending or that the Company intends to initiate.

- 7.10. <u>No Public Offer</u>. Neither the Company nor anyone acting on its behalf has offered securities of the Company or any part thereof or any similar securities for issuance or sale to, or solicited any offer to acquire any of the same from, anyone so as to make the execution and performance of this Agreement not in compliance with applicable securities laws.
- 7.11. <u>Full Disclosure</u>. Neither this Agreement (including the Schedules and Exhibits attached hereto) nor any certificate made or delivered in connection herewith contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements herein or therein not misleading, in view of the circumstances in which they were made. To the best knowledge of the Company, there is no material fact or information relating to the business, prospects, condition (financial or otherwise), affairs, operations, or assets of the Company that has not been disclosed to the Lender by the Company.

Each representation and warranty herein is deemed to be made on the effective Date and shall survive and remain in full force and effect after the Effective Date until the earlier of: (i) the conversion of the Loan Amount pursuant to Section 3, *provided*, that the Lender receives representations and warranties in the agreement governing the Private Placement which are no less favorable, in all material respects, than those contained herein; (ii) a period of two (2) years; (iii) a M&A Transaction (as defined in the Articles), or (iv) consummation of an IPO (as defined in the Articles). In the event of any breach or misrepresentation of any covenant, warranty, or representation made by the Company under this Agreement (a "**Misrepresentation**"), the Company shall indemnify the Lender and hold it harmless from and against any and all direct claims, loss, damage, liability, and expense (including reasonable legal fees and costs), actually sustained or incurred by it as a result of or in connection with said Misrepresentation. The liability of the Company to the Lender for claims brought against it by the Lender shall not exceed the Loan Amount. In no case shall the Company be liable to indemnify the Lender for any incidental, indirect, consequential, special or punitive damages. Notwithstanding the foregoing provisions of this Section, no claims shall be asserted under this Section unless the aggregate amount claimed is in excess of \$50,000 (fifty thousand U.S. Dollars), in which case a claim can be submitted for the entire amount at issue, subject to the limits set forth in this Section above. The remedies listed hereinabove are the sole and exclusive remedies, to the exclusion of all other remedies, for any Misrepresentation.

#### 8. <u>Representations and Warranties of the Lender</u>

The Lender hereby represents and warrants to the Company as follows:

8.1. The execution, delivery and performance of this Agreement by it have been duly authorized by all requisite corporate action and will not violate any provision of law, any order of any court or other agency of government, its corporate documents or any provision of any indenture, agreement or other instrument to which it or any of its properties or assets is bound, conflict with, result in a breach of or constitute (with due notice or lapse of time or both) a default under any such indenture, agreement or other instrument or result in the creation or imposition of any charge, attachment or lien upon any of the properties or assets of the Company.

- 8.2. This Agreement has been duly executed and delivered by it and constitutes its legal, valid and binding obligation, enforceable against it in accordance with its terms, subject to (i) applicable bankruptcy, insolvency, reorganization, fraudulent conveyance and moratorium laws and other laws of general application affecting enforcement of creditors' rights generally and (ii) the availability of equitable remedies as such remedies may be limited by equitable principles of general applicability (regardless of whether enforcement is sought in a proceeding in equity or at law).
- 8.3. The Lender is investing in the Company for the Lender's own account (not as a nominee or agent), for its investment only, and not with a view towards the distribution or resale of any securities which may be issued to the Lender ("**Securities**").
- 8.4. The Lender understands that any Securities it may be issued by the Company shall not be registered under Israeli laws (including but not limited to the Israel Securities Law 1968) or other securities laws (including but not limited to the U.S. Securities Act of 1933), that there is no established market for such Securities and that no public market is presently foreseeable.
- 8.5. The Lender has experience in evaluating and investing in private placement transactions of securities in companies similar to the Company and it has such knowledge and experience in financial and business matters so that it is capable of evaluating the merits and risks of its investment in the Company, and has the capacity to protect its own interests and bear the economic risk of its investment in the Company. The Lender has had the opportunity to pose to the Company any and all questions it may have had in connection with its investment in the Company (including, without limitation, questions regarding the due diligence materials asked for and delivered to it, the terms and conditions of the investment in the Company and the business, properties, prospects and financial condition of the Company) and has received, to its satisfaction, answers to all such questions. The Lender has independently evaluated the risks and merits of investing in the Company, has reached a knowledgeable decision to make the investment in the Company and has independently determined that it is a suitable investment for it. The Lender understands that there is no assurance that any exemption from registration under Israeli or foreign securities laws will be available and that, even if available, such exemption may not allow the Lender to transfer all or any portion of any Securities it may be issued, under the circumstances, in the amounts or at the times the Lender might propose.
- 8.6. No agent, broker, investment banker, person, or firm acting in a similar capacity on behalf of or under the authority of the Lender is or will be entitled to any broker's or finder's fee or any other commission or similar fee, directly or indirectly, from the Company and the Company shall be entitled to receive the entire Loan Amount without any deductions or payments of such fees.

## 9. <u>Conditions to Obligations of the Lender</u>

The obligations of the Lender to consummate the transactions contemplated hereby, shall be subject to the satisfaction of each of the following conditions:

- 9.1. The representations and warranties of the Company contained in this Agreement shall have been true and correct in all material respects as of the Effective Date.
- 9.2. The Company shall have delivered to the Lender an opinion of Danziger, Klagsbald & Co., counsel to the Company, in the form attached hereto as <u>Schedule B</u>.
- 9.3. The Company shall have delivered to the Lender minutes of resolutions of the Board in substantially the form attached hereto as <u>Schedule C</u>.

- 9.4. The Company shall have delivered to the Lender a certificate duly executed by an executive officer of the Company in the form attached hereto as <u>Schedule D</u>, dated as of the date hereof.
- 9.5. Any and all preemptive rights or other participation rights with respect to the transactions contemplated hereby shall have been validly waived or satisfied.

#### 10. Observership Right

Until the conversion or repayment of the Loan Amount, the Lender shall be entitled to appoint, replace and terminate, from time to time, at its discretion, one observer to the Board. Such right shall be subject to the applicable provisions in the Articles applying to observers and shall include any rights of such observer (as they may be from time to time).

## 11. Confidentiality

Without derogating from any other agreement or undertaking to which the Lender is or may become subject, and in addition to any such agreement or undertaking, the Lender undertakes that it shall keep in confidence, and not use for any purpose whatsoever except in connection with the exercise of any of its rights under this Agreement, any and all information relating to the Company which has been provided to it by the Company or was otherwise obtained by it ("**Confidential Information**"), except for information: (i) which is or shall be in the public domain not due to any act of the Lender in breach of law or agreement; (ii) which, at the time of disclosure to the Lender was already known to the Lender and was not acquired directly or indirectly from the Company or any of its affiliates, all as may be evidenced by written records of the Lender; (iii) which, at the time of disclosure to the Lender is indirectly or indirectly from the Company or any of its affiliates, all as may be evidenced by written records of the Lender; (iv) was independently developed by the Lender without the use of Confidential Information, as may be evidenced by written records of the Lender; or (v) which the Lender is required to disclose under any applicable law or stock exchange regulations. Notwithstanding the above, the Lender will have the right to disclose its funding of the Company under this Agreement and under the Early Development Program Agreement between the Lender and the Company, dated January 10, 2007.

## 12. <u>Settlement of Conflicts</u>

The laws of the State of Israel, without giving effect to conflict of law rules, shall govern the interpretation and enforcement of this Agreement. The parties hereto agree to submit to the jurisdiction of the courts of Tel-Aviv-Jaffa with respect to the breach or interpretation of this Agreement or the enforcement of any and all rights, duties, liabilities, obligations, powers, and other relations between the parties arising under this Agreement.

#### 13. Miscellaneous

- 13.1. This Agreement embodies the entire agreement between the parties and supersedes all other agreements or understandings between any of the parties in connection with the subject matter hereof. This Agreement cannot be modified, supplemented or rescinded except in writing signed by the Company and the Lender.
- 13.2. The Lender may not assign, transfer, or otherwise dispose of any of its rights, obligations or duties under this Agreement to any other person or entity, except with the prior written consent of the Company, and any assignment in violation of this Section shall be void. Notwithstanding anything to the contrary contained in this Agreement, the Lender may transfer all or any portion of its rights hereunder without restriction to its Affiliates (as defined below) or to any officer or director of the Lender or an Affiliate (*provided*, that with respect to a transfer to an officer or director such transfer not exceed 3% of the Loan Amount) and *provided*, that such transferee agrees to be bound by the terms and conditions of this Agreement. For the purposes of this Agreement, an "Affiliate" of any person or entity means any other person or entity, directly or indirectly, through one or more intermediary persons or entities, controlling, controlled by or under direct or indirect common control with /or having the same beneficial ownership as/ such person or entity. For purposes of this definition, "control" means the power to direct the management and policies of such person or firm, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise

All notices to be given pursuant to this Agreement shall be in writing, and shall be deemed to have been duly given if hand delivered to such party's designated representative, or mailed, postage prepaid, by registered mail, or faxed (with a confirming copy sent by registered mail) and shall be deemed given (i) when so delivered personally; (ii) if mailed, five (5) days after the time of mailing; (iii) if faxed or sent by electronic mail (email), twenty four (24) hours after the time of sending the fax or electronic mail. Addresses for notices (which may be changed from time to time by a written notice pursuant hereto) are:

If to the Lender:

Pan Atlantic Investments Limited Musson Building, 2nd Floor Hincks Street Bridgetown, Barbados West Indies 11000 Attention: Robert J. Bourque, Managing Director Tel: +1-246-436-9756 Fax: +1-246-437-6690

With a copy (which shall not constitute notice) to:

Gross, Kleinhendler, Hodak, Halevy, Greenberg & Co. One Azrieli Center Tel Aviv, 67021 Israel Tel: +972-3-607-4444 Fax: +972 3 607 4411 Attention: Daniel Gamulka, Adv

If to the Company:

BioLineRx Ltd. 19 Hartum Street P.O. Box 45158 Jerusalem 91450, Israel Attention: Vice President Finance and Corporate Development Tel: +972-2-548-9100 Fax:+972-2-548-9101

With a copy (which shall not constitute notice) to:

Danziger, Klagsbald & Co. Attn. Joeri Kreisberg, Adv. 7 Menachem Begin Street Ramat Gan 52521, Israel Tel: +972-3-611-0700 Fax: +972 3-611-0707

13.3.

- 13.4. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and enforceable against the parties actually executing such counterpart, and all of which together shall constitute one and the same instrument.
- 13.5. Each of the parties shall bear its own costs and expenses in negotiating and executing this Agreement, except that subject to and following of the receipt of the Loan Amount, the Company shall reimburse the Lender for its actual put of pocket legal expenses of up to \$10,000 plus applicable value added tax.

IN WITNESS WHEREOF the parties have signed this Bridge Loan Agreement as of the date first herein above set forth.

BIOLINERX LTD.

PAN ATLANTIC INVESTMENTS LIMITED

By:/s/ Morris Laster/s/ Aharon SchwartzName:Morris LasterAharon SchwartzTitle:CEOVP Finance

By:/s/ Robert J. BourqueName:ROBERT J. BOURQUETitle:Managing Director

#### EARLY DEVELOPMENT PROGRAM AGREEMENT

This Early Development Program Agreement (this "**Agreement**") is made as of January 10, 2007, by and between PAN ATLANTIC INVESTMENTS LIMITED, a Barbados company ("**Pan Atlantic**") and BIOLINERX LTD., a company organized under the laws of the State of Israel ("**BioLine**").

#### **RECITALS:**

WHEREAS, BioLine is a drug development company that focuses its research on drug candidates that have demonstrated in vivo results; and

WHEREAS, Pan Atlantic would like to provide financial resources to BioLine in order to encourage research in earlier stage drug development; and

WHEREAS, Pan Atlantic has agreed, pursuant to the terms of this Agreement, to invest the Program Funds (as defined in Section 1 hereto), in BioLine for the purpose of financing a program to be known as the "Early Development Program"; and

WHEREAS, BioLine has agreed to receive the Program Funds, and to allocate Matching Funds (as described in Section 1 hereto);

NOW, THEREFORE, the parties hereby agree as follows:

- 1. <u>Budget</u>.
  - 1.1. <u>Program Funds</u>. Subject to the terms and conditions of this Agreement, Pan Atlantic hereby agrees to invest (or to cause others to invest) in BioLine an aggregate amount of US\$5 million (the "**Program Funds**") in order to finance the Research Projects (as defined in Section 2), to be disbursed in accordance with Section 3 below.
  - 1.2. <u>Right to Invest</u>. In consideration for the commitment of the Program Funds, Pan Atlantic will have the right to invest up to \$5 million in the first public offering of BioLine's shares outside of Israel, at the public offering price. If and to the extent such Program Funds are actually invested by another entity to which Pan Atlantic has assigned its obligations hereunder, such entity will have the right described in this Section 1.2 with respect to the amount invested by such entity, and Pan Atlantic's rights under this Section 1.2 will be reduced accordingly.
  - 1.3. <u>Matching Funds</u>. For every dollar invested by Pan Atlantic hereunder, BioLine will allocate an additional \$0.20 for the Research Projects from resources other than the Program Funds, up to an aggregate amount of US\$1 million (the "**Matching Funds**", and, together with the Program Funds, the "**Budget**").
  - 1.4. <u>Director</u>. No later than June 1, 2007, BioLine shall retain a full-time staff person to administer the Early Development Program. The direct expenses related to the employment of such employee shall be derived from the Budget.

# 2. <u>Research Projects</u>.

2.1. Eligibility. BioLine will use the Program Funds for funding research of drug candidates that have not yet demonstrated in vivo results (each, a "**Research Project**"). At least 70% (seventy percent) of the Research Projects will originate in Israel, with at most 30% (thirty percent) originating outside of Israel. BioLine's Scientific Advisory Board (the "**SAB**") will evaluate each candidate to be a Research Project. A Research Project will be accepted to the Early Development Program if at least one member of the SAB is in favor of such acceptance and one other member abstains.

- 2.2. <u>Budget</u>. BioLine will allocate up to \$100,000 to each Research Project per year, as determined by BioLine. Amounts in excess of \$100,000 per year for any Research Project would require the consent Pan Atlantic.
- 2.3. <u>Duration</u>. Each Research Project will be for a period time no longer than necessary to demonstrate in vivo results, and in any event for no more than two years without Pan Atlantic's consent. At the completion of any Research Project, at BioLine's discretion, the Research Project may be reviewed in depth by the SAB to determine if it should be introduced into the BioLine pipeline for accelerated development into the clinic and beyond.
- 2.4. <u>Rights in Research Projects</u>. BioLine or any of its subsidiaries or affiliates, to the full exclusion of Pan Atlantic, shall retain all rights in the Research Projects, as well as any and all moral rights, to the extent applicable. Pan Atlantic will benefit from the success of the Research Projects through the exercise of its right under Section 1.2

## 3. <u>Disbursement; Deadline</u>.

Program Funds will be transferred to BioLine twice a year, on March 1<sup>st</sup> and on September 1<sup>st</sup> of each year following receipt of a written request from BioLine. Each such request must be for an amount no greater than \$625,000 (unless agreed by Pan Atlantic) and shall include, to the extent applicable and available a description of currently active and contemplated Research Projects and the budgets therefor (the aforesaid shall not be deemed to imply that such funds are restricted only to such specific Research Projects). Pan Atlantic shall not be obligated to make any such transfers for any request received after April 1<sup>st</sup>, 2011.

# 4. Launch; Publicity.

BioLine will make good faith efforts to launch the Early Development Program no later than March 1, 2007. Such launch will include advertisements and other publicity to make the scientific community in Israel aware of the Program. All print and electronic publications about the Program will include a reference to the fact that the Program is underwritten by Pan Atlantic Bank and Trust Limited, a subsidiary of a Canadian company controlled by the Friedberg Family. Notwithstanding anything herein to the contrary, it is agreed that the costs of the launch and on-going publicity, etc. shall be covered by the Program Funds, and funds required for the launch may be requested in addition to the maximum amount set forth in Section 3, provided however that the aggregate amount of all Program Funds shall not exceed the amount set forth in Section 1.1.

# 5. <u>Expense Allocation; Audit Right</u>.

- 5.1. <u>Allocation</u>. BioLine will allocate expenses to the Early Development Program in a manner consistent with generally accepted accounting principles, *provided*, however, that the Program Amount shall not be used to pay for any expenses (such as overhead) that BioLine would have had if the Early Development Program had not been created. Pan Atlantic will have the right, upon reasonable notice, and subject to confidentiality obligations of BioLine towards third parties such as licensors of the Research Projects subject matters, etc., to review BioLine's books and records with respect to BioLine's compliance with its obligations under this Agreement.
- 5.2. <u>Expenses, Taxes and Benefits</u>. It is understood and agreed that nothing in this Agreement is intended to, nor will it result in, Pan Atlantic being responsible for the payment of expenses relating to the Research Projects, including without limitation rent, taxes, salaries, social security or national insurance payments, insurance, workers' compensation payments, disability insurance or similar items, including interest and penalties thereon.

## 6. <u>Term and Termination</u>.

- 6.1. This Agreement shall commence on the date hereof and continue until the earlier of (i) completion of the disbursement of the entire Program Funds and completion of all Research Projects funded thereby and (ii) termination by the parties as provided in Sections 6.2 or 6.3 below.
- 6.2. If a party fails to meet one or more of any material terms and conditions hereof (a "**default**"), and the defaulting party fails to cure such default within thirty (30) days following notice of default, the non-defaulting party shall have the right to terminate this Agreement.
- 6.3. A party shall have a right to terminate this Agreement immediately should the other party enter into or file on its own a petition or proceeding seeking an order for relief under the bankruptcy or reorganization laws of its respective jurisdiction; have filed against it an involuntary petition or proceeding seeking an order for relief under the bankruptcy or reorganization laws of its respective jurisdiction, which is not dismissed within ninety (90) days after filing; enter into a receivership of any of its assets; enter into a dissolution or liquidation of its assets or an assignment for the benefit of its creditors; or engage in a sale of all or substantially all of its assets as would cause such party to be unwilling to fulfill its obligations under this Agreement.

## 7. <u>Confidentiality</u>.

Without derogating from any other agreement or undertaking to which Pan Atlantic is or may become subject, and in addition to any such agreement or undertaking, Pan Atlantic undertakes that it shall keep in confidence, and not use for any purpose whatsoever except in connection with the exercise of any of its rights under this Agreement, any and all information relating to BioLine and/or any Research Projects which has been provided to it by BioLine or was otherwise obtained by it ("**Confidential Information**"), except for information: (i) which is or shall be in the public domain not due to any act of Pan Atlantic in breach of law or agreement; (ii) which, at the time of disclosure to Pan Atlantic was already known to Pan Atlantic and was not acquired directly or indirectly from BioLine or any of its affiliates, all as may be evidenced by written records of Pan Atlantic; (iii) which, at the time of disclosure to Pan Atlantic was already received by Pan Atlantic from a third party who did not acquire it directly or indirectly from BioLine or confidence, all as may be evidenced by written records of Pan Atlantic; (iv) was independently developed by Pan Atlantic without the use of Confidential Information, as may be evidenced by written records of Pan Atlantic; or (v) which Pan Atlantic is required to disclose under any applicable law or stock exchange regulations. Notwithstanding the above, Pan Atlantic or the Friedberg Family will have the right to disclose its funding of BioLine under this Agreement and under the Bridge Loan Agreement between Pan Atlantic and BioLine, dated as of the date hereof.

## 8. <u>Miscellaneous</u>.

8.1. <u>Relationship of Parties</u>. Neither party, their affiliates, nor their employees, consultants, contractors or agents are agents, employees, partners or joint venturers of the other party, nor do they have any authority whatsoever to bind the other party by contract or otherwise. They will not make any representations to the contrary, either expressly, implicitly, by appearance or otherwise.

8.2. Assignment. This Agreement shall be binding upon and inure to the benefit of each party's successors and assigns. Notwithstanding the foregoing, unless otherwise stated herein, (a) Pan Atlantic shall not assign, by operation of law or otherwise, any of its rights or obligations hereunder nor permit the same to be assigned by operation of law, except with BioLine's prior written consent *provided*, however, nothing contained herein shall restrict the ability of Pan Atlantic to assign, by operation of law or otherwise, this Agreement or any of its rights or obligations hereunder, nor prohibit the same to be assigned by operation of law or otherwise, to an Affiliate. that agrees to be bound by all of the terms and conditions in this Agreement and (b) BioLine shall not assign, by operation of law, except with Pan Atlantic's prior written consent *provided*, however, nothing contained herein shall restrict the ability of DioLine to assign, by operation of law or otherwise, this Agreement or any of its rights or obligations hereunder nor permit the same to be assigned by operation of law, except with Pan Atlantic's prior written consent *provided*, however, nothing contained herein shall restrict the ability of BioLine to assign, by operation of law or otherwise, this Agreement or any of its rights or obligations hereunder nor permit the same to be assigned by operation of law, except with Pan Atlantic's prior written consent *provided*, however, nothing contained herein shall restrict the ability of BioLine to assign, by operation of law or otherwise, this Agreement or any of its rights or obligations hereunder, nor prohibit the same to be assigned by operation of law or otherwise, to a sale of substantially all of the assets of BioLine, to a successor-in-interest to it or to an affiliate that agrees to be bound by all of the terms and conditions in this Agreement.

For the purposes of this Agreement, an "Affiliate" of any person or entity means any other person or entity directly or indirectly controlling, controlled by or under direct or indirect common control with, or having the same beneficial ownership as, such person or entity. For purposes of this definition, "control" means the power to direct the management and policies of such person or firm, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise.

8.3. <u>Notices</u>. Any notice or other communication required or which may be given hereunder shall be in writing and either delivered personally to an officer of the addressee or mailed, certified or registered mail, postage prepaid, or by facsimile transmission (with a confirming copy sent by registered mail) and shall be deemed given (i) when so delivered personally; (ii) if mailed, five (5) days after the time of mailing; (iii) if faxed or sent by electronic mail (email), twenty four (24) hours after the time of sending the fax or electronic mail. Addresses for notices are:

If to Pan Atlantic:

Pan Atlantic Investments Limited Musson Building, 2nd Floor Hincks Street Bridgetown, Barbados West Indies 11000 Attention: Robert J. Bourque, Managing Director Tel: +1-246-436-9756 Fax: +1-246-437-6690

With a copy (which shall not constitute notice) to:

Gross, Kleinhendler, Hodak, Halevy, Greenberg & Co. One Azrieli Center Tel Aviv, 67021 Israel Tel: +972-3-607-4444 Fax: +972 3 607 4411 Attention: Daniel Gamulka, Adv

If to BioLine:

BioLineRx Ltd. 19 Hartum Street P.O. Box 45158 Jerusalem 91450, Israel Attention: Vice President Finance and Corporate Development Tel: +972-2-548-9100 Fax:+972-2-548-9101 Danziger, Klagsbald & Co. Attn. Joeri Kreisberg, Adv. 7 Menachem Begin Street Ramat Gan 52521, Israel Tel: +972-3-611-0700 Fax: +972 3-611-0707

- 8.4. <u>Entire Agreement</u>. This Agreement, together with all appendices, exhibits and schedules hereto, constitute the entire understanding and agreement of the parties with respect to the subject matter of this Agreement, and supersede all prior and contemporaneous understandings and agreements, whether written or oral, with respect to such subject matter.
- 8.5. <u>Waivers</u>. No delay or failure by either party to exercise or enforce at any time any right or provision of this Agreement will be considered a waiver thereof or of such party's right thereafter to exercise or enforce each and every right and provision of this Agreement. No single waiver will constitute a continuing or subsequent waiver.
- 8.6. <u>Amendments and Modifications</u>. This Agreement may not be modified or amended, in whole or in part, except in writing signed by both the parties. Such modification or amendment need not be supported by consideration.
- 8.7. <u>Publicity</u>. Except as described in Section 4, nothing contained in this Agreement shall be construed as conferring any right to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of either party to this Agreement (including any contraction, abbreviation, or simulation of any of the foregoing) and each party hereto agrees not to disclose to others the terms and conditions of this Agreement, except as may be required by law or governmental regulation, without the express written consent of the other party.
- 8.8. <u>Force Majeure</u>. Neither Party shall be liable for any non-performance or delay in performance directly or indirectly caused by or resulting from acts of God, fire, flood, accident, riot, war, government intervention, embargoes, strikes, labor difficulties, equipment failure, lack of goods, late delivery by suppliers or other difficulties which are beyond the reasonable control of either party.
- 8.9. <u>Governing Law</u>. The construction, interpretation and performance of this Agreement and all transactions under it shall be governed by the laws of the State of Israel without giving effect to principles of conflicts of laws.
- 8.10. Dispute Resolution. In the event that a dispute cannot be resolved amicably by the parties through negotiations within thirty (30) days of the commencement of such negotiations, the dispute shall be submitted to arbitration in accordance with the Israeli Arbitration Law 1968, with such arbitration to be held in Tel Aviv, Israel. The parties agree that any dispute shall be resolved by one arbitrator, the identity of whom shall be agreed upon by both parties and in the event that the parties shall fail to agree on the identity of such person within thirty (30) days from the date on which either party asked for the appointment of an arbitrator, the identity of the arbitrator shall be decided by the competent courts of Tel Aviv. The arbitration shall be conducted in English. Any decision resulting from such arbitration shall be final and binding upon the parties to this Agreement and on any other persons participating in the arbitration. Judgment upon the award may be entered in any court having jurisdiction thereon.

<u>Counterparts</u>. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

\* \* \* \*

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[Remainder of this page intentionally blank]

**IN WITNESS WHEREOF**, the parties have caused this Early Development Program Agreement to be signed by their respective duly authorized representatives as of the date first above written.

# PAN ATLANTIC INVESTMENTS LIMITED

By: /s/ Robert J. Bourque Name: Robert J. Bourque Title: Managing Director

BIOLINERX LTD.

By: /s/ Yuri Shoshan Name: Yuri Shoshan Title: Vice President, Finance and Corporate Development

#### CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. ASTERISKS DENOTE OMISSIONS.

#### **EXHIBIT 10.16**

#### LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the "**Agreement**") is entered into as of this 25 day of November, 2007 (the "**Effective Date**"), by and among BioLine Innovations Jerusalem, LP, a limited partnership formed and existing under the laws of the State of Israel, having a place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem, 91450, Israel ("**BioLine**"), and Innovative Pharmaceutical Concepts (IPC) Inc., a company formed and existing under the laws of the British Virgin Islands, having a place of business at Geneva Place, 2nd Floor, 333 Waterfront Drive, P.O. Box 3339, Road Town, Tortola, British Virgin Islands ("Licensor").

WHEREAS, Licensor is the owner of inventions related to Pharmaceutical Preparations useful for Treating Tumors and Lesions of the Skin; and

WHEREAS, BioLine wishes to obtain an exclusive license with respect to the foregoing invention(s) in order to develop and commercialize products based thereon, and Licensor wishes to grant BioLine a license with respect thereto, all in accordance with the terms and conditions of this Agreement;

**NOW, THEREFORE,** for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

## 1. Definitions.

Whenever used in this Agreement with an initial capital letter, the terms defined in this Section 1, whether used in the singular or the plural, shall have the meanings specified below.

"Additional Ingredient" shall mean any compound or substance which (i) is contained in a product and (ii) when administered to a patient has a therapeutic or prophylactic clinical effect independent of a Licensed Product, either directly or by acting synergistically with or otherwise enhancing the effect of other compounds or substances contained in such product.

"Affiliate" shall mean, with respect to a party, any person, organization or entity controlling, controlled by or under common control with, such party, including, with respect to a limited partnership, its limited partners, general partners, and any person, organization or entity controlling, controlled by or under common control with, such party. For purposes of this definition only, "control" of another person, organization or entity shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the activities, management or policies of such person, organization or entity, whether through the ownership of voting securities, by contract or otherwise. Without limiting the foregoing, control shall be presumed to exist when a person, organization or entity (i) owns or directly controls fifty percent (50%) or more of the outstanding voting stock or other ownership interest of the other organization or entity, or (ii) possesses, directly or indirectly, the power to elect or appoint fifty percent (50%) or more of the members of the governing body of the organization or other entity.

<sup>1</sup> 

"Calendar Quarter" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31, for so long as this Agreement is in effect.

"Combination Product" shall mean a product, substance or devise which comprises a Licensed Product and at least one Additional Ingredient.

"Commercially Reasonable Efforts" shall mean (i) with respect to any objective by an entity, reasonable, diligent, good faith efforts to accomplish such objective as other entities in the business of such entity (together with its Affiliates as a group) would normally use in the ordinary course of business and research to accomplish a similar objective under similar circumstances; and (ii) with respect to research, development and commercialization of any Licensed Product hereunder, shall mean those efforts and resources normally used by other entities in the business of such entity (together with its Affiliates as a group) for a product owned by it or to which it has rights, which is of similar market potential at a similar stage in its development or product life as such Licensed Product.

"Development Plan" shall have the meaning set out in Section 5.1.

"Development Results" shall mean all data, summaries, analyses, reports and other results and information relating to the Licensed Technology generated by or on behalf of BioLine in the exercise of its rights and its performance under this Agreement.

**"First Commercial Sale"** shall mean the first sale of a Licensed Product by BioLine, an Affiliate of BioLine or a Sublicensee to an unaffiliated third party after Regulatory Approval has been achieved in the country in which such Licensed Product is sold. Sales for test marketing, sampling and promotional uses, clinical trial purposes or compassionate or similar use shall not be considered to constitute a First Commercial Sale.

"FDA" shall mean the United States Food and Drug Administration.

"Government Programs" shall mean the Biotech Incubators Program of the Office of the Chief Scientist of the Israeli Ministry of Industry and Trade, and any other funding programs sponsored by the Israeli or other governments.

"Grants" shall mean any funds or benefits received by BioLine from governmental, quasi-governmental or other non-profit sources for the development of Licensed Products or other benefits, including but not limited to grants provided within the context of Government Programs.

**"IND"** shall mean (i) an Investigational New Drug Application, as defined in the U.S. Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder, that is required to be filed with the FDA before beginning clinical testing of a Licensed Product in human subjects, or any successor application or procedure, and (ii) any comparable application filed with a Regulatory Agency in any other country or jurisdiction.

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"Licensed Product" shall mean any product that comprises, contains or incorporates Licensed Technology.

"Licensed Technology" shall mean the Licensed Patents, and all inventions, know-how and other intellectual property owned by or licensed to Licensor related thereto.

**"Licensed Patents"** shall mean (i) the patents and/or patent applications set forth on <u>Exhibit A</u> attached hereto, (ii) all national-phase member patents and patent applications corresponding thereto, (iii) all improvements, updates, modifications and enhancements thereto made by Licensor by the Effective Date (if any), and (iv) all provisional applications, continuations, continuations-in-part, divisions, reissues, renewals, and patents granted thereon, all patents-of-addition, reissue patents, re-examinations and extensions or restorations by existing or future extension or restoration mechanisms, including, without limitation, supplementary protection certificates or the equivalent thereof, all related to the foregoing. <u>Exhibit A</u> shall include and shall be updated from time to time to reflect inclusion of new Licensed Patents.

**"M&A Transaction"** shall mean a transaction in which all or substantially all of the partnership interests of BioLine and/or all or substantially all of the assets or share capital of its general and/or limited partner(s) are acquired by or assigned to a third party.

"Net Sales" shall mean the gross amount billed or invoiced by or on behalf of BioLine and/or its Affiliates (the "Invoicing Entity") on sales of Licensed Products (whether made before or after the First Commercial Sale of the Licensed Product), <u>less</u> the following: (a) customary trade, quantity, or cash discounts to the extent actually allowed and taken; (b) amounts repaid or credited by reason of rejection or return; (c) to the extent separately stated on purchase orders, invoices, or other documents of sale, any taxes or other governmental charges levied on the production, sale, transportation, import, export, delivery, or use of a Licensed Product which is paid by or on behalf of the Invoicing Entity; (d) payment to one or more third parties to obtain a Third Party License from such third party(ies) in order to practice the Licensed Technology; and (e) outbound transportation, packing and delivery charges, as well as prepaid freight (including shipping insurance) actually incurred; *provided, however*, that:

(i) In any transfers of Licensed Products between the Invoicing Entity and an Affiliate of the Invoicing Entity not for the purpose of resale by such Affiliate, Net Sales shall be equal to the fair market value of the Licensed Products so transferred, assuming an arm's length transaction made in the ordinary course of business; and

(ii) In the event that the Invoicing Entity, or the Affiliate of the Invoicing Entity, receives non-monetary consideration for any Licensed Products or in the case of transactions not at arm's length with a non-Affiliate of the Invoicing Entity, Net Sales shall be calculated based on the fair market value of such consideration or transaction, assuming an arm's length transaction made in the ordinary course of business.

Sales of Licensed Products by an Invoicing Party to an Affiliate of such Invoicing Party, for resale by such Affiliate, shall not be deemed Net Sales and Net Sales shall be determined based on the total amount invoiced or billed by such Affiliate on resale to an independent third party purchaser.

"Regulatory Agency" shall mean the FDA or equivalent agency or government body of another country.

**"Regulatory Approval"** shall mean (i) approval by the FDA permitting commercial sale of a Licensed Product, or (ii) any comparable approval permitting commercial sale of a Licensed Product granted by the applicable Regulatory Agency in any other country or jurisdiction.

"Sublicense" shall mean any right granted, license given, or agreement entered into, by BioLine to or with any other person or entity, under or with respect to or permitting any use of any of the Licensed Technology (or any part thereof) or otherwise permitting the development, manufacture, marketing, distribution and/or sale of Licensed Products (regardless of whether such grant of rights, license given or agreement entered into is referred to or is described as a sublicense or as an agreement with respect to the development and/or manufacture and/or sale and/or distribution and/or marketing of Licensed Products).

"Sublicense Receipts" shall mean any payments or other consideration that BioLine or an Affiliate of BioLine actually received in connection with a Sublicense, or the grant of an option to obtain a Sublicense, including without limitation royalties, license fees, milestone payments, license maintenance fees and equity; *provided, however*, that in the event that BioLine or an Affiliate of BioLine receives non-monetary consideration in connection with a Sublicense or the grant of an option to obtain a Sublicense or in the case of transactions not at arm's length, Sublicense Receipts shall be calculated based on the fair market value of such consideration or transaction, assuming an arm's length transaction made in the ordinary course of business; and *provided further* that Sublicense Receipts will be reduced by any amounts returned by BioLine or an Affiliate to a Sublicensee on account of refunds or rebates given in respect of Sublicense Receipts or payment to one or more third parties to obtain a Third Party License from such third party(ies) in order to practice the Licensed Technology. For the avoidance of doubt, Sublicensing Receipts shall not include any amounts received as Grants, in connection with Government Programs, or otherwise as research grants from national or international not-for-profit funding bodies, or in connection with an M&A Transaction.

"Sublicensee" shall mean a person or entity granted a Sublicense in accordance with Section 2.2, including any sublicensees of other Sublicensees.

"Third Party License" shall mean a license from an unaffiliated third party to one or more valid and enforceable patents issued in the United States or any other jurisdiction, the claims of which cover one or more functional components that is essential for the efficacy of the Licensed Product.

**"Trial"** shall mean a clinical trial or trials performed by BioLine or a third party engaged by BioLine either in countries of the European Union or in the USA, as part of Phase I and Phase II clinical trials, pursuant to which treatment based on the Licensed Technology is administered to not less than sixty (60) subjects. It is agreed that following the receipt of the Trial's Final Clinical Study Report from the Clinical Research Organization (CRO), it shall have the right to treat more subjects in Israel.

# 2. License Grant.

2.1. License. Subject to the terms of this Agreement, Licensor hereby grants to BioLine an exclusive, worldwide license under Licensor's rights in the Licensed Technology to research, have researched, develop, have developed, manufacture, have manufactured, use, market, distribute, offer for sale, sell, have sold, export and import Licensed Products and/or provide services relating thereto, and to conduct or have conducted clinical trials. For purposes of this Section 2.1, the term "exclusive" means that Licensor shall not have any right to grant such licenses or rights to any third party or engage in any of the foregoing.

# 2.2. Sublicenses.

**2.2.1.** *Sublicense Grant.* BioLine shall be entitled to grant Sublicenses or other rights to third parties under the license granted pursuant to Section 2.1. Such Sublicenses shall be made for consideration and in arm's length transactions.

**2.2.2.** *Sublicense Agreements.* Sublicenses shall only be granted pursuant to written agreements. BioLine shall provide Licensor with a copy of each sublicense agreement within (30) days of receipt of an executed draft thereof from the Sublicensee. Each such sublicense agreement shall contain, inter alia, provisions to the following effect:

**2.2.2.1.** All provisions necessary to ensure BioLine's ability to perform its obligations under this Agreement, including reporting and audit requirements;

**2.2.2.2.** In the event of termination of the license set forth in Section 2.1 above (in whole or in part – e.g. termination in a particular country), any existing agreements that contain a Sublicense of, or other grant of right with respect to, Licensed Technology shall terminate to the extent of such Sublicense or other grant of right; *provided, however*, that, for each Sublicensee, upon termination of the Sublicense agreement with such Sublicensee, if the Sublicensee is not then in breach of such Sublicensee agreement with BioLine such that BioLine would have the right to terminate such Sublicense, Licensor shall be obligated, at the request of such Sublicensee, to enter into a new agreement with such Sublicensee on substantially the same terms as those contained in such Sublicense agreement; and *provided, further*, that such terms shall be amended, if necessary, to the extent required to ensure that such Sublicense agreement does not impose any obligations or liabilities on Licensor which are not included in this Agreement; and

**2.2.3.** A Sublicense shall be entitled to Sublicense its rights under a Sublicense agreement, and so forth through a chain of sublicenses, provided that each such sublicense shall be subject to execution of a written agreement consistent with the terms of this Section, and shall be made for consideration and in arm's length transactions.

2.3. **Contractors and Affiliates.** BioLine shall have the right to utilize third party contractors in connection with BioLine's activities in exploiting the license granted hereunder. Provided that such contractors perform activities on BioLine's behalf, and BioLine maintains control of and remains solely responsible for such activities, the provisions of Section 2.2 shall not apply with respect to such contractors. Sublicenses to Affiliates of BioLine shall not be considered Sublicenses under this Agreement.

# 3. Title.

Subject to the license granted to BioLine pursuant to the terms of this Agreement, all rights, title and interest in and to the Licensed Technology are and shall be owned solely and exclusively by Licensor. Licensor shall not accept any funding from any third party for research relating or connected to the Licensed Technology without the prior written consent of BioLine.

# 4. Patent Filing, Prosecution and Maintenance.

**4.1. Filing, Prosecution and maintenance.** BioLine shall have the first right to prepare, file, prosecute and maintain any patent applications and patents, in respect of the Licensed Technology and/or any part thereof, and at BioLine's sole expense, provided that such patent applications and patents shall be registered in the name of Licensor. BioLine shall provide Licensor with copies of all patent applications and Licensor undertakes to cooperate in a timely manner with BioLine's efforts to register the patent, including by executing any documents as may be required for such purpose. BioLine shall have to pay, on time, all future payments necessary to prosecute and maintain all patent applications and/or patents in respect of the Licensed Technology, as set forth on Exhibit A attached hereto, and all patent applications and/or patents which BioLine decided to file under this Section 4.1.

**4.2.** [<sup>\*\*\*</sup>]

4.3 **Consultation.** BioLine shall consult with Licensor regarding the preparation, filing and prosecution of all patent applications, and the maintenance of all patents, included within the Licensed Patents, including, without limitation, the content, timing and jurisdiction of the filing of such patent applications and their prosecution, and other details and overall global strategy pertaining to the procurement and maintenance of the Licensed Patents. To avoid doubt, Licensor and BioLine may agree not to pursue the filing and/or maintenance of patents in certain jurisdictions. All Licensed Patents shall be filed, prosecuted and maintained by the parties through a law or patent attorney firm selected by BioLine, subject to Licensor's approval, not to be unreasonably withheld. BioLine shall reimburse Licensor for all documented patent-related expenses incurred by Licensor with respect to the filing, prosecution and maintenance of the Licensed Patents within thirty (30) days after Licensor invoices BioLine in respect thereof; *provided, however*, that (i) BioLine is copied on all correspondence in respect of the aforementioned filing, prosecution and maintenance activities, and (ii) all such expenses are approved in advance and in writing by BioLine.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

**4.4. No Warranty.** Nothing contained herein shall be deemed to be a warranty by any of the parties that they can or will be able to obtain patents on patent applications included in the Licensed Patents, or that any of the Licensed Patents will afford adequate or commercially worthwhile protection.

# 5. Diligence and Information Exchange.

**5.1. Diligence.** BioLine shall use Commercially Reasonable Efforts, and/or shall cause its Affiliates and/or Sublicensees to use Commercially Reasonable Efforts, to develop Licensed Products based upon the road-map and timetable for the development of the Licensed Products in accordance with a development plan (the "**Development Plan**") set out in Exhibit B attached hereto. It is understood that the Development Plan is subject to change at BioLine's discretion in order to meet the development obligations set out above. Notwithstanding the foregoing, BioLine shall [\*\*\*]. It is hereby agreed that BioLine shall consider in good faith to further invest in research and development based on the Licensed Technology, including the design of a disposable pen-like application device, improvement of tissue preservation and histopathology and treatment of additional skin conditions such as viral and/or fungal infections of the skin.

**5.2. Steering Committee, Consultation and Progress Reports.** The parties shall establish a steering committee (the "**Committee**") to oversee the exercise of the License. Each party shall be entitled to designate one representative to the Committee (the "**Representative**"), which shall meet at least twice per calendar year. The Representatives shall be bound by the confidentiality arrangements set out in this Agreement. BioLine agrees to consult with Licensor, via the Licensor Representative, in respect of significant decisions related to the exercise of the License. In the context of the Steering Committee, BioLine shall (i) provide Licensor via Licensor's Representative with periodic reports concerning all material activities undertaken in respect of the exercise of the License, and (ii) keep Licensor fully informed via Licensor's Representative concerning all material activities undertaken in respect of the exercise of the License. For the avoidance of doubt, the Committee shall be a forum for the exchange of information between the parties with respect to the foregoing, shall act only in an advisory capacity and shall not have any decision-making powers.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

5.3. Grants and Government Programs. Licensor acknowledges and agrees that BioLine may apply for Grants as part of Government Programs for the funding of the development and commercialization of Licensed Products. Licensor agrees to perform such further acts and execute such further documents as may reasonably be necessary to support the preparation and submission of the aforementioned Grants. If BioLine receives Grants and the associated Government Programs so require, this Agreement will become subject to the applicable laws and regulations governing such Grants including, without limitation, the Law for the Encouragement of Industrial Research and Development, 5744-1984 as amended or supplemented from time to time and all regulations promulgated thereunder, the rules and regulations of the Chief Scientist (the "OCS") and the relevant directives of the Director General of the Ministry of Trade, Industry and Employment, and the rules and regulations of the Incubator Program of the OCS.

## 6. Consideration.

**6.1. Payments.** Subject to the terms below, BioLine shall pay Licensor a license fee of [\*\*\*] (the "Licensee Fee"). The License Fee shall be payable as follows:

6.1.1. [\*\*\*] shall be paid to Licensor within ten (10) days following the execution of this Agreement.

6.1.2. [\*\*\*]

6.1.2.1. [\*\*\*]

6.1.2.2. [\*\*\*]

6.1.3. [\*\*\*]

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

6.1.4. The License Fee shall be non-refundable.

6.2 Royalty Payments. In the event that BioLine itself will actually manufacture and/or sell Licensed Products under the license, then BioLine will pay to Licensor [\*\*\*] of Net Sales on a Licensed Product-by-Licensed Product and country-by-country basis until the last to expire of any patent included within the Licensed Technology in such country.

**6.3. Payments on Sublicense Receipts.** BioLine shall pay Licensor an amount equal to [\*\*\*] of all Sublicense Receipts received by BioLine from the exploitation of the license granted hereunder (the "**Sublicense Payment**").

**6.4. Combination Products.** Notwithstanding anything to the contrary set forth herein, in the event a Licensed Product is sold by BioLine or an Affiliate of BioLine in the form of a Combination Product, Net Sales from such Combination Product, for purposes of determining royalty payments, shall be determined by multiplying the actual Net Sales of such Combination Product during the applicable royalty reporting period, by the fraction A/(A+B) where: "A" is the average sale price of the Licensed Product contained in the Combination Product when sold separately by BioLine or its Affiliate; and "B" is the average price of the other Additional Ingredients included in the Combination Product when sold separately by its supplier, in each case during the applicable royalty reporting period or if sales of both the Licensed Product and/or other Additional Ingredients did not occur in such period, then in the most recent royalty reporting period in which sales of both occurred. In the event that such average sale price cannot be determined for both the Licensed Product and all other Additional Ingredients included in the Combination Product, Net Sales for the purpose of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product, Net Sales for the purpose of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Products by the fraction of C/(C+D) where "C" is the fair market value of the Licensed Product; and "D" is the fair market value of all other Additional Ingredients included in the Combination Product. In such event, the parties shall negotiate in good faith to arrive at a determination of the respective fair market values of the Licensed Product and all other Additional Ingredients included in the Combination Product.

## 7. Reports, Payments and Records.

### 7.1. Reports and Payments.

**7.1.1.** *Reports.* Within thirty (30) days after the conclusion of each Calendar Quarter commencing with the first Calendar Quarter in which BioLine or an Affiliate of BioLine first receives Net Sales or Sublicense Receipts, BioLine shall deliver to Licensor a report containing the following information:

Quarter;

(a) the number of units of Licensed Products sold by BioLine and its Affiliates in each country for the applicable Calendar

Calendar Quarter;

(b) the gross amount billed for the Licensed Product sold by BioLine and its Affiliates in each country during the applicable rter;

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

deductions;

(c)

(d) the total amount payable to Licensor in U.S. dollars on Net Sales for the applicable Calendar Quarter, together with the exchange rates used for conversion on the date that the sale was recognized in accordance with IFRS (IAS 21); and

(e) a calculation of any Sublicense Receipts for the applicable Calendar Quarter.

The report shall state if no amounts are due to Licensor for any Calendar Quarter.

**7.1.2.** *Payment.* Concurrent with the delivery of each report delivered pursuant to Section 7.1.1, BioLine shall remit to Licensor all amounts due pursuant to Section 6 for the applicable Calendar Quarter.

7.2. Records. BioLine shall maintain, and shall cause its Affiliates and Sublicensees to maintain, complete and accurate records of Licensed Products that are made, used, marketed or sold under this Agreement, any amounts payable to Licensor in relation to such Licensed Products and all Sublicense Receipts received by BioLine and its Affiliates, which records shall contain sufficient information to permit the Licensor to confirm the accuracy of any reports or notifications delivered to Licensor under Section 7.1. The relevant party shall retain such records relating to a given Calendar Quarter for at least seven (7) years after the conclusion of that Calendar Quarter. During such seven (7) year period, Licensor shall have the right, at Licensor's expense, to cause an independent, certified public accountant, who is bound by a suitable confidentiality arrangement with BioLine, to inspect BioLine's and the relevant Affiliates' records during normal business hours for the sole purpose of verifying any reports and payments delivered under this Agreement. Such accountant shall not disclose to Licensor or any third party any information gained during the course of such inspection, except that such accountant may disclose to Licensor and BioLine information gained during the course of such inspection relating to the accuracy of reports and payments delivered under this Agreement. The parties shall reconcile any underpayment or overpayment within thirty (30) days after the accountant delivers the results of the audit. In the event that any audit performed under this Section 7.2 reveals an underpayment in excess of five percent (5%) in any calendar year, the audited party shall bear the full cost of such audit. Licensor may exercise its rights under this Section 7.2 only twice every year per audited party and only with twenty (20) business days prior notice to the audited party. BioLine shall cause its Affiliates and Sublicensees to comply with the terms of this Section 7.2.

**7.3. Audited Report.** BioLine shall furnish Licensor, and shall cause its Affiliates who make, use, market or sell Licensed Products to furnish Licensor, within ninety (90) days after the end of each calendar year, commencing at the end of the calendar year of the First Commercial Sale, with a report, certified by an independent certified public accountant, relating to royalties and other payments due to Licensor pursuant to this Agreement in respect to the previous calendar year and containing the same details as those specified in Section 7.1 in respect to the previous calendar year.

**7.4. Payment Method.** Each payment due to Licensor under this Agreement shall be made by wire transfer of funds to Licensor's accounts in accordance with written instructions provided by Licensor.

**7.5. Withholding and Similar Taxes.** If applicable laws require that taxes be withheld from any amounts due to Licensor under this Agreement, BioLine shall (a) deduct these taxes from the remittable amount, (b) pay the taxes to the proper taxing authority, and (c) promptly deliver to Licensor a statement including the amount of tax withheld and justification therefore, and such other information as may be necessary for tax credit purposes. For the avoidance of doubt, all amounts to be paid to Licensor pursuant to this Agreement are exclusive of Value Added Tax. BioLine shall add value added tax, as required by law, to all such amounts.

# 8. Confidential Information

#### 8.1. Confidentiality.

8.1.1. Licensor Confidential Information. BioLine agrees that, without the prior written consent of Licensor, in each case, during the term of this Agreement and for a period of seven (7) years from date of disclosure, it will keep confidential, and not disclose or use Licensor Confidential Information (as defined below) other than for the purposes of this Agreement. BioLine shall treat such Licensor Confidential Information with the same degree of confidentiality as it keeps its own confidential information, but in all events no less than a reasonable degree of confidentiality. BioLine may disclose the Licensor Confidential Information only (a) to employees and consultants of BioLine or of its Affiliates or Sublicensees who have a "need to know" such information in order to enable BioLine to exercise its rights or fulfill its obligations under this Agreement and are legally bound by agreements which impose confidentiality and non-use obligations comparable to those set forth in this Agreement, and (b) to actual and potential business partners, collaborators, investors, contractors, service providers and consultants, provided, however, in each case, that such recipient of Confidential Information first enters into a legally binding agreement with BioLine which imposes confidentiality and non-use obligations with respect to Confidential Information comparable to those set forth in this Agreement and has a minimum term of five (5) years from date of signature of the binding agreement. For purposes of this Agreement, "Licensor Confidential Information" means any scientific, technical, trade or business information relating to the subject matter of this Agreement designated as confidential or which otherwise should reasonably be construed under the circumstances as being confidential disclosed by or on behalf of the Licensor or any of its employees or researchers to BioLine, whether in oral, written, graphic or machine-readable form, except to the extent such information: (i) was known to BioLine at the time it was disclosed, other than by previous disclosure by or on behalf of the Licensor or any of its employees or researchers, as evidenced by BioLine's written records at the time of disclosure; (ii) is at the time of disclosure or later becomes publicly known under circumstances involving no breach of this Agreement; (iii) is lawfully and in good faith made available to BioLine by a third party who is not subject to obligations of confidentiality to the Licensor with respect to such information; (iv) is explicitly approved for release by written authorization of Licensor; (v) is required by law or court order to be disclosed; or (vi) is independently developed by BioLine without the use of or reference to the Licensor Confidential Information, as demonstrated by documentary evidence.

8.1.2. BioLine Confidential Information. Licensor agree that, without the prior written consent of BioLine, in each case, during the term of this Agreement and for a period of seven (7) years thereafter, it will keep confidential, and not disclose or use BioLine Confidential Information (as defined below) other than for the purposes of this Agreement. Licensor shall treat such BioLine Confidential Information with the same degree of confidentiality as it keeps its own confidential information, but in all events no less than a reasonable degree of confidentiality. Licensor may disclose the BioLine Confidential Information only to employees and consultants of Licensor or of its Affiliates who have a "need to know" such information in order to enable Licensor to exercise its rights or fulfill its obligations under this Agreement and are legally bound by agreements which impose confidentiality and non-use obligations comparable to those set forth in this Agreement. For purposes of this Agreement, "BioLine Confidential Information" means any scientific, technical, trade or business information relating to the subject matter of this Agreement designated as confidential or which otherwise should reasonably be construed under the circumstances as being confidential disclosed by or on behalf of BioLine pursuant to this Agreement, whether in oral, written, graphic or machinereadable form, except to the extent such information: (i) was known to Licensor at the time it was disclosed, other than by previous disclosure by or on behalf of BioLine as evidenced by Licensor's written records at the time of disclosure; (ii) is at the time of disclosure or later becomes publicly known under circumstances involving no breach of this Agreement; (iii) is lawfully and in good faith made available to Licensor by a third party who is not subject to obligations of confidentiality to BioLine with respect to such information; (iv) is explicitly approved for release by written authorization of BioLine; (v) is required by law or court order to be disclosed; or (vi) is independently developed by Licensor without the use of or reference to the BioLine Confidential Information, as demonstrated by documentary evidence.

**8.2. Disclosure of Agreement.** Each party may disclose the terms of this Agreement to the extent required, in the reasonable opinion of such party's legal counsel, to comply with applicable laws, as well as to Sublicensees and prospective and current investors, pursuant to appropriate non-disclosure arrangements. If a party discloses this Agreement or any of the terms hereof in accordance with this Section 8.2, such party agrees, at its own expense, to seek confidential treatment of portions of this Agreement or such terms, as may be reasonably requested by the other party.

**8.3. Publicity.** Without derogating from Section 8.2, BioLine may make announcements, publications, presentations and similar disclosures (i) relating to the subject matter of this Agreement, (ii) in connection with the marketing or sale of any Licensed Products, or (iii) in respect of the progress of the exercise of the license granted hereunder without the approval of Licensor, *provided, however*, that in so doing BioLine does not disclose any Licensor Confidential Information without having obtained the prior written consent of Licensor. Except as provided in the immediately preceding sentence, no party will make any public announcement regarding this Agreement without the prior written approval of the other party.

# 9. Patent Infringement.

# 9.1 Enforcement of Patent Rights.

**9.1.1.** *Notice.* In the event any party becomes aware of any possible or actual infringement or unauthorized possession, knowledge or use of any Licensed Patents (collectively, an "**Infringement**"), that party shall promptly notify the other parties and provide them with details regarding such Infringement.

**9.1.2.** *Suit by BioLine*. BioLine shall have the right, but not the obligation, to take action in the prosecution, prevention, or termination of any Infringement of Licensed Patents. Should BioLine elect to bring suit against an infringer and Licensor is joined as party plaintiff in any such suit, Licensor shall have the right to approve the counsel selected by BioLine to represent BioLine and Licensor, such approval not to be unreasonably withheld. The expenses of such suit or suits that BioLine elects to bring, including any expenses of Licensor incurred in conjunction with the prosecution of such suits or the settlement thereof, shall be paid for entirely by BioLine and BioLine shall hold Licensor free, clear and harmless from and against any and all costs of such litigation, including reasonable attorneys' fees. BioLine shall not compromise or settle such litigation without the prior written consent of Licensor, which consent shall not be unreasonably withheld or delayed. In the event BioLine exercises its right to sue pursuant to this Section 9.1.2, it shall first reimburse itself out of any sums recovered in such suit or in settlement thereof for all costs and expenses of every kind and character, including reasonable attorneys' fees, necessarily involved in the prosecution of any such suit. If, after such reimbursement, any funds shall remain from said recovery, then Licensor shall receive an amount equal to [\*\*\*] of such funds and the remaining [\*\*\*] of such funds shall be retained by BioLine.

**9.1.3.** Suit by Licensor. If BioLine does not take action in the prosecution, prevention, or termination of any Infringement pursuant to Section 9.1.2 above, and has not commenced negotiations with the infringer for the discontinuance of said Infringement, within ninety (90) days after receipt of notice to BioLine by Licensor of the existence of an Infringement, Licensor may elect to do so. Should Licensor elect to bring suit against an infringer and BioLine is joined as party plaintiff in any such suit, BioLine shall have the right to approve the counsel selected by Licensor to represent Licensor and BioLine, such approval not to be unreasonably withheld. The expenses of such suit or suits that Licensor elects to bring, including any expenses of BioLine free, clear and harmless from and against any and all costs of such litigation, including reasonable attorneys' fees. Licensor shall not compromise or settle such litigation without the prior written consent of BioLine, which consent shall not be unreasonably withheld or delayed. In the event Licensor exercise its right to sue pursuant to this Section 9.1.3, it shall first reimburse itself out of any sums recovered in such suit or in settlement thereof for all costs and expenses of every kind and character, including reasonable attorneys' fees, necessarily involved in the prosecution of any such suit. If, after such reimbursement, any funds shall remain from said recovery, [\*\*\*].

**9.1.4.** *Own Counsel.* Each party shall always have the right to be represented by counsel of its own selection and at its own expense in any suit instituted under this Section 9 by another party for Infringement.

**9.1.5.** *Cooperation.* Each party agrees to cooperate fully in all reasonable respects in any action under this Section 9 which is controlled by another party, provided that the controlling party reimburses the cooperating party promptly for any reasonable costs and expenses incurred by the cooperating party in connection with providing such assistance.

**9.1.6.** *Standing*. If a party lacks standing and the other party has standing to bring any such suit, action or proceeding, then such other party shall do so at the request of and at the expense of the requesting party. If the non-controlling party is joined in any such suit, action or proceeding, such party shall execute all papers and perform such other acts as may be reasonably required in the circumstances.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

**9.2 Legal Action against a Party.** Each Party will provide the others with prompt notice of any action, suit or proceeding brought against it, alleging the infringement of the intellectual property rights of a third party by reason of the discovery, development, manufacture, use, sale, importation, or offer for sale of a Licensed Product or otherwise due to the use or practice of the Licensed Technology.

# 10. Warranties; Limitation of Liability.

## 10.1. Representations and Warranties.

**10.1.1.** Licensor hereby represents and warrants that (i) it has sole and exclusive ownership of the patents and/or patent applications listed in <u>Exhibit A</u> attached hereto; (ii) it has not granted any rights in or to Licensed Technology that are inconsistent with the rights granted to BioLine under this Agreement; (iii) it has the right to grant the license granted under this Agreement free and clear of any third party rights or claims; (iv) it will not transfer, assign, grant rights to, sell, lease or otherwise dispose of or encumber the Licensed Technology other than as may be expressly permitted herein; and (v) there are no legal claims, demands, threats or proceeding of any sort by any third party against the Licensor contesting the ownership or validity of the Licensed Patents, or claiming that the practice of the Licensed Patents in the manner contemplated by this Agreement would infringe the rights of such third party.

**10.1.2.** BioLine hereby represents and warrants that it (i) is a drug development company, (ii) has received and carefully reviewed, to its satisfaction, all the information it considers necessary or appropriate for deciding whether to enter into this Agreement, and (iii) has reached the decision to fulfill its obligations hereunder as a result of careful consideration. Without derogating from the aforementioned, BioLine further represents that it has had an opportunity to ask questions of and receive answers from Licensor regarding the intellectual property and the inventions of Licensor and has performed its independent due diligence with respect thereto after having received from Licensor the due diligence materials it requested.

**10.2. Compliance with Law.** BioLine warrants that it will comply with applicable laws and regulations relating to the development, manufacture, use, and sale of Licensed Products.

**10.3. No Warranty.** Except as otherwise expressly provided in this Agreement, neither party makes any warranty with respect to any technology, patents, goods, services, rights or other subject matter of this Agreement, and each party hereby disclaims warranties of merchantability, fitness for a particular purpose and non-infringement with respect to any and all of the foregoing. It is further specifically agreed that no claim shall be made by either party against the other party (including such party's directors, officers, employees, shareholders and agents and their respective successors, heirs and assigns) based on representations, written and/or oral, that are not specifically mentioned in this Agreement.

**10.4. Limitation of Liability.** Notwithstanding anything else in this Agreement or otherwise, neither Licensor nor BioLine will be liable to the other with respect to any subject matter of this Agreement under any contract, negligence, strict liability or other legal or equitable theory for (i) any indirect, incidental, consequential or punitive damages or lost profits or (ii) cost of procurement of substitute goods, technology or services.

## 11. Indemnification.

11.1. Indemnity. BioLine shall indemnify, defend, and hold harmless Licensor, its directors, officers, employees and agents and their respective successors, heirs and assigns (the "Licensor Indemnitees"), against any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon any of the Licensor Indemnitees in connection with any claims, suits, actions, demands or judgments ("Claims") arising out of any theory of liability (including without limitation actions in the form of tort, warranty, or strict liability and regardless of whether such action has any factual basis) concerning the use of any Licensed Technology by BioLine, or any of its Affiliates or Sublicensees, or concerning any product, process, or service that is made, used, or sold pursuant to any right or license granted by Licensor to BioLine under this Agreement (except in cases where, and to the extent that, such claims, suits, actions, demands or judgments result from the negligence or willful misconduct on the part of any of the Licensor Indemnitees in which case Licensor shall indemnify BioLine and the provisions hereof shall apply *mutatis mutandis*).

**11.2. Procedures.** If any Licensor Indemnitee receives notice of any Claim, Licensor shall, as promptly as is reasonably possible, give BioLine notice of such Claim; *provided, however*, that failure to give such notice promptly shall only relieve BioLine of any indemnification obligation it may have hereunder to the extent such failure diminishes the ability of BioLine to respond to or to defend the Licensor Indemnitee against such Claim. Licensor and BioLine shall consult and cooperate with each other regarding the response to and the defense of any such Claim and BioLine shall, upon its acknowledgment in writing of its obligation to indemnify the Licensor Indemnitee, be entitled to and shall assume the defense or represent the interests of the Licensor Indemnitee in respect of such Claim, that shall include the right to select and direct legal counsel and other consultants to appear in proceedings on behalf of the Licensor Indemnitee and to propose, accept or reject offers of settlement, all at its sole cost; *provided, however*, that no such settlement shall be made without the written consent of the Licensor Indemnitee, such consent not to be unreasonably withheld. Nothing herein shall prevent the Licensor Indemnitee from retaining its own counsel and participating in its own defense at its own cost and expense.

**11.3. Insurance.** BioLine shall maintain insurance that is reasonably adequate to fulfill any potential obligation to the Licensor Indemnitees consistent with industry standards. BioLine shall provide Licensor, upon request, with written evidence of such insurance.

# 12. Term and Termination.

**12.1. Term.** The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Section 12, shall continue in full force and effect on a Licensed Product-by-Licensed Product and country-by-country basis until the expiration of all payment obligations pursuant to Section 6 for such Licensed Product.

**12.2. Effect of Expiration.** Following the expiration of this Agreement pursuant to Section 12.1 (and provided the Agreement has not been earlier terminated pursuant to Section12.3, in which case Section 12.4.1 shall apply), BioLine shall have a fully-paid up, non-exclusive, worldwide license (with the right to grant sublicenses) under the Licensed Technology to research, have researched, develop, have developed, manufacture, have manufactured, use, market, distribute, offer for sale, sell, have sold, export and import Licensed Products and/or provide services relating thereto.

#### 12.3. Termination.

# **12.3.1.** Termination Without Cause and for Scientific, Regulatory or Medical Reasons.

**12.3.1.1.** BioLine may terminate this Agreement without cause upon thirty (30) days prior written notice to Licensor; *provided, however*, that in the event that BioLine exercises such right prior to the completion of the Trial, BioLine shall pay for the completion of the Trial; and *provided further* that the total amount that BioLine shall be obligated to pay in respect of the Trial (including amounts spent by BioLine prior to the exercise of the termination right hereunder, but excluding the Licensee Fee mentioned in Section 6.1) shall in no event exceed the sum of six hundred thousand United States Dollars (US \$600,000). For the avoidance of doubt, BioLine shall not be obligated to pay any amounts hereunder in the event that BioLine terminates the Agreement pursuant to this subsection 12.3.1.1 after the completion of the Trial.

**12.3.1.2.** BioLine may terminate this Agreement at any time upon sixty (60) days' prior written notice to Licensor for scientific, regulatory or medical reasons which would prevent BioLine from continuing the development of the Licensed Technology pursuant to the Development Plan as may be determined by BioLine's Scientific Advisory Board ("SAB"). Prior to the exercise of such right, Licensor shall have the right to present orally and/or in writing its opinion regarding the proposed termination to the SAB and offer its solutions for the obstacles and/or problems raised by the SAB. For the purpose of preparing for its presentation to the SAB, Licensor may contract with an independent expert to assist with such preparation and such expert shall have the right to present before the SAB. BioLine agrees to contribute up to [\*\*\*] to offset any documented costs directly incurred by Licensor in retaining such expert against presentation of appropriate invoices. It is specifically agreed between the parties that in the event that BioLine terminates the Agreement pursuant to this subsection 12.3.1.2, regardless of whether such termination occurs prior to the completion of the Trial, BioLine shall not be obligated to pay any amounts in respect of the completion of the Trial.

#### 12.3.2. Termination for Default.

**12.3.2.1.** In the event that BioLine commits a material breach of its obligations under this Agreement and fails to cure that breach within thirty (30) days after receiving written notice thereof from Licensor, Licensor may terminate this Agreement immediately upon written notice to BioLine. Notwithstanding the foregoing, in the event that any breach is not susceptible of cure within the stated period and BioLine uses diligent good faith efforts to cure such breach, the stated period will be extended by an additional thirty (30) days. In the event of an uncured material breach by BioLine, Licensor may elect not to terminate this Agreement but, instead, to sue BioLine for damages arising from such breach.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

**12.3.2.2.** In the event that Licensor commits a material breach of its obligations under this Agreement and fails to cure that breach or default within thirty (30) days after receiving written notice thereof from BioLine, BioLine may terminate this Agreement immediately upon written notice to Licensor. Notwithstanding the foregoing, in the event that any breach or default is not susceptible of cure within the stated period and Licensor uses diligent good faith efforts to cure such breach or default during the initial thirty (30) day cure period, the stated period will be extended by an additional thirty (30) days. In the event of an uncured material breach by Licensor, BioLine may elect not to terminate this Agreement but, instead, to sue Licensor for damages arising from such breach.

#### 12.3.3. Bankruptcy.

**12.3.3.1.** Either BioLine or Licensor may terminate this Agreement upon notice to the other if the other party becomes insolvent, is adjudged bankrupt, applies for judicial or extra-judicial settlement with its creditors, makes an assignment for the benefit of its creditors, voluntarily files for bankruptcy or has a receiver or trustee (or the like) in bankruptcy appointed by reason of its insolvency, or in the event an involuntary bankruptcy action is filed against the other party and not dismissed within ninety (90) days, or if the other party becomes the subject of liquidation or dissolution proceedings or otherwise discontinues business.

**12.3.3.2.** Notwithstanding the foregoing, in the event a receiver or trustee (or the like) is appointed or BioLine has entered into a settlement with its creditors and BioLine is otherwise meeting its obligations pursuant to this Agreement, Licensor shall not be entitled to terminate this Agreement as contemplated under Section 12.3.3.1 during such period.

#### 12.4. Effect of Termination.

**12.4.1.** *Termination of Rights.* Upon termination by BioLine pursuant to Section 12.3.1, 12.3.2 or 12.3.3 hereof, or by Licensor pursuant to Sections 12.3.2 or 12.3.3 hereof (except in the circumstances set out in Section 12.3.3.2): (a) the rights and licenses granted to BioLine under Section 2 shall terminate; (b) all rights in and to the Licensed Technology shall revert to Licensor and BioLine shall not be entitled to make any further use whatsoever of the Licensed Technology nor shall BioLine research, develop, manufacture, use, market, distribute, offer for sale, sell, export or import Licensed Products and/or provide services relating thereto; and (c) any existing agreements that contain a sublicense of the Licensed Technology shall terminate to the extent of such sublicense; *provided, however*, that, for each Sublicensee, upon termination of the sublicense agreement with such Sublicensee, Licensor shall be obligated, at the request of such Sublicensee, to enter into a new license agreement with such Sublicensee on substantially the same terms as those contained in such Sublicense agreement and *provided further* that such terms shall be amended, if necessary, to the extent required to ensure that such sublicense agreement does not impose any obligations or liabilities on Licensor which are not included in this Agreement.

**12.4.2** Transfer of Development Results. In the event BioLine terminates this Agreement pursuant to Section 12.3.1 or Licensor terminates this Agreement pursuant to Sections 12.3.2 or 12.3.3 hereof (except in the circumstances set out in Section 12.3.3.2), BioLine shall promptly transfer and assign to Licensor all Development Results and all right, title and interest therein; *subject, however*, to any conditions preventing or governing such transfer and assignment set out in the applicable laws and regulations governing the Grants received by BioLine and used in generation of the Development Results, ("Grant Transfer Conditions"), in which case BioLine will not be required to transfer and assign the Development Results as contemplated above *unless and until* Licensor either (i) agrees in writing to assume all obligations required by the Grant Transfer Conditions, or (ii) reaches another arrangement with the grantors of the Grants which absolves BioLine of any liability to such grantors with respect to the transfer and/or assignment of the Development Results. In the event that the Development Results are transferred and assigned to Licensor as set out above, BioLine shall receive a perpetual carried interest in the commercial proceeds of the exploitation of the Licensed Technology as follows: [\*\*\*]

**12.4.3.** *Accruing Obligations.* Termination of this Agreement shall not relieve the parties of obligations occurring prior to such termination, including obligations to pay amounts accruing hereunder up to the date of termination.

**12.5. Survival.** The parties' respective rights, obligations and duties under Sections 8, 10.2, 10.4, 11, 12 and 13, as well as any rights, obligations and duties which by their nature extend beyond the expiration or termination of this Agreement, shall survive any expiration or termination of this Agreement.

# 13. Miscellaneous.

**13.1. Entire Agreement.** This Agreement (together with all schedules and exhibits attached hereto, which constitute an integral part of the Agreement) is the sole agreement with respect to the subject matter hereof and, except as expressly set forth herein, supersedes all other agreements and understandings between the parties with respect to same.

**13.2. Notices.** Unless otherwise specifically provided, all notices required or permitted by this Agreement shall be in writing and may be delivered personally, or may be sent by facsimile or certified mail, return receipt requested, to the following addresses, unless the parties are subsequently notified of any change of address in accordance with this Section 13.2:

If to BioLine:

BioLine Innovations Jerusalem, LP 19 Hartum Street P.O. Box 45158 Jerusalem 91450 Israel Attention: VP Finance, BioLineRx, Ltd. Fax: 972-2-548-9101

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

With a copy (which shall not constitute notice) to:	Yigal Arnon & Co., Law Offices 22 Rivlin Street Jerusalem, 94263 Israel Attention: Barry Levenfeld, Adv. Fax: 972-2-623-9236
If to the Licensor:	Innovative Pharmaceutical Concepts (IPC) Inc. Geneva Place, 2nd Floor, 333 Waterfront Drive P.O. Box 3339, Road Town, Tortola British Virgin Islands Attention: Dr. P. Burstein Fax: 972-3-540-2779
With a copy (which shall not constitute notice) to:	Yoram L. Cohen, Ashlagi, Fisher, Eshel – Law Offices 2 Weizman Street Tel-Aviv, 64239 Israel Attention: Zvi Fisher, Adv. Fax: 972-3-693-1919 Email: zvi@caflaw.co.il

Any notice shall be deemed to have been received as follows: (i) by personal delivery, upon receipt; (ii) by facsimile or email, receipt confirmed, one business day after transmission or dispatch; (iii) by airmail, three (3) business days after delivery to the postal authorities by the party serving notice.

**13.3. Governing Law and Jurisdiction.** This Agreement shall be governed by and construed in accordance with the laws of the State of Israel, without regard to the application of principles of conflicts of law, except for matters of patent law, which, other than for matters of inventorship on patents, shall be governed by the patent laws of the relevant country of the patent. The parties hereby consent to personal jurisdiction in Tel Aviv, Israel and agree that any lawsuit they file to enforce their respective rights under this Agreement shall be brought in the competent court in Tel Aviv.

**13.4. Binding Effect.** This Agreement shall be binding upon and inure to the benefit of the parties and their respective legal representatives, successors and permitted assigns.

13.5. Headings. Section and subsection headings are inserted for convenience of reference only and do not form a part of this Agreement.

**13.6. Counterparts.** This Agreement may be executed simultaneously in two or more counterparts, each of which when taken together shall constitute one and the same instrument.

**13.7. Amendment; Waiver.** This Agreement may be amended, modified, superseded, and any of the terms may be waived, only by a written instrument executed by each party or, in the case of waiver, by the party waiving compliance. The delay or failure of any party at any time or times to require performance of any provisions hereof shall in no manner affect the rights at a later time to enforce the same. No waiver by either party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

**13.8. No Agency or Partnership.** The parties to this Agreement are independent contractors. Nothing contained in this Agreement shall give any party the right to bind another, or be deemed to constitute either parties as agents for each other or as partners with each other or any third party.

**13.9. Assignment and Successors.** This Agreement may not be assigned by either party without the consent of the other, which consent shall not be unreasonably withheld, except that each party may, without such consent, assign this Agreement and the rights, obligations and interests of such party, in whole or in part, to any of its Affiliates, to any purchaser of all or substantially all of its assets or research to which the subject matter of this Agreement relates, or to any successor corporation resulting from any merger or consolidation of such party with or into such corporation.

**13.10.** Force Majeure. Neither party will be responsible for delays resulting from causes beyond the reasonable control of such party, including without limitation, regulatory delay, fire, explosion, flood, war, strike, or riot, provided that the non-performing party uses commercially reasonable efforts to avoid or remove such causes of non-performance and continues performance under this Agreement with reasonable dispatch whenever such causes are removed.

**13.11. Interpretation.** The parties hereto acknowledge and agree that: (i) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting party shall not be employed in the interpretation of this Agreement; and (iii) the terms and provisions of this Agreement shall be construed fairly as to both parties hereto and not in favor of or against either party, regardless of which party was generally responsible for the preparation of this Agreement.

**13.12. Severability.** If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, such provision or provisions shall be reformed to approximate as nearly as possible the intent of the parties, and it is the intention of the parties that the remainder of this Agreement shall not be affected.

[Remainder of page intentionally left blank]

# [Signature page to License Agreement]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Innovative Pharmaceutical Concepts (IPC) Inc.	BioLine Innovations Jerusalem L.P. By its General Partner: BioLine Innovations Jerusalem Ltd.			
By: <u>/s/ P. Burstein</u>	By: <u>/s/ Morris Laster</u> /s/ Allon Reiter			
Name: <u>Dr. Pinchas Burstein</u>	Name:			
Title: <u>Director</u>	Title:			
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# Exhibit A Patents and/or Patent Applications

# [\*\*\*]

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

Development Plan										
ID	Task Name	Start	Finish	Cost	2005	2006	2007	2008	2009	2010
[***]										
[***] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.										

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<u>Exhibit B</u>

**Development Plan** 

# [\*\*\*]

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

# CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. ASTERISKS DENOTE OMISSIONS.

# AMENDED AND RESTATED

# LICENSE AND COMMERCIALIZATION AGREEMENT

# BY AND AMONG

# IKARIA DEVELOPMENT SUBSIDIARY ONE LLC

AND

BIOLINERX LTD.

AND

# BIOLINE INNOVATIONS JERUSALEM L.P.

AUGUST 26, 2009

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# AMENDED AND RESTATED LICENSE AND COMMERCIALIZATION AGREEMENT

This Amended and Restated License and Commercialization Agreement (the "<u>Agreement</u>") is entered into this 26<sup>th</sup> day of August, 2009, by and among **Ikaria Development Subsidiary One LLC**, a Delaware limited liability company having a principal place of business at 6 State Route 173, Clinton, NJ 08809, USA ("<u>Ikaria</u>"), **BioLineRx Ltd.**, a corporation organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel ("<u>BioLineRx Ltd.</u>"), and **BioLine Innovations Jerusalem L.P.**, a limited partnership organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel ("BioLineRx Ltd."), and **BioLine Innovations Jerusalem L.P.**, a limited partnership organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel ("BioLineRx").

# **INTRODUCTION**

WHEREAS, BioLineRx owns or controls certain intellectual property rights covering a liquid polymer composed of Sodium Alginate and Ca-D-Gluconate (designated by BioLineRx as "BL-1040");

WHEREAS, BioLineRx is currently developing the Product (as defined below) as a medical device for the direct treatment of cardiac tissue following acute myocardial infarction;

WHEREAS, BioLineRx is concluding the safety and clinical trials of the Product that were initiated by BioLineRx prior to the Effective Date (as defined below);

WHEREAS, BioLineRx desires to grant to Ikaria the worldwide exclusive rights to Develop, Manufacture, and Commercialize Products (as such capitalized terms are defined below); and

WHEREAS, Ikaria desires to obtain such exclusive rights in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, BioLineRx and Ikaria agree as follows:

# Article I Definitions; Interpretation

When used in this Agreement, each of the following capitalized terms has the meaning set forth in this Article I:

Section 1.1 "<u>Affiliate</u>" shall mean, with respect to a Party, any Person that controls, is controlled by, or is under common control with such Party. For purposes of this Section 1.1, "control" shall refer to (a) in the case of a Person that is a corporate entity, direct or indirect ownership of more than fifty percent (50%) of the stock, shares or membership units having the right to vote for the election of a majority of the directors of such Person, and (b) in the case of a Person that is an entity, but is not a corporate entity, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

Section 1.2 "<u>BGN License Agreement</u>" shall mean that certain License Agreement, dated January 10, 2005, as amended, by and among BioLine Jerusalem L.P. and B.G. Negev Technologies and Applications Ltd. ("<u>BGN</u>") on behalf of Ben Gurion University.

Section 1.3 "<u>BioLineRx Know-How</u>" shall mean all Know-How that is (a) necessary or useful for the Development, Manufacture, or Commercialization of any Product and (b) either (i) is Controlled by BioLineRx as of the Effective Date or (ii) BioLineRx comes to Control during the term of this Agreement.

Section 1.4 "BioLineRx Patent Rights" shall mean Patent Rights that claim or disclose BioLineRx Know-How, including the Patent Rights listed in Exhibit B.

Section 1.5 "<u>BioLineRx Intellectual Property</u>" shall mean BioLineRx Patent Rights (including Patent Rights in the Sublicensed IP), and BioLineRx Know-How (including Know-How in the Sublicensed IP).

Section 1.6 "Business Day" shall mean a day that is not a Saturday, a Sunday or a day on which banking institutions in New York, New York, USA are authorized by law to remain closed.

Section 1.7 "<u>Commercialization</u>" or "<u>Commercialize</u>" shall mean any activities directed to marketing, promoting, distributing, importing, exporting, or selling a product.

Section 1.8 "<u>Commercially Reasonable Efforts</u>" shall mean the efforts, expertise and resources normally used by a Party to Develop, Manufacture and Commercialize a product owned by it or to which it has rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety and efficacy, product profile, difficulty in developing the product, competitiveness of the marketplace for the product, the proprietary position of the product, the regulatory structure involved, the availability and level of reimbursement for such treatment by Third Party payors or health insurance plans, the potential total profitability of the applicable product(s) marketed or to be marketed and other relevant factors affecting the cost, risk and timing of Development and the total potential reward to be obtained if a product is Commercialized. The Parties agree that Commercially Reasonable Efforts shall require a Party to expend efforts, expertise and resources that such Party would normally expend to Develop, use, Manufacture and Commercialize a product owned by it or to which it has rights, taking into account the foregoing factors.

Section 1.9 "<u>Confidential Information</u>" shall mean, with respect to a disclosing Party, all Know-How or other information (whether or not patentable) regarding such Party's technology, products, business information or objectives (whether disclosed before or after the Effective Date) that is of a confidential and proprietary nature, including reports and audits under Section 4.3, the Development Plan, the Commercialization Plan, the terms of this Agreement, and all proprietary tangible materials (and data and information associated therewith) of such Party. Notwithstanding the foregoing, Confidential Information shall not include Know-How or other information that:

(a) was rightfully known or used by the receiving Party or its Affiliates without an obligation of confidentiality prior to its date of disclosure to the receiving Party as demonstrated by contemporaneous written records; or

(b) either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party or its Affiliates by sources other than the disclosing Party rightfully in possession of such information and not bound by confidentiality obligations to the disclosing Party; or

(c) either before or after the date of the disclosure to the receiving Party or its Affiliates is or becomes published or otherwise is or becomes part of the public domain through no breach hereof on the part of the receiving Party or its Affiliates; or

(d) is independently developed by or for the receiving Party or its Affiliates without reference to or use of the Confidential Information of the disclosing Party as demonstrated by contemporaneous written records.

Section 1.10 "<u>Control</u>" shall mean the legal authority or right of a Party or its Affiliates to grant a license or sublicense of intellectual property rights to the other Party, or to provide tangible material to or otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party. For the avoidance of doubt, BioLineRx Controls the Sublicensed IP.

Section 1.11 "<u>Cover</u>" or "<u>Covered</u>" shall mean, with respect to a Patent Right and a product, that, in the absence of ownership of (with a retained right to exploit), or a license granted under, a Valid Claim included in such Patent Right, the Manufacture, Development, Commercialization, use, sale, import, or offer for sale, as applicable, of such product would infringe such Valid Claim in the country where such activity occurs.

Section 1.12 "<u>Development</u>" or "<u>Develop</u>" shall mean development activities, including test method development and stability testing, toxicology, formulation, optimization, quality assurance/quality control development, statistical analysis, clinical studies, regulatory affairs, product approval, and registration.

Section 1.13 "Development Term" shall mean the term of development of Products by Ikaria.

Section 1.14 "EU" shall mean the European Union and all the member states thereof, as it may be comprised from time to time.

Section 1.15 "<u>EU Milestone Conditions</u>" shall mean (a) satisfaction of all requirements for [\*\*\*], (b) [\*\*\*] set forth therein, **and** (c) [\*\*\*].

[\*\*\*] Redacted pursuant to a confidential treatment request.

Section 1.16 "Executive Officers" shall mean the Chief Executive Officer of Ikaria (or a senior executive officer of Ikaria designated by Ikaria) and the Chief Executive Officer of BioLineRx (or a senior executive officer of BioLineRx designated by BioLineRx).

Section 1.17 "FDA" shall mean the United States Food and Drug Administration or any successor agency thereof.

Section 1.18 "Field" shall mean any and all uses described or claimed in the BioLineRx Patent Rights.

Section 1.19 "<u>First Commercial Sale</u>" shall mean, with respect to a Product in a country, the first commercial sale of such Product by Ikaria, its Affiliates, distributors, agents or Licensees in such country. Sales for clinical trial purposes or compassionate or similar use shall not be considered to constitute a First Commercial Sale.

Section 1.20	Intentionally Omitted
Section 1.21	Intentionally Omitted
Section 1.22	Intentionally Omitted
Section 1.23	Intentionally Omitted.
Section 1.24	Intentionally Omitted."

Section 1.25 "<u>Know-How</u>" shall mean any tangible or intangible know-how, expertise, information, inventions, discoveries, documents and other works of authorship, copyrights, trade secrets, data, or materials, whether proprietary or not, including ideas, concepts, formulas, methods, procedures, designs, technologies, compositions, plans, applications, technical data, data generated in clinical trials, samples, chemical compounds and biological materials and all derivatives, modifications and improvements thereof.

Section 1.26 "<u>Knowledge</u>" shall mean, with respect to a Party, the Party's actual knowledge together with any knowledge of any of the Party's officers or director-level employees, that a Person in such party's position would be expected to obtain given the exercise of reasonably prudent scientific and business diligence in accordance with the standards of companies of such Party's size in such Party's industry.

Section 1.27 "<u>Licensee</u>" shall mean any Person to whom Ikaria licenses its rights under this Agreement in the manner provided in Section 2.1, including any Third Party contractors.

Section 1.28 "<u>Manufacturing</u>" or "<u>Manufacture</u>" shall mean any activities associated with the production, manufacture, supply, processing, filling, packaging, labeling, shipping, or storage of a product or any components thereof, including process and formulation development, process validation, stability testing, manufacturing scale-up, development and commercial manufacture and analytical development, product characterization, quality assurance and quality control development, testing, and release.

Section 1.29 "<u>Net Sales</u>" shall mean, with respect to a Product, the gross amounts billed by Ikaria, its Affiliates, or Licensees in respect of sales of such Product by Ikaria and its Affiliates or Licensees to unrelated Third Parties, in each case less the following deductions:

(a) Trade, cash, or quantity discounts (including amounts incurred in connection with government mandated rebate programs) actually allowed and taken with respect to such sales;

(b) Tariffs, duties, excises, sales taxes or other taxes imposed upon and paid with respect to the production, sale, delivery, or use of the Product (excluding national, state, or local taxes based on income);

(c) Amounts repaid or credited by reason of billing corrections, rejections, defects, recalls, or returns (due to spoilage, damage, expiration of useful life or otherwise) or because of chargebacks, refunds or retroactive price reductions and allowances for wastage replacement and bad debts;

(d) Portions of invoices sales amounts included in Net Sales in prior periods that are actually written off by Ikaria, its Affiliates, or licenses as uncollectible; and

(e) Postage, freight, shipping, insurance, and other transportation related charges incurred in shipping a Product to Third Parties.

Such amounts shall be determined from the books and records of Ikaria, its Affiliates, or Licensees, maintained in accordance with generally accepted accounting principles, consistently applied. For the avoidance of doubt, in no event will fines, penalties or other monetary damages assessed against Ikaria, its Affiliates or Licensees by any governmental authority for violation of any applicable law, result in an appropriate deduction to Net Sales.

If one or more Products is sold as part of a Combination Product (as defined below), the Net Sales from the Combination Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales (as determined above) of the Combination Product, during the applicable royalty reporting period, by the fraction, A/(A+B), where A is the average sale price of the Product(s) when sold separately in finished form and B is the average sale price of the other components included in the Combination Product when sold separately in finished form, in each case in the applicable country during the applicable royalty reporting period or, if sales of both the Product(s) and the other components did not occur in such country in such period, then in the most recent royalty reporting period in which sales of both occurred. If such average sale price cannot be determined for both the Product(s) and all other components included in such Combination Product. Net Sales for the purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the fraction of C/(C+D) where C is the fair market value of the Product(s) and D is the fair market value of all other components included in the Combination Product. In such event, the Parties shall negotiate in good faith to arrive at a determination of the respective fair market values of the Product(s) and all other components included in the Combination Product. If the Parties are unable to agree on such determination within sixty (60) days, then such matter shall be resolved as provided in Article IX.

As used above, the term "<u>Combination Product</u>" means any therapeutic medical product that includes both (i) one or more Product(s) and (ii) other component(s).

Section 1.30 "<u>On-Going Phase I/II Trial</u>" shall mean that certain clinical trial of a Product that was initiated by BioLineRx prior to and that is ongoing as of the Effective Date, the protocol for which is attached hereto as <u>Schedule 1.30</u>.

Section 1.31 "Other On-Going Trials" shall mean those pre-clinical and CMC trials (other than the On-Going Phase I/II Trial) that were initiated by BioLineRx prior to, and that are ongoing as of, the Effective Date, descriptions of which are attached hereto as <u>Schedule 1.31</u>.

Section 1.32 "Party" shall mean BioLineRx or Ikaria; "Parties" shall mean BioLineRx and Ikaria.

Section 1.33 "<u>Patent Rights</u>" shall mean United States and foreign patents and patent applications (including provisional applications) and all substitutions, divisionals, continuations, continuations-in-part, reissuances, reexaminations, registrations, renewals, confirmations, supplementary protection certificates and extensions thereof.

Section 1.34 "<u>Person</u>" shall mean any natural person or any corporation, company, partnership, joint venture, firm, university, other entity, governmental authority, or subdivision thereof.

Section 1.35 "<u>Pivotal Clinical Trial</u>" shall mean a randomized, controlled clinical trial of a Product designed to demonstrate statistically significant clinical efficacy and safety in human patients (in conjunction with performance of a therapeutic procedure) pursuant to a clinical study agreed with the FDA, which trial the FDA accepts as a pivotal clinical trial necessary for Regulatory Approval of such Product. An outline of the structure of the initial Pivotal Clinical Trial is attached as <u>Schedule 1.35</u>.

Section 1.36 "<u>Primary Indication</u>" shall mean the diagnosis, prevention, mitigation, or treatment of injury to myocardial tissue via the administration of a Product to a human patient.

Section 1.37 "<u>Product</u>" shall mean a liquid polymer composed of Sodium Alginate and Ca-D-Gluconate (designated by BioLineRx as "BL-1040"), or any back-ups or second-generation polymers or polymer combinations thereof that is Developed under the Development Program.

Section 1.38 "<u>Regulatory Approval</u>" shall mean, with respect to a jurisdiction, the approval of the applicable Regulatory Authority required to market and sell a Product in such jurisdiction. For clarity, Regulatory Approval for a Product shall occur:

(a) in the United States, on the date when the FDA approves a Premarket Approval (PMA) application;

(b) in Europe, on the date when such Product may first be placed on the market as a medical device (as such terms are defined in Art. 1 Paragraphs 2(a) and (h) of Directive 93/42/EEC, as amended) bearing the CE marking according to Art. 17 of Directive 93/42/EEC, as amended, in any member state of the EU; and

(c) in Japan, on the date when the Ministry of Health approves a marketing authorization.

Section 1.39 "<u>Regulatory Authority</u>" shall mean any national (*e.g.*, the FDA), supra-national or other regulatory agency or governmental entity involved in the granting of Regulatory Approval for, or in the regulation of human clinical studies of, therapeutic medical devices.

Section 1.40 "<u>Royalty Term</u>" shall mean, with respect to a Product in a country of the Territory, the period of time commencing on the First Commercial Sale of such Product in such country and ending upon the earlier of (a) the expiration of the last-to-expire Valid Claim in the BioLineRx Patent Rights that Covers the sale or use of such Product in the Field in such country, or (b) the date of a judicial determination from which no appeal can be taken of invalidity of a set of claims in the BioLineRx Patent Rights that Cover the sale or use of such Product in the Field in such country and that are asserted through litigation (whether in an infringement action, a declaratory judgment action, or otherwise) to exclude a Third Party from selling or using a product in the Field in such country.

Section 1.41 "Sublicensed IP" shall mean that portion of the BioLineRx Intellectual Property licensed to BioLineRx pursuant to the BGN License Agreement.

Section 1.42 "Successful Completion" shall mean:

(a) with respect to the On-Going Phase I/II Trial, no treatment-related safety findings during the treatment period and the six (6) month follow up period, that were considered by the Independent Safety Monitoring Board for the On-Going Phase I/II Trial (in accordance with and subject to the Independent Safety Monitoring Board Charter attached hereto as Schedule 1.42(a)) to be of sufficient concern to discontinue the On-Going Phase I/II Trial;

(b) with respect to the Interim Analysis of the Pivotal Clinical Trial/Phase IIb Proof of Concept, safety and efficacy data from completion of all patients at the [\*\*\*] follow up demonstrates more than a [\*\*\*]probability of meeting pre-specified endpoints at [\*\*\*] in the Pivotal Clinical Trial, and no apparent safety signal in the treatment group for the entire cohort at all times;

(c) with respect to the Pivotal Clinical Trial for the Primary Indication, safety and efficacy data from completion of all patients at the [\*\*\*] follow up meets the primary endpoint and demonstrates a positive benefit-to-risk ratio to enable FDA submission; and

(d) with respect to all other clinical trials of a Product, that the JDC has determined that the final results of such clinical trial have achieved the success criteria established by the JDC with respect to such clinical trial.

Section 1.43 "<u>Territory</u>" shall mean the entire world.

[\*\*\*] Redacted pursuant to a confidential treatment request

Section 1.44 "Third Party" shall mean any Person other than a Party or any of its Affiliates or Licensees.

Section 1.45 "<u>Valid Claim</u>" shall mean a claim of any issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, reexamination, disclaimer, or otherwise.

Section 1.46 <u>Additional Definitions</u>. Each of the following terms is defined in the section of this Agreement indicated below:

<u>Term</u>	<u>Section</u>
" <u>Agreement</u> "	Preamble
" <u>Bankruptcy Code</u> "	Section 2.5
" <u>BGN</u> "	Section 1.2
" <u>BioLineRx</u> "	Preamble
" <u>BL-1040</u> " " <u>Breaching Party</u> ." " <u>Combination Product</u> " " <u>Commercialization Plan</u> " " <u>Competitive Infringement</u> " " <u>Effective Date</u> " " <u>Effective Date</u> " " <u>Existing Product Agreements</u> " " <u>Ikaria</u> "	Section 1.37 Section 8.2 Section 1.29 Section 3.7 Section 5.3(a) Section 2.1 Section 2.3 Preamble
" <u>Development Plan</u> "	Section 3.1
" <u>Development Program</u> "	Section 3.1
" <u>Force Majeure Event</u> "	Section 10.7
" <u>Indemnified Party</u> "	Section 10.1(c)
" <u>Indemnifying Party</u> "	Section 10.1(c)
" <u>Invalidity Claim</u> "	Section 5.3(d)
" <u>Joint Development Committee</u> " or " <u>JDC</u> "	Section 3.2
"Joint Manufacturing Committee" or "JMC"	Section 3.6(c)
"Lead Party"	Section 5.3(e)
"Losses"	Section 10.1(a)
"New Indication"	Section 2.4
"New Indication Invention"	Section 5.1(a)
"Non-Breaching Party"	Section 8.2
"OCS"	Section 2.1
"SEC"	Section 6.1
"Severed Clause"	Section 10.11
" <u>Technology Exchange</u> "	Section 3.5

#### <u>Term</u>

## "<u>Technology Exchange Plan</u>" "<u>Third Party Payment</u>"

#### Section

Section 3.5 Section 4.2(b)

Section 1.47 Interpretation. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine, and neuter forms. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation". The word "will" shall be construed to have the same meaning and effect as the word "shall". The word "or" shall be construed to have the same meaning and effect as "and/or". This Agreement has been prepared jointly with the assistance of counsel and shall not be strictly construed against either Party. The captions or headings of the sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and shall have no effect on the meaning of the provisions hereof. Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument, or other document herein shall be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements, or modifications set forth herein or therein), (b) any reference to any laws herein shall be construed as referring to any law, statute, rule, regulation, ordinance, or other pronouncement having the effect of law of any federal, national, multinational, state, provincial, county, city, or other political subdivision, domestic or foreign, as they from time to time may be enacted, repealed, or amended, (c) any reference herein to any Person shall be construed to include the Person's successors and assigns, (d) the words "herein", "hereof", and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) any reference herein to the words "mutually agree" or "mutual written agreement" shall not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as such Party may determine in such Party's sole discretion, and (f) all references herein to Articles, Sections, Exhibits, or Schedules shall be construed to refer to Articles, Sections, Exhibits, and Schedules of this Agreement.

#### Article II <u>Grant of Rights</u>

BioLineRx License Grant to Ikaria; Consent of OCS. Subject to the terms and conditions of this Agreement, including the consent of the Section 2.1 Office of the Chief Scientist of the State of Israel ("OCS"), BioLineRx hereby grants to Ikaria the exclusive, royalty-bearing right and license in the Territory under the BioLineRx Intellectual Property (including, for clarity, a sublicense under the Sublicensed IP) to Develop, Manufacture and Commercialize Products for use in the Field. Subject to the consent of BioLineRx, which consent shall not be unreasonably withheld, conditioned or delayed, the foregoing license includes the right to grant sublicenses under the BioLineRx Intellectual Property, provided that, with respect to sublicenses granted under the Sublicensed IP, Ikaria shall (a) grant such sublicenses only for consideration and at arm's-length transactions, and (b) grant such sublicenses only pursuant to written agreements that contain such terms and conditions as may be required for Ikaria to comply with this Agreement. BioLineRx shall use its best efforts to obtain the written consent of the OCS to this Agreement within [\*\*\*] days after August 26<sup>th</sup>, 2009, which consent must be in a form that is satisfactory to each Party. If the OCS has still not provided such consent during such [\*\*\*] days, Ikaria shall have the right to require BioLineRx to continue to use best efforts to obtain such consent within the subsequent [\*\*\*] day period. In addition, (i) Ikaria shall have the right to have a representative present at all interactions between BioLineRx's representatives and the OCS relating to such consent, (ii) BioLineRx shall (A) provide Ikaria with a reasonable opportunity to review and approve the request for consent submitted to the OCS and (B) keep Ikaria fully informed as to the progress of such request for consent and shall consult with Ikaria in good faith with respect thereto, (iii) BioLineRx shall not engage in any activities or discussions with any Third Party relating to the subject matter of this Agreement, including pursuing any other transactions relating to the BioLineRx Intellectual Property, without Ikaria's consent, and (iv) Ikaria shall have the right, prior to the Effective Date, to unilaterally modify this Agreement to comply with the specific, formal, written requests of the OCS, provided that such modifications have no detrimental financial impact on BioLineRx under this Agreement. Notwithstanding BioLineRx's obligation to exercise best efforts to obtain the consent from the OCS as described above. BioLineRx shall not be required to (v) agree to any request by the OCS that would require BioLineRx to pay to the OCS an aggregate amount of more than [\*\*\*] or (z) obtain a consent based on the characterization of this Agreement as a "transfer of know-how outside of Israel" under Section 19B of the Israeli Law for the Encouragement of Industrial Research & Development, 1984. Notwithstanding anything herein to the contrary, subject to Section 8.6, the provisions of this Agreement other than this Section 2.1, Section 2.2, Article VII, Section 8.6 and Article X shall not be effective until such consent has been obtained and each Party has delivered the certificate set forth in Section 7.8 (the "Effective Date").

Section 2.2 <u>Non-Competition</u>. During the term of this Agreement, BioLineRx shall not, within the Territory, directly or indirectly (including through its Affiliates), conduct research or discovery activities, Develop, Manufacture (except as set forth in Section 3.6), Commercialize, or grant any rights or options or provide assistance to any Third Party to conduct research or discovery activities, Develop, Manufacture (except as set forth in Section 3.6) or Commercialize, (a) the Product or (b) any compound, substance, polymer, or product (whether pharmaceutical or device in nature) the method of action or effect of which is similar to any Product.

Section 2.3 <u>Existing Product Agreements</u>. BioLineRx hereby agrees that, upon the written request of Ikaria, BioLineRx shall assign to Ikaria each of the agreements listed in <u>Schedule 2.3</u> attached hereto (the "<u>Existing Product Agreements</u>"), and all of its rights, title, and interest therein. BioLineRx shall cooperate with Ikaria, including by executing and recording documents, as may be necessary to effectuate such assignments and the exercise by Ikaria of its rights under the Existing Product Agreements.

Section 2.4 Intentionally Omitted.

[\*\*\*] Redacted pursuant to a confidential treatment request.

Section 2.5 <u>Section 365(n) of the Bankruptcy Code</u>. All rights and licenses granted under or pursuant to any Section of this Agreement, including under this Article II and with respect to any BioLineRx Intellectual Property subject to Technology Exchange under Section 3.5, are rights to "intellectual property" (as defined in Section 101(35A) of Title 11 of the United States Code (such Title, the "<u>Bankruptcy Code</u>")). Each of Ikaria and BioLineRx hereby acknowledges "embodiments" of such intellectual property for purposes of Section 365(n) of the Bankruptcy Code shall include (a) copies of research data, (b) laboratory samples, (c) product samples, (d) formulas, (e) laboratory notes and notebooks, (f) data and results related to clinical studies, (g) regulatory filings and approvals, (h) rights of reference in respect of regulatory filings and approvals, (i) research data and results, and (j) marketing, advertising, and promotional materials, in each case, that relate to such intellectual property. Each Party shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code or analogous legislation in any other jurisdiction. Upon the institution by or against BioLineRx of any assignment for the benefit of creditors, composition, or any bankruptcy, reorganization, arrangement, insolvency, or similar proceedings under the laws of any jurisdiction, Ikaria shall further be entitled to a complete duplicate of, or complete access to, as appropriate, any such intellectual property (including embodiments thereof), and such intellectual property and embodiments, if not already in its possession, shall be promptly delivered to Ikaria, unless BioLineRx elects to continue, and continues, to perform all of its obligations under this Agreement.

Section 2.6 <u>Retained Rights</u>. Except as otherwise specifically provided for in this Agreement, each Party retains all rights and licenses to exploit its own intellectual property.

#### Article III <u>Development; Manufacturing; Commercialization</u>

Section 3.1 <u>General</u>. Ikaria shall be solely responsible for conducting and funding all Development activities pursuant to the Development Plan, and shall have the sole right to Develop, Manufacture, and Commercialize Products in the Field in the Territory. Subject to its obligations under Section 3.8, Ikaria shall prepare a non-binding plan (the "<u>Development Plan</u>") for the Development of Product(s) (the "<u>Development Program</u>"). The Development Plan shall include an estimated budget setting forth Ikaria's anticipated development costs. Ikaria shall provide BioLineRx with a copy of its then-current Development Plan at least [\*\*\*] per year, but no later than [\*\*\*]days following the beginning of each year. The initial Development Plan is attached hereto as Schedule 3.1, which shall be non-binding, including any timelines or milestones that may be included therein. In addition, Ikaria shall, within [\*\*\*] days after the Effective Date, provide BioLineRx with a revised draft protocol for the Interim Analysis of the Pivotal Clinical Trial/Phase IIb Proof of Concept and the Pivotal Clinical Trial, after taking into account any comments BioLineRx may wish to provide based on the initial draft of the protocol attached hereto as Schedule 1.35, that would include modifications designed to maximize the likelihood of obtaining reasonable reimbursement for one or more Products in any one or more of the following countries: [\*\*\*]. Upon the Successful Completion of the Interim Analysis of the Pivotal Clinical Trial/Phase IIb Proof of Concept, or, failing that, upon the Successful Completion of the Pivotal Clinical Trial, kereafter, submit a formal written request for a reimbursement price for one or more Product(s) to the applicable governmental agency in one or more of the following countries: [\*\*\*].

#### [\*\*\*] Redacted pursuant to a confidential treatment request.

#### Section 3.2 Joint Development Committee.

(a) The Parties shall establish a Joint Development Committee (the "Joint Development Committee" or "JDC"), comprised of [\*\*\*] representatives of Ikaria and [\*\*\*] representatives of BioLineRx, to oversee the Development of Products. Each Party shall make its initial designation of its representatives not later than [\*\*\*] days after the Effective Date. Each Party may change any one or more of its representatives to the Joint Development Committee at any time upon notice to the other Party.

(b) The JDC shall meet at least [\*\*\*] during the Development Term or more or less frequently as the JDC may agree. The JDC may meet in person or by means of a telephone or video conference call. One meeting of the JDC per year shall be held in person at Ikaria's headquarters in Clinton, NJ and one meeting of the JDC per year shall be held in person at BioLineRx's headquarters in Israel, provided, that the Parties' representatives may participate in person, via telephone, or video conference in their discretion. Each Party shall use reasonable efforts to cause its representatives to attend the meetings of the JDC. If a representative of a Party is unable to attend a meeting, such Party may designate an alternate to attend such meeting in place of the absent representative. Each Party shall bear its own costs with respect to its participation on the JDC. Prior to every meeting of the JDC, Ikaria will provide to the JDC detailed reports describing Ikaria's current clinical and development activities and plans.

(c) The JDC shall be the vehicle by which BioLineRx may offer insight and guidance to Ikaria with respect to (i) establishing the Development Plan setting forth the Development Program's objectives and the activities to be conducted, (ii) reviewing and updating the Development Plan from time to time, (iii) monitoring the progress and results of the Development Program, (iv) determining future Development Program activities, including Development activities relating to Manufacturing, to be conducted during the Development Term, and (v) establishing success criteria for the clinical trials (other than those for which success criteria are set forth in this Agreement), and determining whether the results of such clinical trials have achieved the applicable success criteria.

(d) The JDC shall only act unanimously, with each Party given one (1) vote regardless of the number of representatives. If, however, the JDC is unable to reach agreement with respect to any matter within [\*\*\*] days, the matter shall be referred to the Parties' respective Executive Officers for resolution. If the Executive Officers are not able to resolve any such matter by consensus within [\*\*\*] days following referral, Ikaria's Executive Officer shall have the right to decide the matter taking into account Ikaria's obligation to use Commercially Reasonable Efforts under Section 3.8.

#### [\*\*\*] Redacted pursuant to a confidential treatment request.

Notwithstanding anything in this Section 3.2, neither Party shall have a unilateral right to resolve any dispute involving the breach or alleged breach of this Agreement, to amend or modify this Agreement or the Parties' respective rights and obligations hereunder or, except as expressly provided in this Section 3.2, any Development Plan or the Parties' respective rights and obligations thereunder.

Section 3.3 <u>On-Going Trials</u>. BioLineRx shall retain control of, bear all costs relating to the On-Going Phase I/II Trial and the Other On-Going Trials, and shall exercise Commercially Reasonable Efforts to continue and complete the On-Going Phase I/II Trial and the Other On-Going Trials, which shall be managed by BioLineRx. BioLineRx may modify the On-Going Phase I/II Trial and the Other On-Going Trials, including any changes to the protocols therefor, only with the prior written consent of Ikaria, which consent shall not be unreasonably withheld, conditioned or delayed.

Section 3.4 <u>Regulatory Matters</u>. Ikaria shall prepare and submit all filings with Regulatory Authorities relating to Products, which filings shall be in Ikaria's name, <u>provided that</u> Ikaria shall provide BioLineRx [\*\*\*] days prior notice to enable BioLineRx to review and provide any comments on such submissions. With respect to regulatory matters concerning Products, BioLineRx shall cooperate with Ikaria in the preparation and support of each application for Regulatory Approval and shall provide Ikaria with such reasonable assistance as Ikaria may request. For example, upon Ikaria's request, BioLineRx shall describe the materials in sufficient and reasonable detail as requested by Ikaria, the Manufacturing techniques and other appropriate characteristics of Products (and the components thereof), and provide Ikaria with such other information related to the Products, including materials, chemistry, Manufacturing, technical dossier and controls data, batch records, analytical and quality control, device master files (if applicable), data from the On-Going Phase I/II Trial or Other On-Going Trials, or other information as Ikaria may reasonably request.

#### Section 3.5 <u>Technology Exchange</u>.

(a) As soon as reasonably practicable after Ikaria's written request, BioLineRx shall complete the activities assigned to BioLineRx as set forth on the technology exchange plan attached hereto as <u>Exhibit A</u> (the "<u>Technology Exchange Plan</u>"), to effect the transfer to Ikaria (or Ikaria's designee(s)) of all embodiments of and information relating to BioLineRx Intellectual Property reasonably necessary for the exercise of Ikaria's rights under the license granted pursuant to Section 2.1, including the Manufacturing of Products ("<u>Technology Exchange</u>"). BioLineRx shall make available to Ikaria (or Ikaria's designee(s)) such number of technical personnel as may be set forth in the Technology Exchange Plan to answer any questions or provide instruction as reasonably requested by Ikaria (or Ikaria's designee(s)) concerning the items delivered pursuant to this Section 3.5, in connection with the Development, Manufacture and Commercialization of Products hereunder. Each Party shall bear its own costs with respect to the Technology Exchange.

## [\*\*\*] Redacted pursuant to a confidential treatment request.

(b) The Joint Development Committee shall be responsible for coordinating the technology exchange activities under the Technology Transfer Plan. Each Party shall cooperate with the other Party in such other Party's conduct of technology exchange activities under the Technology Exchange Plan.

(c) If Ikaria desires that BioLineRx provide technology exchange services beyond the scope of the Technology Exchange Plan, BioLineRx shall provide such services on terms to be agreed upon in good faith by the Parties. Notwithstanding the foregoing, BioLineRx shall provide Ikaria with reasonable access to BioLineRx's employees and consultants involved prior to the Effective Date and during the term of this Agreement with the Development of any Product.

#### Section 3.6 <u>Manufacturing</u>.

(a) Ikaria shall be solely responsible for the Manufacture of Products for Development or for Commercialization in the Field in the Territory, which Ikaria may conduct itself or through Affiliates or Licensees.

(b) BioLineRx Ltd. shall have the option (either directly or through an Affiliate), exercisable in its sole discretion no later than [\*\*\*] months prior to the date on which Ikaria intends to file for Regulatory Approval in the U.S., to Manufacture Product pursuant to the terms of a supply agreement to be negotiated in good faith by the Parties, provided that (i) BioLineRx may exercise the foregoing option only to the extent that it has the demonstrated ability to manufacture the Product, including compliance with cGMP and all applicable laws and regulations, including those of the FDA and EMEA, (ii) BioLineRx shall bear all expenses required to establish and qualify the BioLineRx manufacturing site, including the costs of scale-up batches, process validation batches and stability batches, (iii) BioLineRx shall not be entitled to assign such option or to utilize subcontract manufacturing, and (iv) neither Party shall have any obligation to enter into such agreement unless all of the terms and conditions thereof are acceptable to both Parties. If BioLineRx Ltd. exercises such option and the Parties enter into a supply agreement, (x) Ikaria shall be required to purchase no less than twenty percent (20%) of its requirements for the Product from BioLineRx, and (y) the per unit price for the Product shall be the [\*\*\*], provided that the price shall not exceed [\*\*\*]%) of the Net Sales price per unit of Product; provided, further, that if BioLineRx at any time shall fail to supply Product on time or such supply is otherwise disrupted, the minimum purchase requirement set forth in the preceding clause (x) shall no longer apply. Any clinical supply provided to Ikaria by BioLineRx would be provided at cost.

#### [\*\*\*] Redacted pursuant to a confidential treatment request.

(c) The Parties will discuss the most efficient structure for the Manufacture and supply of Product for Development and Commercialization purposes. If the Parties determine that coordination in Manufacturing is appropriate, the Parties will establish a Joint Manufacturing Committee (the "Joint <u>Manufacturing Committee</u>" or "JMC") to coordinate Manufacturing efforts. If established, the JMC would be comprised of [\*\*\*] representatives of Ikaria and [\*\*\*] representatives of BioLineRx, to oversee the Manufacturing of Products. Each Party would make its initial designation of its representatives not later than [\*\*\*] days after the Parties agreed to establish the JMC. Each Party shall designate as its representatives individuals who have the requisite experience and knowledge to discuss the Manufacturing of Products. Each Party would be permitted to change any one or more of its representatives to the JMC at any time upon notice to the other Party.

(d) The JMC would meet at least [\*\*\*] or more or less frequently as the JMC may agree. The location of such meetings shall be as mutually agreed by the Parties. The JMC may also meet by means of a telephone or video conference call. Each Party shall use reasonable efforts to cause its representatives to attend the meetings of the JMC. If a representative of a Party is unable to attend a meeting, such Party may designate an alternate to attend such meeting in place of the absent representative. Each Party would bear its own costs with respect to its participation on the JMC.

(e) The JMC would only act unanimously. If, however, the JMC is unable to reach agreement with respect to any matter within [\*\*\*] days, the matter shall be referred to the Parties' respective Executive Officers for resolution. If the Executive Officers are not able to resolve any such matter by consensus within [\*\*\*] days following referral, Ikaria's Executive Officer shall have the right to decide the matter taking into account Ikaria's obligation to use Commercially Reasonable Efforts under Section 3.8.

Section 3.7 <u>Commercialization</u>. Ikaria shall be solely responsible for conducting, itself or through Affiliates or Licensees, the Commercialization of Products in the Field in the Territory, including (a) contracting with customers and booking sales, (b) setting the price and terms and conditions under which a Product may be sold to customers, and (c) handling of managed care accounts, and, subject to Section 1.29, Section 4.2(b), Section 5.2(d), Section 5.3(e) and Section 10.1(b), as between the Parties, Ikaria shall bear all costs associated therewith. Ikaria shall produce and update from time to time a comprehensive Commercialization plan (the "<u>Commercialization Plan</u>"), which shall include plans for Commercializing Product in each major market in which Ikaria does not then have a presence. The Commercialization Plan shall include a preliminary timeline for the initial Commercialization of Products, which is intended as a planning and informational tool and shall not constitute a binding obligation on Ikaria, and shall be subject to adjustment by Ikaria from time to time, <u>provided</u>, <u>that</u>, Ikaria shall provide BioLineRx with prior written notice of any material proposed change to a timeline. The most recent preliminary Commercialization Plan is attached hereto as <u>Schedule 3.7</u>.

Section 3.8 <u>Efforts</u>. Ikaria shall use Commercially Reasonable Efforts, either itself or through Affiliates or Licensees, (a) to Develop at least one Product in the Territory and (b) to Commercialize at least one Product in the Territory.

#### [\*\*\*] Redacted pursuant to a confidential treatment request.

## Article IV <u>Financial Provisions</u>

# Section 4.1 <u>Milestone Payments</u>.

(a) <u>Development and Regulatory Milestones</u>. With respect to each of the following milestones, Ikaria shall pay BioLineRx the corresponding payment set forth below within [\*\*\*] days after the achievement by Ikaria, its Affiliates or Licensees of such milestone:

MILESTONE	Р	AYMENT
1.Effective Date	\$	7,000,000
2.Successful Completion of On-Going Phase I/II Trial	\$	10,000,000
3.[***]		
4.[***]		
5.[***]		
6.[***]		
Total Development and Regulatory Milestone Payments	\$	132,500,000
(b) <u>Commercialization Milestones</u> . Ikaria shall pay each of the following milestone payments to BioLineRx within [***] d	lays af	ter the

(b) <u>Commercialization Milestones</u>. Ikaria shall pay each of the following milestone payments to BioLineRx within [\*\*\*] days after the achievement of such milestone:

MILESTONE	PAYMI	ENT
7. Annual Net Sales in Territory exceed \$[***] in a Calendar Year	\$	[***]
8.Annual Net Sales in Territory exceed \$[***] in a Calendar Year	\$	[***]
9.Annual Net Sales in Territory exceed \$[***] in a Calendar Year	\$	[***]

Each of the milestones set forth in Section 4.1(a) and Section 4.1(b) shall be paid only once regardless of the number of Products that achieve such milestone.

[\*\*\*] Redacted pursuant to a confidential treatment request.



Section 4.2 <u>Royalties on Net Sales of Products</u>. During the Royalty Term applicable to each Product, and subject to adjustment as set forth in Section 4.2(b), Ikaria shall pay to BioLineRx royalties on a Product-by-Product basis, with the amount of such royalties calculated as a percentage of Net Sales in a calendar year for such Product as set forth below:

 Net Sales
 Royalty

 Up to [\*\*\*]
 [\*\*\*]

 [\*\*\*]
 [\*\*\*]

(a) <u>Royalties Payable Only Once</u>. The obligation to pay royalties is imposed only once with respect to Net Sales of the same unit of a Product.

(b) Royalty Reductions for Third Party Payments. Ikaria shall use Commercially Reasonable Efforts to avoid any Third Party Payments. Ikaria shall provide BioLineRx written notice within [\*\*\*] days of its receipt of any request or demand that Ikaria, its Affiliates or any Licensee obtain a license or immunity from suit from any Third Party in order for Ikaria, its Affiliates, or any Licensee to exercise or use the rights granted to Ikaria herein. If Ikaria is required to obtain a license or immunity from suit from any Third Party in order for Ikaria, its Affiliates, or any Licensee to exercise or use the rights granted to Ikaria herein, and Ikaria, its Affiliates, or any Licensee pays any Third Party any up-front fee, milestone, royalty, or other payment (each, a "<u>Third Party Payment</u>") in connection with such license or immunity from suit, Ikaria shall have the right to set off against any amounts payable to BioLineRx under this Article IV [\*\*\*]%) of any Third Party Payments <u>provided that</u> in no event will the royalty paid to BioLineRx on Net Sales in the applicable country fall below [\*\*\*]%). If the amount of Third Party Payments that Ikaria is entitled to set off exceeds the amount otherwise payable to BioLineRx in subsequent periods until Ikaria has been credited for the full amount it is entitled to carry over the excess for set off against amounts payable to BioLineRx in subsequent periods until Ikaria has been credited for the full amount it is entitled to set off. Prior to paying any Third Party Payments. If the Parties shall obtain an analysis from their respective counsel in respect of the validity of the claim of any Third Party seeking Third Party Payments. If the Parties are unable to agree on an assessment of the claim, the Parties shall jointly engage mutually acceptable independent patent counsel not regularly employed by either Party to assess such claims. Ikaria shall substitute the decision of such independent patent counsel for that of its own counsel with respect to deciding whether to obt

(c) <u>Duration of Payments</u>. The amounts payable to BioLineRx under Section 4.2 shall be paid on a Product-by-Product and country-by-country basis until the expiration of the Royalty Term for such Product in such country.

[\*\*\*] Redacted pursuant to a confidential treatment request.

(d) <u>Price Concessions</u>. Ikaria shall not, and shall ensure that its Affiliates and Licensees do not, sell or distribute the Product at a discount (including in the form of government mandated rebates) (with or without consideration) in return substantially for (i) concessions or consideration received in transactions involving products or services other than the Product or (ii) concessions from any government or governmental authority relating to products or services other than the Product.

#### Section 4.3 <u>Reports and Accounting</u>.

(a) <u>Reports; Payments</u>. Ikaria shall deliver to BioLineRx, within [\*\*\*] days after the end of each calendar quarter, reasonably detailed written accountings of Net Sales of Products that are subject to payment obligations to BioLineRx for such calendar quarter. Such quarterly reports shall indicate (i) gross sales and Net Sales on a country-by-country basis, (ii) the calculation of payment amounts owed to BioLineRx from such gross sales and Net Sales, and (iii) any amounts set off pursuant to Section 4.2(b) against payments owed to BioLineRx. When Ikaria delivers such accounting to BioLineRx, Ikaria shall also deliver all amounts due under Section 4.2 to BioLineRx for the calendar quarter. All payments shall be made by wire transfer to the account specified in <u>Schedule 4.3(a)</u>.

(b) <u>Audits by BioLineRx</u>. Ikaria shall keep, and shall require its Affiliates and Licensees to keep, complete and accurate records of the most recent [\*\*\*] years relating to gross sales and Net Sales and all information relevant under Section 4.1 and Section 4.2. For the sole purpose of verifying amounts payable to BioLineRx, BioLineRx shall have the right no more than [\*\*\*] per calendar year, at BioLineRx's expense, to engage independent accountants to review such records in the location(s) where such records are maintained by Ikaria, its Affiliates, and its Licensees upon reasonable notice and during regular business hours. Prior to any review conducted pursuant to this Section 4.3(b), BioLineRx's accountants shall have entered into a written agreement with Ikaria limiting the use of such records to verification of the accuracy of payments due under this Agreement and prohibiting the disclosure of any information contained in such records to a Third Party and to BioLineRx for a purpose other than as set forth in this Section 4.3(b). The right to audit any royalty report or quarterly report or payment shall extend for [\*\*\*] years from the end of the calendar year in which such royalty report or quarterly report was delivered or such payment made. Results of such review shall be made available to Ikaria. If the review reflects an underpayment to BioLineRx, such underpayment shall be promptly remitted to BioLineRx. Likewise, if the review reflects an overpayment, Ikaria shall be entitled to reduce any subsequent payments by the amount of the overpayment. If the underpayment to BioLineRx is equal to or greater than [\*\*\*] %) of the amount that was otherwise due, BioLineRx shall be entitled to have Ikaria reimburse BioLineRx's reasonable out-of-pocket costs of such review.

#### [\*\*\*] Redacted pursuant to a confidential treatment request.

Section 4.4 Currency Amounts. All dollar (\$) amounts specified in this Agreement are United States Dollar amounts.

Section 4.5 <u>Currency Exchange</u>. With respect to sales of Products invoiced in U.S. Dollars and other amounts received or paid by Ikaria, its Affiliates or Licensees in U.S. Dollars, such amounts and the amounts payable hereunder shall be expressed in U.S. Dollars. With respect to sales of Products invoiced in a currency other than U.S. Dollars and other amounts received or paid by Ikaria, its Affiliates or Licensees in a currency other than U.S. Dollars, such amounts and the amounts received or paid by Ikaria, its Affiliates or Licensees in a currency other than U.S. Dollars, such amounts and the amounts payable hereunder shall be expressed in their U.S. Dollar equivalent calculated using the applicable rate of exchange reported by *The Wall Street Journal* (Eastern U.S. edition) on the last Business Day of the calendar quarter to which the report under Section 4.3(a) relates. All payments hereunder shall be made in U.S. Dollars.

Section 4.6 <u>Tax Withholding</u>. The Parties shall use all reasonable and legal efforts to reduce tax withholding on payments made to BioLineRx. The Parties agree to cooperate in good faith to provide one another with such documents and certifications as are reasonably necessary to enable Ikaria to minimize any withholding tax obligations. Ikaria shall promptly provide to BioLineRx documentation of the payment of any withholding taxes that are paid pursuant to this Section 4.6, including copies of receipts or other evidence reasonably required and sufficient to allow BioLineRx to document such tax withholdings adequately for purposes of claiming foreign tax credits and similar benefits.

Section 4.7 <u>Upfront Payments Received Under Sublicenses</u>. If Ikaria receives an upfront payment consideration under a sublicense granted to a Third Party under this Agreement, Ikaria shall pay to BioLineRx ten percent (10%) of any such payment within 30 days after actual receipt thereof from the Third Party.

Article V Intellectual Property Ownership, Protection and Related Matters

- Section 5.1 <u>Ownership of Inventions</u>.
  - (a) <u>Intentionally Omitted.</u>
  - (b) Intentionally Omitted.

(c) <u>Inventorship</u>. Questions of inventorship shall be resolved in accordance with United States patent laws. In the event of a dispute regarding inventorship, if the Parties are unable to resolve the dispute, the Parties shall jointly engage mutually acceptable independent patent counsel not regularly employed by either Party to resolve such dispute. The decision of such independent patent counsel shall be binding on the Parties with respect to the issue of inventorship.

#### [\*\*\*] Redacted pursuant to a confidential treatment request.

(d) <u>Further Actions and Assignments</u>. Each Party shall take all further actions and execute all assignments requested by the other Party and reasonably necessary or desirable to vest in the other Party the ownership rights set forth in this Section 5.1.

# Section 5.2 <u>Prosecution and Maintenance of Patent Rights</u>.

#### (a) Intentionally Omitted.

(b) <u>BioLineRx Intellectual Property</u>. Upon the Effective Date, Ikaria shall assume responsibility for the management of the preparation, filing prosecution and maintenance of any and all patent applications, including any interference proceedings related thereto, included in the BioLineRx Intellectual Property (including, for clarity, the Sublicensed IP, BioLineRx Patent Rights and patents and patent applications that claim or disclose BioLineRx Know-How).

(c) <u>BioLineRx Step-in Right</u>. If Ikaria, on a country-by-country basis, declines to file and prosecute, or elects not to take actions necessary to avoid abandonment of, any patent applications or maintain any patent in any country, in each case for which it has responsibility under Section 5.2(a) or Section 5.2(b), it shall give BioLineRx reasonable notice to this effect sufficiently in advance to permit BioLineRx to undertake such filing and prosecution without a loss of rights, and thereafter BioLineRx may, upon written notice to Ikaria, file and prosecute such patent applications and maintain such patents in such country. If BioLineRx files, prosecutes or maintains any such patent application or patent in such country and any resulting Valid Claim of BioLineRx Patent Rights Covering the Product in such country (*i.e.*, there are no other BioLineRx Patent Rights Covering the Product in such country), [\*\*\*].

If BioLineRx exercises the foregoing step-in right following the election by Ikaria to abandon all existing BioLineRx Patent Rights in a given country, Ikaria shall, within [\*\*\*] days following BioLineRx's written request, notify BioLineRx in writing whether Ikaria intends to Commercialize a Product in the Field in such country. If Ikaria notifies BioLineRx that Ikaria has no intent to Commercialize a Product in the Field in such country, BioLineRx may, upon written notice to Ikaria within [\*\*\*] days of receipt of Ikaria's notice of lack of intent, exercise a right to directly Commercialize a Product in the Field in such country. If BioLineRx provides Ikaria with such notice:[\*\*\*]

(d) <u>Costs and Expenses</u>. Ikaria shall pay the costs and expenses of preparing, filing, prosecuting, and maintaining the Patent Rights covered by Section 5.2(a) or Section 5.2(b), [\*\*\*].

[\*\*\*] Redacted pursuant to a confidential treatment request.

(e) <u>Cooperation Between Parties</u>. Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of Patent Rights pursuant to this Section 5.2, including the execution of all such documents and instruments and the performance of such acts as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of such Patent Rights, including Patent Rights that such Party has elected not to pursue, as provided for in subsections (a), (b) and (c) above. In addition, the filing, prosecuting and maintaining Party in subsections (a), (b) and (c) above shall promptly forward to the other Party copies of any substantive correspondence and actions prepared for or received from the U.S. Patent and Trademark Office or any foreign patent office that may materially affect the Patent Rights being prosecuted or maintained. The other Party's patent counsel may provide comments to the filing, prosecuting and maintaining Party. If any comments by the other Party's patent counsel are provided in sufficient time for the filing, prosecuting and maintaining Party to reflect such comments in its correspondence or response, and such comments are reasonably directed to maximizing the coverage of the claims of the Patent Rights being prosecuted or maintained, the filing, prosecuting and maintaining Party shall reflect such comments in its correspondence or response, if its patent counsel deems it prudent to do so.

(f) <u>Coordination with BioLineRx pursuant to the Sublicensed IP</u>. With respect to any Sublicensed IP which Ikaria is responsible for filing, prosecuting, and maintaining, Ikaria shall:

(i) consult with BioLineRx regarding the preparation, filing, and prosecution of all patent applications, and the maintenance of all patents, included within such Sublicensed IP, including the content, timing, and jurisdiction of the filing of such patent applications and their prosecution, and other details and overall global strategy pertaining to the procurement and maintenance of Patent Rights in such Sublicensed IP, and shall file, prosecute, and maintain all such Patent Rights through a law or patent attorney firm selected by Ikaria and approved by BioLineRx (and BioLineRx shall exercise its rights under the BGN License Agreement as may be necessary to obtain BGN's approval); and

(ii) provide BioLineRx with copies of all patent applications that claim or disclose such Sublicensed IP, and BioLineRx shall exercise its rights under the BGN License Agreement to ensure that BGN cooperates in a timely manner with Ikaria's efforts to register such Patent Rights, including by causing BGN to execute any documents as may be required for such purpose.

BioLineRx shall take all actions required to remain in compliance with the BGN License Agreement in connection with the foregoing.

#### Section 5.3 Third Party Infringement.

(a) <u>Notice</u>. Each Party shall promptly report in writing to the other Party during the term of this Agreement any (i) known or suspected infringement of any of the BioLineRx Patent Rights or (ii) unauthorized use of any of the BioLineRx Know-How of which such Party becomes aware, including, in the case of either clause (i) or clause (ii) involving, or that may reasonably lead to, the Development, Manufacture, use or Commercialization of a product or product candidate that is or may be competitive with a Product in the Field ("<u>Competitive Infringement</u>"), and shall provide the other Party with all available evidence supporting such infringement, suspected infringement, unauthorized use or suspected unauthorized use.

#### (b) BioLineRx Intellectual Property; Step-in Rights.

(i) Ikaria shall have the first right, but not the obligation, to initiate a suit or take other appropriate action that either Party reasonably believes is required to protect BioLineRx Intellectual Property from Competitive Infringement. Ikaria shall give BioLineRx sufficient advance notice of its intent to file any such suit or take any such action, and the reasons therefor, and shall provide BioLineRx with an opportunity to make suggestions and comments regarding such suit or action. Thereafter, Ikaria shall keep BioLineRx informed, and shall from time to time consult with BioLineRx regarding the status of any such suit or action and shall provide BioLineRx with copies of all material documents (*i.e.*, complaints, answers, counterclaims, material motions, orders of the court, memoranda of law and legal briefs, interrogatory responses, depositions, material pre-trial filings, expert reports, affidavits filed in court, transcripts of hearings and trial testimony, trial exhibits and notices of appeal) filed in, or otherwise relating to, such suit or action. Any recovery obtained as a result of any proceeding pursuant to this subsection (b)(i), by settlement or otherwise, shall be applied in the following order of priority: (A) first, each Party shall be reimbursed, on a pro rata basis, for all costs incurred by such Party in connection with such suit; and (B) second, [\*\*\*]

(ii) If Ikaria chooses not to initiate a suit or take other appropriate action under subsection (b)(i) above to protect BioLineRx Intellectual Property from Competitive Infringement, Ikaria will so notify BioLineRx of its intention, in which case BioLineRx shall have the right to initiate such suit or take such other appropriate action. BioLineRx shall give Ikaria sufficient advance notice of its intent to file any such suit or take any such action, and the reasons therefor, and shall provide Ikaria with an opportunity to make suggestions and comments regarding such suit or action. Thereafter, BioLineRx shall keep Ikaria informed, and shall from time to time consult with Ikaria regarding the status of any such suit or action and shall provide Ikaria with copies of all material documents (*i.e.*, complaints, answers, counterclaims, material motions, orders of the court, memoranda of law and legal briefs, interrogatory responses, depositions, material pre-trial filings, expert reports, affidavits filed in court, transcripts of hearings and trial testimony, trial exhibits and notices of appeal) filed in, or otherwise relating to, such suit or action. Any recovery obtained as a result of any proceeding pursuant to this subsection (b)(ii), by settlement or otherwise, shall be applied in the following order of priority: (A) first, each Party shall be reimbursed, on a pro rata basis, for all costs incurred by such Party in connection with such suit; and (B) second, any remainder shall be shared [\*\*\*]% for BioLineRx and [\*\*\*]% for Ikaria.

[\*\*\*] Redacted pursuant to a confidential treatment request.

(iii) If BioLineRx chooses not to initiate a suit or take other appropriate action under subsection (b)(ii) above to protect Sublicensed IP from Competitive Infringement and BGN exercises its rights under the BGN License Agreement to prosecute, prevent, or terminate such Competitive Infringement, any amount received by BioLineRx in connection therewith, whether by settlement or otherwise, [\*\*\*].

(c) <u>Claimed Infringement</u>. If a Party becomes aware of any claim that the Development, Manufacture, or Commercialization of Products for use in the Field in the Territory infringes Patent Rights or any other intellectual property rights of any Third Party, such Party shall promptly notify the other Party. In any such instance, Ikaria shall have the exclusive right to settle such claim.

(d) <u>Patent Invalidity Claim</u>. If a Third Party at any time asserts a claim that any BioLineRx Patent Rights is invalid or otherwise unenforceable (an "<u>Invalidity Claim</u>"), whether (i) as a defense in an infringement action brought by Ikaria or BioLineRx pursuant to subsection (b) above, or (ii) in an action brought against Ikaria or BioLineRx referred to in subsection (c) above, or (iii) otherwise, the Parties shall cooperate with each other in preparing and formulating a response to such Invalidity Claim. Neither Party shall settle or compromise any Invalidity Claim without the consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed.

(e) <u>Conduct of Certain Actions; Costs</u>. Ikaria shall have the sole and exclusive right to select counsel for any suit initiated by it referenced in subsection (b)(i) above or against it referenced in subsection (c) above, and BioLineRx shall have the sole and exclusive right to select counsel for any suit initiated by it referenced in subsection (b)(ii) above. If required under applicable law in order for a Party (the "<u>Lead Party</u>") to initiate or maintain such suit, the other Party shall join as a party to the suit. Such other Party shall offer reasonable assistance to the Lead Party in connection therewith at no charge to the Lead Party except for reimbursement of such other Party's reasonable out-of-pocket expenses incurred in rendering such assistance. The Lead Party shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings referenced in the first sentence of this subsection (e), including the fees and expenses of the counsel selected by it. Subject to applicable law, the other Party shall have the right to participate and be represented in any such suit by its own counsel at its own expense.

(f) <u>Coordination with BGN</u>. With respect to any suit to protect Sublicensed IP from infringement for which Ikaria is the Lead Party, notwithstanding anything to the contrary in this Section 5.3:

[\*\*\*] Redacted pursuant to a confidential treatment request.

(i) if required under applicable law in order for Ikaria to initiate or maintain such suit, BioLineRx shall (A) exercise its rights under the BGN License Agreement to cause BGN to join as a party to such suit, (B) exercise its rights under the BGN License Agreement to obtain BGN's approval of counsel selected by Ikaria to represent Ikaria and BGN in such suit, and (C) [\*\*\*];

(ii) Ikaria shall not compromise or settle such suit without the prior written consent of BGN, which consent BioLineRx shall exercise its rights under the BGN License Agreement to obtain; and

(iii) any recovery obtained by Ikaria as a result of such suit, by settlement or otherwise, shall be applied in the following order of priority: (A) first, each Party shall be reimbursed, on a pro rata basis, for all costs incurred by such Party in connection with such suit (for clarity, BioLineRx shall be reimbursed for any costs of BGN paid by BioLineRx in accordance with clause (i)(C) above); (B) second, [\*\*\*]%) of any remainder shall paid to BioLineRx for remittance to BGN as provided in Section 10.1.2 of the BGN License Agreement ; and (C) third, the remaining [\*\*\*]%) shall be retained by Ikaria; [\*\*\*].

#### Article VI

#### Confidentiality; Non-Solicitation; Standstill

Section 6.1 <u>Confidential Information</u>. Each Party agrees that all Confidential Information disclosed to it or its Affiliates by the other Party (a) shall not be used by the receiving Party or its Affiliates except to fulfill its obligations or exercise its rights under this Agreement, (b) shall be maintained in confidence by the receiving Party and its Affiliates, and (c) shall not be disclosed by the receiving Party or its Affiliates to any Third Party who is not a consultant of, or an advisor to, the receiving Party or its Affiliates without the prior written consent of the disclosing Party, which consent the disclosing Party may withhold in its sole discretion. Notwithstanding the foregoing, either Party may disclose Confidential Information of the other Party if such Party is required to make such disclosure by applicable law, regulation or legal process, including by Israeli securities laws, the rules or regulations of the United States Securities and Exchange Commission (the "SEC") or any similar regulatory agency in a country other than the United States or of any stock exchange, including the Tel Aviv Stock Exchange, in which event such Party shall provide prior notice of such intended disclosure to such other Party, if possible under the circumstances, and shall disclose only such Confidential Information of the other Party as is required to be disclosed. If this Agreement shall be included in any report, statement or other document filed by either Party or an Affiliate of either Party pursuant to the preceding sentence, such Party shall use, or shall cause its Affiliate, as the case may be, to use, reasonable efforts to obtain confidential treatment from the SEC, similar regulatory agency or stock exchange of any financial information or other information of a competitive or confidential nature, and shall include in such confidentiality request such provisions of this Agreement as may be reasonably requested by the other Party.

[\*\*\*] Redacted pursuant to a confidential treatment request.

Section 6.2 <u>Disclosures to Employees, Consultants, Advisors, Etc</u>. Each Party agrees that it and its Affiliates shall provide Confidential Information received from the other Party only to the receiving Party's respective employees, consultants, advisors, Licensees and potential Licensees, and to the employees, consultants and advisors of the receiving Party's Affiliates, who have a need to know such Confidential Information to assist the receiving Party in fulfilling its obligations under this Agreement and only under conditions of confidentiality and non-use at least as stringent as the conditions imposed by this Agreement, <u>provided that</u> BioLineRx and Ikaria shall each remain responsible for any failure by its and its Affiliates' respective employees, consultants, advisors, Licensees and potential Licensees to treat such information and materials as required under Section 6.1. For clarity, (a) Ikaria is permitted to disclose Confidential Information to actual or potential Licensees, acquirors or financing sources; and (b) BioLineRx is permitted to disclose this Agreement and the Development Plan to BGN, solely to the extent required under the BGN License Agreement; <u>provided that</u> any such disclosure subjects the receiving Third Party to conditions of confidentiality and non-use at least as stringent as the conditions imposed by this Agreement.

Section 6.3 <u>Non-Solicitation</u>. During the term of this Agreement and continuing for [\*\*\*] months after the termination of this Agreement, neither Party shall directly or indirectly, for its own account or for the account of others, urge, induce, entice, or in any manner whatsoever solicit any employee directly involved in the activities conducted pursuant to this Agreement to leave the employment of the other Party or any of its Affiliates. For purposes of the foregoing, "urge", "induce", "entice" or "solicit" shall not be deemed to mean: (a) circumstances where an employee of a Party initiates contact with the other Party or any of its Affiliates with regard to possible employment; or (b) general solicitations of employment not specifically targeted at employees of a Party or any of its Affiliates, including responses to general advertisements.

Section 6.4 <u>Standstill</u>. Neither Ikaria nor any of its Affiliates shall directly or indirectly, for its own account or for the account of others, acquire more than [\*\*\*]%) of the equity or debt securities of BioLineRx, or urge, induce, entice or solicit any Third Party to acquire the equity or debt securities of BioLineRx, which may be withheld in its sole discretion. The obligations of Ikaria under this Section 6.4 shall terminate in the event that (a) any Third Party initiates a tender or exchange offer, or otherwise publicly proposes or agrees to acquire, a majority of the equity or debt securities of BioLineRx (provided that the restrictions set forth in this Section 6.4 shall be reinstated in the event that such tender or exchange offer, or proposal, is terminated or withdrawn), (b) it is publicly disclosed that voting securities representing at least [\*\*\*] of the total voting power of BioLineRx have been acquired by any one or more Third Parties, (c) BioLineRx publicly announces that it intends to seek a Third Party acquirer (provided that the restrictions set forth in this Section 6.4 shall be reinstated in the event that BioLineRx publicly announces that it no longer is seeking a Third Party acquirer (provided that the restrictions set forth in this Section 6.4 shall be reinstated in the event that BioLineRx publicly announces that it no longer is seeking a Third Party acquirer (provided that the restrictions set forth in this Section 6.4 shall be reinstated in the event that BioLineRx publicly announces that it no longer is seeking a Third Party acquirer (provided that the restrictions set forth in this Section 6.4 shall be reinstated in the event that BioLineRx publicly announces that it no longer is seeking a Third Party acquirer (provided that the restrictions set forth in this Section 6.4 shall be reinstated in the event that BioLineRx publicly announces that it no longer is seeking a Third Party acquirer (provided that the restrictions set forth in this Section 6.4 shall be reinstated in the even

#### [\*\*\*] Redacted pursuant to a confidential treatment request.

Section 6.5 <u>Term</u>. All obligations of confidentiality imposed under this Article VI shall survive until the date that is [\*\*\*] years after the expiration or termination of this Agreement.

Publicity. During the term of this Agreement, the content of any press release or public announcement relating to this Agreement or a Section 6.6 Product shall be mutually approved by the Parties, except that (a) a Party may issue such press release or public announcement if the contents of such press release or public announcement have previously been made public other than through a breach of this Agreement by the issuing Party, (b) a Party may issue such a press release or public announcement if it is advised by counsel that such press release or public announcement is required by applicable law, regulation or legal process, including by Israeli securities laws, the rules or regulations of the SEC or any similar regulatory agency in a country other than the United States or of any stock exchange, including the Tel Aviv Stock Exchange, and (c) Ikaria shall remain free to issue press releases and public announcements regarding the Development, Manufacturing, Commercialization and use of Products in the Field, provided that Ikaria shall provide BioLineRx with advance notice of at least [\*\*\*] days prior to public disclosure of such releases and announcements or such shorter period as required to comply with any applicable law. In addition, BioLineRx shall reasonably implement any changes that Ikaria may recommend with respect to any filing to be made in accordance with the rules or regulations of the SEC or any similar regulatory agency in a country other than the United States or of any stock exchange, including the Tel Aviv Stock Exchange; provided that such Ikaria shall only have the right to comment upon portions of such filings that directly related to Ikaria or this Agreement. Nothing in the foregoing shall require BioLineRx to implement any change that Ikaria may recommend that is not consistent with the rules or regulations of the Israel Securities Authority, Tel Aviv Stock Exchange, the rules or regulations of the SEC, or any similar regulatory agency in a country other than the United States or Israel, as advised in writing by BioLineRx's legal counsel. BioLineRx's legal counsel will provide Ikaria confirmation of such advise.

Section 6.7 <u>Publications</u>. The results of the Development Program may be published by a Party as part of a scientific presentation or publication only after scientific review by and approval of the Joint Development Committee unless the other Party, acting reasonably, disapproves of the presentation or publication in writing within [\*\*\*] days after receipt of the presentation or publication. Either Party may require that such Party's Confidential Information be redacted from such presentation or publication and may reasonably require that other information also be redacted. In addition, at the request of either Party, the date of submission for presentation or publication shall be delayed for a period of time sufficiently long to permit a Party to seek appropriate patent protection. Other than as provided for herein, BioLineRx shall not make any publication regarding any Product or containing any Confidential Information of Ikaria without the prior written consent of Ikaria. Notwithstanding the foregoing, to the extent necessary or appropriate as determined in Ikaria's discretion, Ikaria may disclose information otherwise covered by this Section 6.7 in documents filed with the SEC.

[\*\*\*] Redacted pursuant to a confidential treatment request.

#### Article VII <u>Representations and Warranties</u>

Section 7.1 <u>Representations of Authority</u>. BioLineRx and Ikaria each represents and warrants to the other Party that, except for the consent of the OCS, it has full corporate right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement and that it has the right to grant to the other Party the rights and licenses granted pursuant to this Agreement.

Section 7.2 <u>Consents</u>. BioLineRx and Ikaria each represents and warrants to the other Party that, except for the consent of the OCS, all necessary consents, approvals and authorizations of all government authorities and other Persons required to be obtained by it as of the date hereof in connection with the execution, delivery and performance of this Agreement have been obtained.

Section 7.3 <u>No Conflict</u>. BioLineRx and Ikaria each represents and warrants to the other Party that, notwithstanding anything to the contrary in this Agreement, except for the consent of the OCS, the execution and delivery of this Agreement, the performance of such Party's obligations in the conduct of the collaboration and the licenses and rights to be granted pursuant to this Agreement (a) do not conflict with or violate any requirement of applicable laws or regulations existing as of the date hereof and (b) do not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the date hereof.

Section 7.4 <u>Enforceability</u>. BioLineRx and Ikaria each represents and warrants to the other Party that this Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms.

Section 7.5 Additional BioLineRx Representations. BioLineRx represents and warrants to Ikaria that:

(a) BioLineRx has the right to grant the licenses granted to Ikaria on the terms set forth in this Agreement;

(b) BioLineRx is not engaged with any Third Party in any Development efforts directed to Products in the Field in the Territory other than with respect to the On-Going Phase I/II Trial, the Other On-Going Trials or the Existing Product Agreements;

(c) BioLineRx has provided Ikaria with true and complete copies of each of the Existing Product Agreements, each of which is in full force and effect in accordance with its terms as of the date hereof, and has obtained all consents necessary for the assignment to Ikaria of each of the Existing Product Agreements hereunder, and, following such assignment, Ikaria shall have the legal right to exercise all rights of BioLineRx that existed thereunder immediately prior to such assignment;

(d) to BioLineRx's Knowledge, the BioLineRx Patent Rights listed in <u>Exhibit B</u> are valid and enforceable and constitute all of the Patent Rights necessary or useful for Ikaria to fully exercise and enforce its rights hereunder;

(e) to BioLineRx's Knowledge, the BioLineRx Patent Rights are not being infringed and the BioLineRx Know-How is not being misappropriated by any Third Party;

(f) BioLineRx owns the entire right, title and interest in and to the BioLineRx Intellectual Property (other than the Sublicensed IP) free and clear of any liens, charges, claims and encumbrances, and no other Person has any claim of ownership or right to obtain compensation with respect to such BioLineRx Intellectual Property;

(g) to BioLineRx's Knowledge, the Products developed in the Development Program and the Development, Manufacture and Commercialization of such Products will not infringe or misappropriate any intellectual property rights not licensed to Ikaria hereunder; and

(h) BioLineRx has not received and has no Knowledge of any claim or demand of any Person pertaining to, or any proceeding which is pending or threatened that asserts, the invalidity, misuse or unenforceability of the BioLineRx Patent Rights or that challenges BioLineRx's ownership of the BioLineRx Intellectual Property or that makes any adverse claim with respect thereto, and, to the Knowledge of BioLineRx, there is no basis for any such claim, demand or proceeding.

Section 7.6 BGN License Agreement. BioLineRx represents, warrants and covenants to Ikaria that:

(a) BioLineRx has provided Ikaria with a true and complete copy of the BGN License Agreement, which is in full force and effect in accordance with its terms as of the date hereof;

(b) BioLineRx shall obtain and provide to Ikaria within ten (10) days of execution of this Agreement a written statement from BGN certifying that the terms of this Agreement are consistent with those of the BGN License Agreement, including in the context of Section 13.4.1(c) thereof;

(c) BioLineRx has (i) achieved by its designated performance date each Milestone (as that term is defined in the BGN License Agreement) having a designated performance date on or before the date hereof, or obtained a waiver in respect thereof, and (ii) neither (A) committed any material breach of the its obligations under the BGN License Agreement nor (B) received any notice from BGN of any alleged material breach thereof by BioLineRx or of any Failure (as that term is defined therein);

(d) BioLineRx shall upon receipt by BioLineRx promptly provide Ikaria with a copy of any notice from BGN described in the foregoing clause (c)(ii)(B);

(e) BioLineRx shall not terminate, amend, supplement or otherwise modify the BGN License Agreement without Ikaria's prior written consent;

(f) the rights and obligations of BioLine Jerusalem L.P. under the BGN License Agreement have been assigned and delegated, or otherwise transferred, to BioLineRx;

(g) as between BioLineRx and Ikaria, BioLineRx shall be responsible for any and all payments to be made under the BGN License Agreement;

(h) in the event of any termination of the BGN License Agreement, BioLineRx shall, at Ikaria's request, provide all reasonable assistance to Ikaria in Ikaria's efforts to obtain from BGN an exclusive license to the Sublicensed IP, including through enforcement of the provisions of Sections 5.2.3 and 13.4.1(c) of the BGN License Agreement.

Section 7.7 <u>Employee, Consultant and Advisor Legal Obligations</u>. BioLineRx and Ikaria each represents and warrants that each of its and its Affiliates' employees, consultants and advisors who is or will be involved in performing any obligations hereunder has executed or will have executed an agreement or have an existing obligation under law requiring assignment to such Party of all intellectual property made during the course of and as the result of his, her or its association with such Party or such Affiliate, and obligating such employee, consultant or advisor to maintain the confidentiality of Confidential Information to the extent required under Article VI. BioLineRx and Ikaria each represents and warrants that, to its Knowledge, none of its or its Affiliates' employees, consultants or advisors who is or will be involved in performing any obligations hereunder is, as a result of the nature of such obligations to be performed by the Parties, in violation of any covenant in any contract relating to non-disclosure of proprietary information, non-competition or non-solicitation.

Section 7.8 <u>Accuracy of Representations and Warranties on Effective Date</u>. The representations and warranties of each of the Parties set forth in the preceding sections of this Article VII remain true and accurate on and as of the Effective Date. Each Party shall promptly following receipt of acceptable consent from the OCS deliver to the other Party a certificate to such effect executed by its Chief Executive Officer.

Section 7.9 <u>No Warranties</u>. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING THAT ANY PRODUCTS WILL BE ECONOMICALLY OR TECHNICALLY UTILIZABLE, THAT ANY SALES OF ANY PRODUCTS WILL OCCUR, THAT THE DEVELOPMENT PROGRAM ACTIVITIES WILL BE COMPLETED IN THE EXPECTED TIMEFRAME, OR THAT ANY PRODUCT WILL BE FREE OF ANY THIRD PARTY RIGHTS.

# Article VIII Term and Termination

Section 8.1 <u>Term</u>. The term of this Agreement shall begin on the Effective Date, may be terminated as set forth in this Article VIII, and shall expire on a Product-by-Product and country-by-country basis upon the date of expiration of the Royalty Term for such Product in such country, and shall expire in its entirety upon the last-to-expire Royalty Term, unless earlier terminated as set forth in this Article VIII.



Section 8.2 <u>Termination for Material Breach</u>. Upon any breach of a material provision of this Agreement by a Party (the "<u>Breaching Party</u>"), the other Party (the "<u>Non-Breaching Party</u>") may terminate this Agreement by providing ninety (90) days written notice to the Breaching Party specifying the material breach. The termination shall become effective at the end of the notice period unless the Breaching Party cures such breach during such notice period. Ikaria may terminate this Agreement pursuant to this Section 8.2 immediately upon any termination of the BGN License Agreement.

Section 8.3 <u>Development-Related Termination</u>. Ikaria shall have the right to terminate this Agreement upon sixty (60) days prior written notice, if Ikaria at any time determines, in its sole judgment, that the results of the Development Program do not warrant further Development of Products.

Section 8.4 Effect of Certain Terminations and Expiration.

(a) If this Agreement is terminated by Ikaria under Section 8.2:

(i) The licenses granted by BioLineRx to Ikaria under Section 2.1 and, notwithstanding any other provision in this Agreement to the contrary, Ikaria's obligations under Section 4.2, shall survive;

- (ii) Section 2.2 shall survive until Ikaria is no longer obligated to pay royalties to BioLineRx under Section 4.2; and
- (iii) Section 5.1 and Section 5.3 shall survive.

(b) If this Agreement is terminated by either BioLineRx under Section 8.2, or by Ikaria under Section 8.3, the licenses granted under Section 2.1 shall terminate as of the effective date of such termination; provided, however, that Ikaria, its Affiliates, and its Licensees shall be afforded a commercially reasonable period of time (but no less than [\*\*\*] months) to sell off any then existing or in process stocks of the Products, subject to the terms and conditions of this Agreement, including the payment of royalties thereon.

(c) Upon any termination or expiration of this Agreement, each Party shall return to the other Party any tangible property owned by the other Party, including any books and records and Confidential Information, in accordance with the reasonable instructions given by the other Party, with any shipping costs to be borne by the other Party, <u>provided</u>, <u>however</u>, <u>that</u> a Party may retain a copy of any regulatory records it is required to maintain in accordance with applicable law.

# [\*\*\*] Redacted pursuant to a confidential treatment request.

Section 8.5 <u>Survival</u>. In the event of any expiration or termination of this Agreement, (a) all financial obligations under Article IV and Article V owed as of the effective date of such expiration or termination shall remain in effect, including such obligations that have accrued, but have not been invoiced, as of such effective date, and (b) the obligations set forth in Section 5.1, Article VI, Article IX and Article X, and all other terms, provisions, representations, rights and obligations contained in this Agreement that by their express terms survive expiration or termination of this Agreement (including Section 8.4 and this Section 8.5), shall survive and all other terms, provisions, representations, rights and obligations contained in this Agreement shall terminate.

Section 8.6 <u>Termination Prior to Effective Date</u>. Notwithstanding anything to the contrary in this Article VIII, Ikaria may terminate this Agreement prior to the Effective Date, with no liability to BioLineRx, if the OCS does not consent to the Agreement in a form reasonably satisfactory to both Parties within forty-five (45) days after the execution of this Agreement. The provisions of Article X (except for Section 10.1(a)) and this Section 8.6 shall survive such termination, and all other terms, provisions, representations, rights and obligations contained in this Agreement shall terminate.

#### Article IX Dispute Resolution

Section 9.1 <u>Negotiation</u>. Any controversy, claim or dispute arising out of or relating to this Agreement shall be settled, if possible, through good faith negotiations between the Parties.

Section 9.2 <u>Escalation</u>. If the Parties are unable to settle any dispute after good faith negotiations pursuant to Section 9.1 after [\*\*\*] days, such dispute (except for any matter that by its express terms shall be resolved as provided in this Agreement, including any matter arising under Section 3.2 or Section 3.6) shall be referred to the Executive Officers to be resolved by negotiation in good faith as soon as is practicable but in no event later than [\*\*\*] days after referral.

Section 9.3 <u>Mediation</u>. Solely with respect to a dispute as to whether Ikaria has breached its obligations to use Commercially Reasonable Efforts as set forth in Section 3.8, if the Executive Officers are unable to settle such dispute after good faith negotiations pursuant to Section 9.2 within [\*\*\*] days after referral to the Executive Officers, the Parties shall, within [\*\*\*] days thereof, engage a mutually agreeable Third Party mediator on a non-binding basis to assist the Parties in determining whether such a breach has occurred. The Parties agree that they will participate in good faith in an effort to resolve the dispute in an informal, inexpensive and expeditious manner and that any mediator selected shall agree to render any judgments in a timely manner, but no later than [\*\*\*] days after the mediator is selected. All expenses of the mediator will be shared equally by the Parties.

[\*\*\*] Redacted pursuant to a confidential treatment request.

Section 9.4 Litigation. If the Executive Officers are unable to settle any dispute after good faith negotiations pursuant to Section 9.2 (other than a dispute as to whether Ikaria has breached its obligations to use Commercially Reasonable Efforts as set forth in Section 3.8) within [\*\*\*] days after referral, or if the Parties continue to dispute whether Ikaria has breached its obligations to use Commercially Reasonable Efforts as set forth in Section 3.8 following mediation pursuant to Section 9.3, then either Party may seek resolution of the dispute (except for any matter that by its express terms shall be resolved as provided in this Agreement, including any matter arising under Section 3.2 or Section 3.6) through remedies available at law or in equity from any court of competent jurisdiction as set forth in Section 10.3.

Section 9.5 <u>Equitable Relief</u>. Each Party acknowledges and agrees that the other Party would be damaged irreparably if any of the provisions of Article II, Article V and Article VI are not performed in accordance with their specific terms or otherwise are breached. Accordingly, each Party agrees that the other Party shall be entitled to an injunction or other equitable relief to prevent breaches of such provisions, to preserve status quo, and to enforce specifically such provisions in any action instituted in any court having jurisdiction over the Parties and the matter, in addition to any other remedy to which it may be entitled, at law or in equity.

### Article X <u>Miscellaneous Provisions</u>

#### Section 10.1 Indemnification.

(a) <u>By Ikaria</u>. Ikaria agrees to defend BioLineRx, its Affiliates and their respective directors, officers, employees and agents at Ikaria's cost and expense, and shall indemnify and hold harmless BioLineRx and its Affiliates and their respective directors, officers, employees and agents from and against any liabilities, losses, costs, damages, fees or expenses (collectively, "Losses") arising out of any Third Party claim to the extent relating to (i) any breach by Ikaria of any of its representations, warranties or obligations pursuant to this Agreement, or (ii) personal injury, property damage, product liability or other damage resulting from the Development, Manufacture, use or Commercialization of a Product by Ikaria or its Affiliates or Licensees, excluding any claim for which BioLineRx indemnifies Ikaria under subsection (b) below.

(b) <u>By BioLineRx</u>. BioLineRx agrees to defend Ikaria, its Affiliates and their respective directors, officers, employees and agents at BioLineRx's cost and expense, and shall indemnify and hold harmless Ikaria and its Affiliates and their respective directors, officers, employees and agents from and against any Losses arising out of any Third Party claim to the extent relating to (i) any breach by BioLineRx of any of its representations, warranties or obligations pursuant to this Agreement, (ii) personal injury, property damage or other damage resulting from the conduct of the On-Going Phase I/II Trial or the Other On-Going Trials by or on behalf of BioLineRx or its Affiliates, (iii) the BGN Agreement, or (iv) any allegation that the practice of the BioLineRx Intellectual Property rights in the Development Program infringes or misappropriates any Third Party intellectual property rights, to the extent BioLineRx had Knowledge that such practice would infringe or misappropriate such Third Party intellectual property rights on or before the Effective Date.

Claims for Indemnification. A Person entitled to indemnification under this Section 10.1 (an "Indemnified Party") shall give prompt written (c)notification to the Party from whom indemnification is sought (the "Indemnifying Party") of the commencement of any action, suit or proceeding relating to a Third Party claim for which indemnification may be sought or, if earlier, upon the assertion of any such claim by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third Party claim as provided in this Section 10.1(c) shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice). Within [\*\*\*] days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such action, suit, proceeding or claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense. The Party not controlling such defense may participate therein at its own expense. The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which consent the Indemnifying Party shall not unreasonably withhold, condition or delay. The Indemnifying Party shall not agree, without the prior written consent of the Indemnified Party, which consent the Indemnified Party shall not unreasonably withhold, condition or delay, to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party.

Section 10.2 <u>Governing Law</u>. This Agreement shall be construed and the respective rights of the Parties determined in accordance with the laws of the State of New York, USA (other than any principle of conflict or choice of laws that would cause the application of the laws of any other jurisdiction).

Section 10.3 <u>Submission to Jurisdiction</u>. Each Party (a) submits to the jurisdiction of any state or federal court sitting in the State of New York, USA in any action or proceeding arising out of or relating to this Agreement, (b) agrees that all claims in respect of such action or proceeding may be heard and determined in any such court, (c) waives any claim of inconvenient forum or other challenge to venue in such court, and (d) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court, unless the state or federal courts sitting in the State of New York decline to exercise jurisdiction over any such action or proceeding or if those courts lack proper jurisdiction, then any action or proceeding arising out of or relating to this Agreement may be brought in any other U.S. court of competent jurisdiction. Each Party agrees to accept service of any summons, complaint or other initial pleading made in the manner provided for the giving of notices in Section 10.6, <u>provided that</u> nothing in this Section 10.3 shall affect the right of either Party to serve such summons, complaint or other initial pleading in any other manner permitted by law.

[\*\*\*] Redacted pursuant to a confidential treatment request.

Section 10.4 <u>Assignment</u>. Ikaria may assign this Agreement or any right hereunder, or delegate any obligation hereunder, in its sole discretion, to (a) any Affiliate of Ikaria or (b) any entity acquiring all or substantially all of the assets of Ikaria Holdings, Inc. and its Affiliates. All other assignments by Ikaria, including (i) to any entity acquiring all or substantially all of the assets of Ikaria to which this Agreement relates or (ii) to any entity with which or into which Ikaria may consolidate or merge, are subject to BioLineRx's prior approval, which approval shall not be unreasonably withheld, conditioned or delayed. BioLineRx may assign its right to receive payments hereunder to a Third Party, in its sole discretion, but BioLineRx shall not otherwise be permitted to assign this Agreement, in whole or in part, without the prior written consent of Ikaria, which approval shall not be unreasonably withheld, conditioned or delayed. Any assignments in contravention of this Section 10.4 shall be null and void.

Section 10.5 <u>Entire Agreement; Amendments</u>. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes all previous arrangements between the Parties with respect to the subject matter hereof, whether written or oral, except for that certain Mutual Non Disclosure Agreement between the Parties dated February 25, 2009. Without limiting the generality of the foregoing, this Agreement hereby supersedes and replaces in its entirety the License and Commercialization Agreement by and among the parties dated as of July 5<sup>th</sup>, 2009. To the extent that any provision of this Agreement conflicts with any provisions of such Mutual Non Disclosure Agreement, the provision of this Agreement shall control. Except as set forth in Section 2.1(iv), any amendment or modification to this Agreement shall be made in writing signed by both Parties.

Section 10.6 Notices.

Notices to Ikaria shall be addressed to:

Ikaria Development Subsidiary One LLC 6 State Route 173 Clinton, NJ 08809, USA Attention: Chief Executive Officer

with copy to:

Ikaria Holdings, Inc. 6 State Route 173 Clinton, NJ 08809, USA Attention: General Counsel

Notices to BioLineRx Ltd. shall be addressed to:

BioLineRx Ltd. 19 Hartum Street P.O. Box 45158 Jerusalem 91450, Israel Attention: Chief Executive Officer

with copy to:

Arent Fox LLP 1050 Connecticut Avenue Washington, DC 20036, USA Attention: John Dwyer, Esq.

Notices to BioLine Innovations Jerusalem L.P. shall be addressed to:

BioLine Innovations Jerusalem L.P. 19 Hartum Street P.O. Box 45158 Jerusalem 91450, Israel Attention: Chief Executive Officer

with copy to:

Arent Fox LLP 1050 Connecticut Avenue Washington, DC 20036, USA Attention: John Dwyer, Esq.

Any Party may change its address by giving notice to the other Party in the manner herein provided. Any notice required or provided for by the terms of this Agreement shall be in writing and shall be (a) sent by registered or certified mail, return receipt requested, postage prepaid, (b) sent via a reputable international courier service, (c) sent by facsimile transmission, or (d) personally delivered, in each case properly addressed in accordance with the paragraph above. The effective date of notice shall be the actual date of receipt by the Party receiving the same.

Section 10.7 <u>Force Majeure</u>. No failure or omission by a Party in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from any cause or causes beyond the control of such Party, including the following: acts of God; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; and invasion (each such event, a "<u>Force Majeure Event</u>") and <u>provided that</u> such Party cures such failure or omission resulting from one of the above causes as soon as is practicable after the occurrence of one or more of the above-mentioned causes.

Section 10.8 <u>Independent Contractors</u>. It is understood and agreed that the relationship between the Parties hereunder is that of independent contractors and that nothing in this Agreement shall be construed as authorization for either BioLineRx or Ikaria to act as agent for the other.

Section 10.9 Limitations of Liability. NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, OR FOR LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 10.9 IS INTENDED TO LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY WITH RESPECT TO THIRD PARTY CLAIMS; (B) ANY LOSSES, INCLUDING LOST PROFITS, ARISING FROM ANY (I) BREACH OF A PARTY'S OBLIGATIONS WITH RESPECT TO THE OTHER PARTY'S CONFIDENTIAL INFORMATION, (II) BREACH BY BIOLINERX OF THE EXCLUSIVE RIGHTS GRANTED IN SECTION 2.1 OR THE COVENANT CONTAINED IN SECTION 2.2, OR (III) USE OF ANY PATENT RIGHTS OR KNOW-HOW LICENSED HEREUNDER BEYOND THE SCOPE OF SUCH LICENSE; OR (C) ANY LOSSES ARISING AS A RESULT OF A PARTY'S FRAUD, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

Section 10.10 <u>No Implied Waivers; Rights Cumulative</u>. No failure on the part of BioLineRx or Ikaria to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence thereto, nor shall any single or partial exercise of any such right, power, remedy or privilege preclude any further or other exercise thereof or the exercise of any other right, power, remedy or privilege.

Section 10.11 <u>Severability</u>. If, under applicable law or regulation, any provision of this Agreement is invalid, incomplete or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement (such invalid, incomplete or unenforceable provision, a "<u>Severed</u> <u>Clause</u>"), this Agreement shall endure except for the Severed Clause. The Parties shall consult one another and use reasonable efforts to agree upon a valid, complete and enforceable provision that is a reasonable substitute for the Severed Clause in view of the intent of this Agreement.

Section 10.12 <u>Execution in Counterparts; Facsimile Signatures</u>. This Agreement may be executed in counterparts, each of which, when so executed and delivered, shall be deemed to be an original, and all of which, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission shall be deemed to be original signatures.

#### REMAINDER OF PAGE LEFT EMPTY; NEXT PAGE IS THE SIGNATURE PAGE

IN WITNESS WHEREOF, the Parties have executed this License and Commercialization Agreement as of the Effective Date.

IKARIA DEVELOPMENT SUBSIDIARY ONE LLC

By:	/s/ Matthew M. Bennett
Name:	Matthew M. Bennett
Title:	Senior Vice President

BIOLINERX LTD.

By:	/s/ Morris Laster M.D.
Name:	Morris Laster M.D.
Title:	CEO

BIOLINE INNOVATIONS JERUSALEM L.P. by its General Partner, BioLine Innovations Jerusalem, Ltd.

By:	/s/ Morris Laster M.D.
Name:	Morris Laster M.D.
Title:	Director

# SCHEDULE 1.30

# PROTOCOL FOR ON-GOING PHASE I/II TRIAL

[PROTOCOL IMMEDIATELY FOLLOWS]



# **CLINICAL STUDY**

# Protocol No. BL-1040.01 Version 5.00 Incorporating Amendments 1, 2, 3 and 4 Safety and Feasibility Final

# A Phase I, multi-center, open label study designed to assess the safety and feasibility of the injectable BL-1040 implant to provide scaffolding to infarcted myocardial tissue

# **BioLine Innovations Jerusalem**

**Confidentiality Statement** 

This document contains information that is the property of BioLine Innovations Jerusalem and therefore is provided to you in confidence for review by you, your staff, an applicable ethics committee/institutional review board and regulatory authorities. It is understood that this information will not be disclosed to others without written approval from BioLine Innovations Jerusalem, except to the extent necessary to obtain informed consent from those persons to whom BL-1040 may be administered.

Annotated Protocol incorporating Amendment 1, Amendment 2, Amendment 3, and Amendment 4 01 December 2008





Protocol BL-1040.01, Version **5.00** Safety and Feasibility study of BL-1040 **Final** 

PROTOCOL NUMBER:	BL-1040.01 Safety and Feasibility
DATE OF PROTOCOL:	Final, <b>01 December</b> 2008 Version 2 incorporating Amendment 1, 07 August 2007 Version 3 incorporating Amendment 2, 03 December 2007 Version 4 incorporating Amendment 3, 17 April 2008 <b>Version 5 incorporating Amendment 4, 27 November 2008</b>
PROTOCOL TITLE:	A Phase I, multi-center, open label study designed to assess the safety and feasibility of the injectable BL-1040 implant to provide scaffolding to infarcted myocardial tissue
SPONSOR:	BioLine Innovations Jerusalem

# **Responsible study personnel:**

e-mail:

Name:	Prof. Moshe Phillip, MD, Vice-President of Medical Affairs, Sr. Clinical Advisor	
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Address:	Gewerbestrasse 24, CH-4123 Allschwil, Switzerland	
Phone:	+41-61-487-1400	
Fax:	+41-61-487-1401	
Authorized representati	ve: Voisin Consulting	
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Phone:	+33-1-41-31-8300	
Fax:	+33-1 41-31-8309	

Annotated Protocol incorporating Amendment 1, Amendment 2, Amendment 3, and Amendment 4 01 December 2008

voisin@voisinconsulting.com



e-mail:

## Protocol BL-1040.01, Version **5.00** Safety and Feasibility study of BL-1040 **Final**

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e-mail:	ken.carlson@averionintl.com
Medical Monitor, Europe	
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Annotated Protocol incorporating Amendment 1, Amendment 2, Amendment 3, and Amendment 4 01 December 2008

christian.tueni@averionintl.com

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# **Investigator's Signature Page**

INVESTIGATOR:

Name:

Address: Phone: Fax: e-mail:

I, the undersigned, have reviewed this Protocol, including Appendices, and I will conduct the clinical study as described and will adhere to GCP/ICH and all the ethical and regulatory considerations stated. I have read and understood the contents of the Investigator Brochure.

Date/Place \_\_\_\_

Signature \_\_\_\_\_ (Name of Investigator)

Annotated Protocol incorporating Amendment 1, Amendment 2, Amendment 3, and Amendment 4 01 December 2008

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# **Sponsor Signature Page**

Sponsor: Address: BioLine Innovations Jerusalem 19 Hartum St., POB 45158 Jerusalem, Israel 91450

Phone: Fax: e-mail: +972-2-548-9100 +972-2-548-9101 <u>info@biolineRx.com</u>

I have read the protocol and confirm that the protocol follows the current GCP guidelines.

Date/Place \_\_\_\_\_

Date/Place \_\_\_\_\_

Signature \_\_\_\_\_ (Prof Moshe Phillip, VP of Medical Affairs, Sr. Clinical Advisor)

Signature \_\_\_\_\_ (Shmuel Tuvia, PhD, Project Manager)

Date/Place \_\_\_\_\_

Signature \_\_\_\_\_ (Moti Gal, Clinical Operations Manager)

Annotated Protocol incorporating Amendment 1, Amendment 2, Amendment 3, and Amendment 4 01 December 2008

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Protocol BL-1040.01, Version **5.00** Safety and Feasibility study of BL-1040 **Final** 

# Medical Advisor Signature Page

Name: Address: Prof Jonathan Leor, MD Head, Neufeld Cardiac Research Institute. Tel-Aviv University Sheba Medical Center Tel-Hashomer 52621 Israel

Phone: Fax: +972-3-534-8685 +972-3-5351139

I have read the protocol and confirm that the protocol follows the current GCP guidelines.

Date/Place \_\_\_\_\_

Signature \_\_\_\_\_ (Jonathan Leor, MD, Medical Advisor)

Annotated Protocol incorporating Amendment 1, Amendment 2, Amendment 3, and Amendment 4 01 December 2008

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BL-1040.01

STUDY NUMBER

# Synopsis

TITLE OF THE STUDY	A Phase I, multi-center, open label study designed to assess the safety and feasibility of the injectable BL-1040 implant to provide scaffolding to infarcted myocardial tissue
STUDY CENTER/ COUNTRY	Approximately <b>10</b> centers in <b>3</b> countries: <del>Netherlands,</del> Belgium, Germany, Israel
PLANNED STUDY PERIOD + CLINICAL PHASE	Q1 2008 to <b>Q1 2010</b> Phase I
INDICATION AND RATIONALE	Heart failure after myocardial infarction (MI) is often precipitated by early and progressive extracellular matrix degradation and pathological remodeling of the left ventricle (LV). In response to MI, a series of molecular, cellular and physiological responses are triggered, which can lead to early infarct expansion (infarct thinning), which may result in early ventricular rupture or aneurysm formation and the transition to heart failure. Late remodeling involves the left ventricle globally and is associated with time-dependent dilatation, and the distortion of ventricular shape. The failure to normalize increased wall stresses results in progressive dilatation, recruitment of border zone myocardium into the infarct, and deterioration in contractile function. Current anti-remodeling therapies are clearly limited, as many ventricles continue to enlarge and mortality and morbidity remain significantly high. Based on the mechanism of LV remodeling, it has been hypothesized that injection of biomaterials into the infarct could thicken the infarct, arrest infarct expansion, prevent LV dilatation and reduce wall stress that initiates progressive adverse LV remodeling. BL-1040 Myocardial Implant is a non-pharmacologic cross-linked alginate solution administered via intracoronary (IC) injection to infarcted tissue, forming a flexible, three-dimensional mechanical scaffold. BL-1040 Myocardial Implant presents a novel, safe and non-surgical therapy that directly addresses the stability and structural integrity of myocardial tissue while potentially preventing post infarction remodeling, primarily via limiting left ventricle dilation.
OBJECTIVES	<ul> <li>To evaluate the safety of the BL-1040 myocardial implant in patients after MI at high risk for LV remodeling and CHF.</li> <li>To provide feasibility data in order to initiate and conduct a pivotal clinical study evaluating the safety and efficacy of the BL-1040 implant in patients following myocardial infarction.</li> </ul>
ENDPOINTS	<ul> <li>Primary safety endpoints</li> <li>Occurrence of all adverse events including but not limited to</li> <li>All MIs</li> <li>Cardiovascular hospitalization</li> <li>Serious ventricular arrhythmias sustained: <ul> <li>VT (symptomatic or sustained VT [duration longer than 30 seconds or 100 beats, or associated with hemodynamic collapse])</li> <li>VF</li> <li>symptomatic bradycardia, pauses of longer than 3.0 seconds, complete atrioventricular block, Mobitz II atrioventricular block</li> </ul> </li> <li>Symptomatic heart failure (NYHA criteria + physical examination OR hospitalization due to heart failure)</li> <li>Renal failure</li> <li>Stroke</li> <li>Death</li> </ul>

Annotated Protocol incorporating Amendment 1, Amendment 2, Amendment 3, and Amendment 4 01 December 2008

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		LV dimensions (end-systolic volume index, end-diastolic volume index, left ventricular mass) regional (infarct related) and global wall motion score
DESIGN	Multi-center, open label	
PATIENTS	NUMBER MAIN INCLUSION CRITERIA	<ul> <li>Maximum 30</li> <li>Signed informed consent</li> <li>18 to 75 years of age, inclusive</li> <li>Male or female</li> <li>Negative pregnancy test for women of child-bearing potential, or surgically sterile, or post menopausal</li> <li>Acute MI defined as: <ol> <li>Typical rise and gradual fall (troponin) or more rapid rise and fall (CK-MB) of biochemical markers of myocardial necrosis with at least one of the following: a) ischemic symptoms; b) development of pathologic Qwaves on the ECG; c) ECG changes indicative of ischemia (ST segment elevation or depression)</li> <li>First anterior or inferolateral STEMI or Qwave MI (QMI Anterior: V1-V3 or V1-V4 or V1-V5 or V1-V6.QMI Inferior: L2, L3, AVF, or L2, L3, AVF+ V5, V6 or L2, L3, AVF+ V6-V9 [posterior leads])</li> <li>Regional wall motion score index (at least 4 out of 16 akinetic segments)</li> </ol> </li> <li>One or more of the following: <ul> <li>LVEF &gt;20% and &lt;45% measured and calculated by 2-dimensional measurement</li> <li>Biomarkers: peak CK &gt; 2000 IU</li> <li>Infarct size &gt; 25% as measured by MRI</li> </ul> </li> <li>Successful revascularization with PCI with 1 stent only, within 7 days of the index MI (only safe and MRI compatible stents)</li> </ul>
	MAIN EXCLUSION CRITERIA	<ul> <li>At time of application of study device, patient must have patent infarct related artery (IRA) and TIMI flow grade = 3</li> <li>History of CHF, Class I to Class IV, as per NYHA criteria</li> <li>History of prior LV dysfunction</li> <li>At time of application of study device - Killip III-IV (pulmonary edema, cardiogenic shock - hypotension [systolic &lt; 90 mmHg] and evidence of peripheral hypoperfusion [oliguria, cyanosis, sweating]) or HR &gt; 100 bpm</li> <li>Patient with pacemaker</li> <li>Prior CABG</li> <li>Prior MI</li> <li>History of stroke</li> <li>Significant valvular disease (moderate or severe)</li> <li>Patient is a candidate for CABG or PCI on non-IRA</li> <li>Patient is being considered for CRT within the next 30 days</li> </ul>

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		<ul> <li>Renal insufficiency (eGFR &lt; 60)</li> <li>Chronic liver disease (&gt; 3 times upper limit of normal)</li> <li>Life expectancy &lt; 12 months</li> <li>Current participant in another clinical trial, or participation in another</li> <li>Any contraindication to coronary angiography, MRI or PCI procedure</li> <li>Patient taking anti-coagulation medication prior to MI</li> <li>Pregnant or lactating women; pregnancy confirmed by urine pregnance</li> </ul>	S
STUDY DEVICE	ROUTE OF APPLICATION	Administered via intracoronary (IC) injection, using multiple commerci	ially available devices
	DURATION AND FREQUENCY	2 mL of BL-1040 administered for no longer than <b>30</b> seconds	
	FORMULATION	Calcium D-Gluconate (Gluconic acid hemicalcium salt)	
		PRONOVA UP VLVG (Generic name: Sodium Alginate) Water for Injection USP/EP	
SAFETY EVALUATION	S		
TIMING AND	Screening		
ASSESSMENTS		ny, PCI and stent (as part of treatment of MI)	
PERFORMED	Physical examination     Vital signs		
	• Vital signs • 12-lead ECG		
	• Blood and urine sampli • Total CK/CK MB	ng for laboratory safety parameters (biochemistry, hematology and urinalys	iis)
	· NT-proBNP		
	• Mandatory echocardiog	raphy; MRI as an additional measurement is encouraged	
	Telephone contact, 1 wee	ek post-procedure	
	• Phone call to confirm s	tatus of patient discharged from the hospital	
	Day 1 and during hospita	alization	
		aily during hospitalization	
	• Vital signs daily during		
		nd after administration of BL-1040; daily during hospitalization (after completion of 12-lead ECG)	
	$\cdot$ Blood and urine sampl	ing for laboratory safety parameters (biochemistry, hematology and urina us 48 hours) and on day of discharge (only if not done within the previous	
		ured prior to, and 8, 16, 24 and 48 hours after administration of BL-1040	
	• NT-proBNP on Day 1 previous 48 hours)	(only if not done within the previous 48 hours) and on day of discharge	(only if not done within the
	· continuous ECG during		
		ion (for implantation of BL-1040)	
	• PTT or ACT measurem	ents, during procedure only (prior to implantation of BL-1040 and prior to	removal of sheath)

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	<ul> <li>Follow-up visits (Days 30, 90 180 [End of Study]; Months 12, 24, 36, 48 and 60)</li> <li>Physical examination</li> <li>Vital signs</li> <li>12-lead ECG</li> <li>24 hour ambulatory Holter monitoring</li> <li>Blood and urine sampling for laboratory safety parameters (biochemistry, hematology and urinalysis)</li> <li>NT-proBNP (through Day 180 only)</li> <li>Mandatory echocardiography; MRI as an additional measurement is encouraged (MRI through Day 180 only)</li> <li>Minnesota Living with Heart FailureÒ questionnaire</li> </ul>
	AEs and SAEs will be collected throughout the study
PROCEDURE	Patient is admitted to the hospital as a result of an AMI. As part of the inclusion criteria for this study, the patient will undergo revascularization with PCI stent implantation. Within 7 days of the index MI, the patient will undergo an echocardiogram to determine LVEF. Although not mandatory, the patient will be encouraged to undergo an MRI as an additional assessment. If the patient satisfies inclusion/exclusion criteria, a 2 <sup>nd</sup> cardiac catheterization will be performed to administer BL-1040 after revascularization but within 7 days of the index AMI. BL-1040 is applied via intracoronary injection through the infarct related artery. Patients discharged from the hospital will be contacted by phone on Day 8 for a safety follow-up. Follow-up examinations are scheduled for Day 30, Day 90 and Day 180 (End of Study) post-procedure. In addition, the patient will return to the hospital at Months 12, 24, 36, 48 and 60 for yearly follow-up assessments, as part of a long-term safety follow-up.
STATISTICAL METHODS	All data recorded will be presented in data listings and summary tables, as appropriate. Missing values will not be replaced. No formal hypothesis testing will be performed. All participants who received BL-1040 will be included in the safety analysis. Any excluded cases will be documented together with the reason for exclusion. All decisions on exclusions from the analysis will be finalized prior to database lock. Continuous variables (age, height, weight) will be summarized using mean, median, standard deviation, minimum, maximum, and number of available observations. Qualitative variables will be summarized by counts and percentages. An interim safety analysis will be performed after 5 patients have completed the Day 30 visit, on all data collected up to this timepoint.

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#### Schedule of Events

Visits/Week	Hospitalization			Post discharge follow-up					
Study days	Screening Day (-7) to Day (-1)	Day 1 Day of application <sup>1</sup>	Daily during hospitalization <sup>2</sup>	Day of discharge	Telephone Contact Day 8 (± 1 day)	Day 30 (± 5 days)	Day 90 (± 5 days)	Day 180 (± 7 days) End of Study Visit	Follow-up Safety Visits (Months 12, 24, 36, 48 60, ± 30 days)
AMI	X	upplication	nospitalization	uischurge	( <u> </u>	(± 5 duy5)	(± 5 days)	Study Visit	± 50 ddy5)
Hospitalization	<	X		>					
Coronary angiography, PCI, stent <sup>3</sup>	Х								
Informed consent	Х								
Inclusion/exclusion criteria	Х								
Pregnancy test	X								
Demography; medical history; concurrent illnesses	X	V	V	v		v	V	V	V
Physical examination Vital signs (temperature, arterial BP, weight)	X X	X X	X X	X X		X X	X X	X X	X X
12-lead ECG	X	X <sup>4</sup>	X	X		X	X	X	X
Laboratory safety parameters	X <sup>5</sup>	л Х <sup>6</sup>	Λ	X <sup>6</sup>		X	X	X	X
Total CK/CK MB	X	х <sup>7</sup> Х <sup>7</sup>		$\Lambda^{1}$		Λ	Λ	Λ	Λ
NT-proBNP	X	л Х <sup>6</sup>		X <sup>6</sup>		Х	Х	Х	
•	X	Λ		Λ		X	X	X	Х
Echocardiography/MRI <sup>8</sup> Continuous ECG monitoring	Λ	X <sup>9</sup>				Л	Λ	Λ	Λ
Cardiac catheterization; application of BL-1040;									
coronary angiography		Х							
PTT or ACT measurements		X <sup>10</sup>							
24-hour ambulatory Holter monitoring		X				Х	Х	Х	Х
Safety contact for discharged patients					Х				
Minnesota Living with Heart FailureÒ						Х	Х	Х	Х
Serious/Adverse events and concomitant medication	Х	Х	Х	Х		Х	Х	Х	Х

1. Device to be administered within 7 days of AMI

2. Patient must remain hospitalized for at least 48 hours after procedure.

3. Done as treatment of AMI

4. Prior to and after administration of BL-1040

5. Troponin I or T to be measured at Screening only

6. If not done within previous 48 hours

7. Parameters to be assessed prior to, and 8, 16, 24 and 48 hours after administration of BL-1040

8. Echocardiography to be done at each visit. MRIs are to be encouraged as an additional assessment through Day 180, but are contingent upon patient agreement. MRIs are not to be requested as part of the Follow-up Safety visits.

9. Patient to be connected prior to implantation of BL-1040, and for the duration of the procedure

10. Measured prior to implantation of BL-1040, and prior to removal of sheath

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Appendix A: Declaration of Helsinki

Appendix B: Minnesota Living with Heart FailureÒ questionnaire

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## List of Abbreviations

	List of Addreviations
AE(s)	Adverse event(s)
ALT	Alanine transminase
AMI	Acute myocardial infarction
AST	Aspartate transaminase
BP	Blood pressure
bpm	Beats per minutes
BUN	Blood urea nitrogen
CABG	Coronary artery bypass graft
CHF	Chronic heart failure
CRF	Case Report Form
CRT	Cardiac Resynchronization Therapy
CV	Cardiovascular
ECG	Electrocardiogram
EF	Ejection fraction
eGFR	Estimated glomerular filtration rate
EOS	End of study
GCP	Good Clinical Practice
GGT	Gamma glutamyl transferase
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practices
HPF	High power field
HR	Heart rate
IC	Intracoronary
ICH	International Conference on Harmonization
IRA	Infarct related artery
ISMB	Independent Safety Monitoring Board
LDH	Lactate dehydrogenase
LV	Left ventricle
LVEF	Left ventricular ejection fraction
MedDRA	Medical Dictionary for Regulatory Activities
	Milligram
mg MI	Myocardial infarction
min	Minute
mL	Milliliter
MRI	
NCE	Magnetic resonance imaging
	New chemical entity N-terminal prohormone brain natriuretic peptide
NT-proBNP NYHA	New York Heart Association
°C	
OTC	Degrees centigrade Over the Counter
PCI	Primary coronary intervention
QMI	Qwave myocardial infarction
SAE(s)	Serious Adverse Event(s)
SAS	Statistical Analysis System
STEMI	ST-segment elevation myocardial infarction
TIMI	Thrombolysis in Myocardial Infarction
VF	Ventricular fibrillation
VT	Ventricular tachycardia

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## 1 Introduction

#### 1.1 Background

1.1.1 Acute Myocardial Infarction- Definition

Acute myocardial infarction (AMI) is defined as death or necrosis of myocardial cells. It is a diagnosis at the end of the spectrum of myocardial ischemia or acute coronary syndromes. AMI occurs when myocardial ischemia exceeds a critical threshold and overwhelms myocardial cellular repair mechanisms that are designed to maintain normal cardiac function. Ischemia at this critical threshold level, when present for an extended time period, results in irreversible myocardial cell damage and cell death.

#### 1.1.2 Infarction types and pathogenesis

Critical myocardial ischemia may arise as a result of increased myocardial metabolic requirement and/or reduction in the delivery of oxygen and nutrients to the myocardium through the coronary circulation, or both. An interruption in the supply of myocardial oxygen and nutrients occurs when blood flow to the myocardium is interrupted by occlusion of a coronary artery. Often, this event is caused by a thrombus superimposed on an ulcerated or unstable atherosclerotic plaque that left untreated for as little as a 20-40 minutes, can lead to irreversible cell damage and cell death. A high-grade (> 75%) permanent coronary artery stenosis due to atherosclerosis or a dynamic stenosis coupled with coronary vasospasm can also reduce the supply of oxygen and nutrients and be a factor involved in AMI. Additional cardiac valvular pathologies and low cardiac output states associated with a decreased aortic diastolic pressure, which is the prime component of coronary perfusion pressure, can also precipitate AMI.

#### 1.1.3 Mechanisms of myocardial damage

The severity of an AMI is dependent on three factors: the level of the occlusion in the coronary artery, the length of time of the occlusion, and the presence or absence of collateral circulation. In general, the more proximal the coronary occlusion, there is a greater risk of an increased area of necrosis. The larger the AMI, the chance of death due to a mechanical complication or pump failure increases. In addition, the longer the time period of vessel occlusion, there is a greater chance of irreversible myocardial damage distal to the occlusion.

The death of myocardial cells first occurs in the area of myocardium that is most distal to the arterial blood supply, the endocardium. As the duration of the occlusion increases, the area of myocardial cell death enlarges, extending from the endocardium to the myocardium and ultimately to the epicardium. The area of myocardial cell death then spreads laterally to areas of watershed or collateral perfusion. The extent of myocardial cell death defines the magnitude of the AMI. If blood flow can be restored to at-risk myocardial tissue will eventually be completely replaced by fibrous infarct tissue. In the early stages after an AMI, the damage causes deterioration of cardiac muscle contractility and structural integrity. This results in thinning of the walls of the heart, which can have severe consequences including rupture at the site, expansion of the area of damage, and the formation of blood clots. After some weeks or months, this can evolve to dilatation of the heart, which further reduces its ability to pump blood efficiently, resulting in heart failure.

#### 1.1.4 Treatment of AMI

The goal of treatment for AMI is early reperfusion by rapid revascularization of the occluded culprit coronary artery both by medical means to dissolve the clot with thrombolytics or by cardiac catheterization with primary coronary intervention (PCI) and deployment of stents to maintain patency of the culprit coronary artery. However, while re-opening of the culprit coronary vessel can prevent the development of a large AMI and prevent further loss of viable myocardium, it does not affect myocardial tissue that has already undergone irreversible damage. An undeniable adverse outcome of AMI is progressive worsening of ventricular function that, if left unattended, culminates in the syndrome of congestive heart failure. To date, no treatment has been developed to reliably prevent the deterioration of ventricular function that follows a large AMI. Treatment options for AMI and for the resulting heart failure include medical management, heart transplantation, mechanical circulatory assist devices (left ventricular assist device, etc.), and surgical ventricular restoration, all of which have specific limitations.

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#### **1.2** Rationale and justification

BL-1040 Myocardial Implant presents a novel, safe and non-surgical therapy that directly addresses the stability and structural integrity of myocardial tissue in this patient population. BL-1040 potentially prevents post infarction remodeling primarily via limiting left ventricle (LV) dilation, while the untreated patient LV will continue to dilate or enlarge. BL-1040, by creating a scaffold, may stabilize the AMI and limit post AMI expansion manifested as LV dilation.

There are currently no other available medical and/or surgical interventions that directly address the stability and structural integrity of myocardial tissue damaged as a result of AMI. In the setting of an AMI, an inflammatory response triggers the degradation of the extracellular matrix, thus weakening of the collagen cross-link structure or structural "backbone" of the myocardium. Degradation of the extracellular matrix leads to infarct expansion manifested by myocardial wall thinning and often, aneurysmal dilation with subsequent ventricular enlargement. This process results in progressive LV remodeling and increased LV wall stress. The latter can increase myocardial oxygen consumption, a condition that the infarcted and/or failing LV can ill afford and one that can contribute to increased long-term mortality and morbidity.

LV dilation is the predominant cause for morbidity and mortality in congestive heart failure [2]. demonstrated that patients with LV end systolic volume smaller than 95 mL showed a 94 % survival after 5 years while LV patients with LV end systolic volume greater than 130 mL showed a 52 % survival after 5 years. Both diastolic and systolic were the main predictors for mortality. Patients with end-stage ischemic heart failure presenting dilated LV with an akinetic/dyskinetic region over 35% and with left ventricular end systolic index >60 mL/m2 are offered LV reconstruction or surgical ventricular restoration (SVR) in order to reduce LV volume and to restore normal LV shape. Overall, in a large number of studies performed using SVR, there is strong evidence that SVR is safe and effective, showing significant reduction in mortality and readmission levels together with significant improvement in ejection fraction as well as in LV end systolic/diastolic index.

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## 2 Study Objectives

The objectives of this study are:

- to evaluate the safety of the BL-1040 myocardial implant in patients after MI at high risk for LV remodeling and CHF, and
- to provide feasibility data in order to initiate and conduct a pivotal clinical study evaluating the safety and efficacy of the BL-1040 implant in patients following myocardial infarction.

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## **3** Safety Endpoints

## 3.1 **Primary endpoints**

Primary safety endpoints include:

- occurrence of all adverse events including but not limited to
  - all MIs
  - cardiovascular hospitalization
  - · serious ventricular arrhythmias sustained
    - VT (symptomatic or sustained VT [duration longer than 30 seconds or 100 beats, or associated with hemodynamic collapse])

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- · VF
- symptomatic bradycardia, pauses of longer than 3.0 seconds, complete atrioventricular block, Mobitz II atrioventricular block
- symptomatic heart failure (NYHA criteria + physical examination OR hospitalization because of heart failure)
- renal failure
- stroke
- death

## 3.2 Secondary endpoints

Secondary safety endpoints include:

- · change from baseline in LV dimensions (end-systolic volume index, end-diastolic volume index, left ventricular mass)
- $\cdot$  change from baseline in regional (infarct related) and global wall motion score
- · change from baseline in ejection fraction
- · cardiac rupture
- NT-proBNP

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## 4 Investigational Plan

## 4.1 Summary of study design

This is an open label, multi-center, sequentially enrolled, Phase I study to assess the safety and feasibility of the injectable BL-1040 myocardial implant to provide scaffolding to infarcted myocardial tissue.

Patients who experience an MI will be admitted to the hospital. As part of the treatment for the MI, patients will undergo PCI and stent implantation. Patients will also undergo an echocardiography (and if they agree, an MRI) to determine the extent of damage to the infarct related artery (IRA). Patients who satisfy inclusion/exclusion criteria will be enrolled into the study. The BL-1040 myocardial implant will be injected into the IRA, distally to the implanted stent.

The first 2 patients will be sequentially enrolled. After both patients have completed Day 30 assessments, and after approval by the Independent Safety Monitoring Board (ISMB), the decision will be made to enroll 3 additional patients. After the ISMB reviews the Day 30 assessments of these patients, the decision will be made to enroll a maximum of 25 additional patients. Details are provided in Sec. 4.2.

Both female and male patients must agree to use effective contraception (as agreed with the Investigator) for 6 months (180 days) after the procedure.

## 4.1.1 Estimated study duration

The study is planned to last from Q1 2008 to **Q1 2010**. The clinical study phase is 180 days for each patient. A long term safety follow-up will include visits at Months 12, 24, 36, 48, and 60. Patients will be consented for the entire 5 year period.

## 4.1.2 Number of Patients

The maximum number of patients enrolled in this study will be 30.

## 4.2 Sequential enrollment

The first 2 patients will be sequentially enrolled into the study. After the 1<sup>st</sup> patient has completed Day 30 assessments, the Independent Safety Monitoring Board (ISMB, Sec. 4.3) will review the patient's data through Day 30. The ISMB will then decide whether to give approval to enroll the 2<sup>nd</sup> patient. After the 2<sup>nd</sup> patient has completed Day 30 assessments, the ISMB will again review the data and provide approval for enrollment of the next 3 patients. After all 3 patients have completed Day 30 assessments, the ISMB will review the data from these patients and provide approval for opening enrollment to the balance of the patients (maximum of 25).

#### 4.3 Responsibilities of the Independent Safety Monitoring Board

An Independent Safety Monitoring Board (ISMB) will be established prior to the start of the study to monitor the safety of BL-1040 during the conduct of the protocol. This ISMB will consist of physicians with expertise in cardiovascular disease, particularly in the area of coronary artery disease and with experience monitoring safety of drugs and/or devices for cardiovascular applications, and will have no participation in the trial in any other capacity.

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The ISMB will ensure that this study meets the highest standards of patient safety. During the study the ISMB will have the following main responsibilities:

- review 30 day safety data patients from the first 2 sequentially enrolled patients to determine whether 3 additional patients may be enrolled; after reviewing the 30 day safety data from these 3 patients, will determine whether the balance of patients may be enrolled
- within 30 days of enrolment of each successive group of 5 patients receiving the device, will review all SAEs occurring to date and will recommend continuation, discontinuation, or modification of the procedure or protocol, based on a determination of whether the occurrence of serious, unexpected, or device-related adverse events (Sec. 7) might outweigh the potential benefit achievable with the device
- · review emerging findings in patients and identify potential safety concerns with BL-1040
- will receive information, on an expedited basis, on all Serious Adverse Events (SAEs), clinically significant laboratory values/vital signs, ECG abnormalities and data from patients who decided to prematurely discontinue the study. All SAES that occur in the cath lab during or after the procedure to administer BL-1040 should be reviewed promptly by the ISMB. The ISMB will review this information and may decide to interrupt, alter, or terminate the trial
- will adjudicate whether or not an event is unexpected, based on a pre-specified list of expected SAEs within the study population.

#### 4.3.1 Stopping Criteria

Given the uncontrolled nature of the study, and the small sample size, it is not practical to provide a quantitative stopping rule. Moreover, given the severely ill nature of the patients who will be enrolled in the study (those with large myocardial infarction and substantial LV dysfunction), adverse cardiac outcomes, including fatal ones, are to be expected in this population, regardless of participation in the study.

The study will be stopped when any of the following occur:

- 1. Completion of the study
- 2. ISMB and sponsor judge that the study treatment appears to be unsafe for patients. The ISMB will make this assessment based not only upon the frequency of observed complications, but also upon the character and qualitative nature of the events. This determination will be made in the context of clinical judgement of experienced cardiologists regarding the expected outcome in this population of patients and whether observed outcomes differ substantively from the expectation.

The committee reserves the right to stop the study after analysis of outcomes of sequential procedures. A decision to stop will be considered by the ISMB in the event of occurrence of severe, unusual or unexpected events.

3. The ISMB may consider putting the trial on hold or terminating it and will base it decision on weighing the balance between potential but hypothetical benefits and possible risks to the participants in the study.

## 4.4 Inclusion criteria

The inclusion criteria for this study are:

· voluntarily signed the informed consent form prior to the conduct of any study specific procedures

• male or female inpatients aged 18 to 75, inclusive

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- negative pregnancy test for all women of child-bearing potential, or surgically sterilized (i.e. tubal ligation, hysterectomy) prior to Screening, or postmenopausal for at least 1 year
- · acute MI defined as:
  - o typical rise and gradual fall (troponin) or more rapid rise and fall (CK-MB) of biochemical markers of myocardial necrosis with at least one of the following: a) ischemic symptoms; b) development of pathologic Qwaves on the ECG; c) ECG changes indicative of ischemia (ST segment elevation or depression)
  - o first anterior or inferolateral STEMI or Qwave MI (QMI Anterior: V1-V3 or V1-V4 or V1-V5 or V1-V6.QMI Inferior: L2, L3, AVF, or L2, L3, AVF+ V5, V6 or L2, L3, AVF+ V6-V9 [posterior leads])
  - o regional wall motion score index (at least 4 out of 16 akinetic segments)
- · one or more of the following:
  - o LVEF >20% and <45% measured and calculated by 2-dimensional measurement
  - o Biomarkers: peak CK > 2000 IU
  - o infarct size > 25% as measured by MRI
- successful revascularization with PCI with 1 stent only, within 7 days of the index MI (only safe and MRI compatible stents)
- at time of application of device patient must have patent infarct related artery (IRA) and TIMI flow grade = 3

#### 4.5 Exclusion criteria

Exclusion criteria for this study are:

- · history of CHF, Class I to Class IV, as per NYHA criteria
- · history of prior LV dysfunction
- at time of application of study device Killip III-IV (pulmonary edema, cardiogenic shock hypotension (systolic < 90 mmHg) and evidence of peripheral hypoperfusion (oliguria, cyanosis, sweating) or HR > 100 bpm
- patient with pacemaker
- prior CABG
- prior MI
- history of stroke
- significant valvular disease (moderate or severe)
- · patient is a candidate for CABG or PCI on non-IRA
- · patient is being considered for CRT within the next 30 days
- renal insufficiency (eGFR < 60)
- · chronic liver disease (> 3 times upper limit of normal)
- life expectancy < 12 months
- · current participant in another clinical trial, or participation in another trial within the last 6 months
- · any contraindication to coronary angiography, MRI or PCI procedures
- · patient taking anti-coagulation medication prior to MI
- · pregnant or lactating women; pregnancy confirmed by urine pregnancy test
- patients with a reasonable likelihood for non-compliance with the protocol
- · any other reason that, in the Investigator's opinion, prohibits the inclusion of the patient into the study

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#### 4.6 Withdrawal criteria during the study

Each patient has the right to withdraw from the trial at any time for any reason.

The Investigator must make at least 3 documented attempts to contact those patients who do not return for the scheduled follow-up visits. Attempts must be recorded in the patient's file.

The Sponsor reserves the right to terminate the study at any time.

Upon withdrawal from the study any time after administration of study device, the patient will undergo the End of Study assessments (Section 6.2.1.5; Table 6.1).

Dropouts that occur after implantation of BL-1040 will not be replaced.

### 4.7 Treatment allocation

This is an open label study. All patients will be treated with BL-1040. Patient eligibility will be established prior to treatment with BL-1040.

If a patient discontinues from the study, the patient number will not be reused.

#### 4.8 Method of blinding and unblinding

As this is an open label study, there will be no blinding or unblinding procedure.

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## 5 Product Overview

## 5.1 BL-1040

BL-1040 myocardial implant is a non-pharmacologic, non-surgical, cross-linked alginate solution administered via intracoronary (IC) injection to infarcted tissue. BL-1040 completely disintegrates into its constituent polymers within approximately 90 days after deposition, and is excreted in the urine.

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## 5.2 Formulation

The formulation of BL-1040 is shown in Table 5.1.

### Table 5.1 Formulation of BL-1040

0.3% Calcium D-Gluconate (Gluconic acid hemicalcium salt) 1% PRONOVA UP VLVG Generic name: Sodium Alginate Water for Injection USP/EP Sigma, Dr. Paul Lohmann GmbH KG FMC BioPolymer/ NovaMatrix

#### 5.3 Dosage and application

BL-1040 will be administered to the coronary vasculature using multiple commercially available devices. Table 5.2 provides a list of the commercially available components that will be required in order to delivery the Bl-1040 implant.

## Table 5.2 List of Commercially Available BL-1040 Delivery Devices

#### **BL-1040 Implant Delivery Devices**

- 1 Standard endovascular sheath (femoral or radial or brachial)
- 2 Standard coronary guiding catheter (example Launcher, ref LA6AR10SH)
- 3 Guidewire 0.014 inch (example Boston Scientific, ref. 383931-035J)
- 4 Torque device (example Boston Scientific, ref. K903606))
- 5 Guidewire introducer (example Input Ref. 87311)
- 6 Microcatheter designed for coronary intravascular use such as multipurpose probing endovascular microcatheter. Example:(Boston Scientific Catalog number SCH 50058) or Transit microcatheter, (Cordis Endovascular Systems, MiMI Lakes, Fla.) or Renegase Hi-Flo microcatheter (Boston Scientific)
- 7. Disposable syringe, Intmed 5 mL sterile CE, ISO9001, ISO13488

Cardiac catheterization should be done according to the guidelines of the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards. All angiographies will be evaluated by a core laboratory. BL-1040 is delivered intra-coronary (IC) via a microcatheter that is intended for coronary intravascular use.

The timing of BL-1040 administration is within 7 days after the index MI. Two (2) mL of BL-1040 will be injected IC through the infarct related artery supplying the infarcted area. BL-1040 may not be mixed with any contrast medium.

All patients will be treated in the same manner.

Detailed instructions for the application of BL-1040 are provided in a separate Instruction Manual.

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#### 5.4 Labelling/Packaging

BL-1040 will be packed in a sterile cylindrical injection vial, type A glass. Vials are filled with sterile BL-1040 and sealed with a 20 mm rubber stopper, spun-on aluminum seal and a flip-off top.

All packages will be labeled according to the GMP guideline Volume 4, Annex 13 Manufacture of Investigational Medicinal Products (July 2003 Revision 1) [1] and local laws.

BL-1040 will be packed in labeled boxes, with at least the following information: study number, patient number, route of administration, storage guidelines, batch number, expiry date, instructions for administration, manufacturer name/code, and "Investigational use only".

The Sponsor must notify the Site Investigator, who has the overall responsibility for the study device, of the anticipated date of arrival.

#### 5.5 Storage

The Site Investigator is responsible for ensuring that BL-1040 is stored in a safe refrigerated location (2-8° C) with controlled access. At this temperature, BL-1040 has a shelf life of 3 months. The temperature must be monitored once daily, and recorded on a temperature log.

BL-104 must be removed from the refrigerator and kept at room temperature 30 minutes prior to administration.

#### 5.6 Compliance

BL-1040 will be administered by the Investigator only, and will not be dispensed to the patient or any other personnel.

#### 5.7 BL-1040 accountability

Under no circumstances is it permitted to use study supplies for any purposes other than those specified in the protocol.

The Investigator will be provided with forms to enable accurate recording of all investigational product at all times. The Investigator must sign a statement that he/she has received BL-1040 for the study. At any time the figures of supplied, used and remaining BL-1040 must match. At the end of the study, it must be possible to reconcile delivery records with those of used and unused stocks. Account must be given of any discrepancies.

At the end of the study, all unused BL-1040 supplies and empty containers must be returned to the Sponsor.

#### 5.8 Concomitant medication

The following medications may only be administered as indicated:

- ceftriaxone may not be administered during the 48 hours immediately prior to the administration of BL-1040, and for the 48 hours immediately following administration of BL-1040
- · calcium solutions may not be administered during the first week of the study

The introduction of any medication not allowed by the protocol at any point in the study will require a discussion between the Investigator and the Sponsor. If, in the opinion of the Investigator, it becomes necessary to administer any medication during the study, the Investigator will determine the dose and time of intake, and document the medication(s) in the patient's CRF.

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Patients must be instructed not to begin any new medication before consulting with the Investigator (unless required for emergency medical use). The patient must be instructed that this prohibition applies to over-the-counter products as well as prescription drugs.

All patients will receive optimal medical therapy according to the relevant, updated guidelines from the European Society of Cardiology [3,4,5]. Optimal therapy including aspirin, anticoagulation if indicated, angiotensin-converting-enzyme inhibition, beta-blockade, aldosterone antagonists, when appropriate, and lipid-lowering therapy, unless contraindicated. Clopidogrel therapy will be initiated before PCI and continued for 1 year after myocardial infarction [3].

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### 6 Study Procedures

### 6.1 General study aspects

This is an open label, multi-center study to assess the safety and feasibility of the injectable BL-1040 myocardial implant to provide scaffolding to infarcted myocardium.

Patients will be admitted to the hospital for treatment of an acute myocardial infarction (AMI), to include angioplasty and implantation of a-stent/s. Within 7 days of successful revascularization, patients will undergo an echocardiogram for assessment of the extent of the changes to the heart, and to verify cardiac inclusion/exclusion criteria. MRIs are to be encouraged as an additional assessment, but are contingent upon the agreement of the patient. After the echocardiogram/MRI, but still within 7 days of the index AMI, patients will undergo a 2<sup>nd</sup> cardiac catheterization to administer BL-1040. Patients will remain hospitalized for at least 48 hours after the procedure.

The BL-1040 scaffold will be injected into one infarct related artery (IRA), distally to the implanted stent/s. Patients will undergo cardiac monitoring before, during and after the procedure: a 12-lead ECG will be done prior to and after administration of BL-1040; patients will be connected to a continuous ECG monitor and will have continuous hemodynamic measurements during the procedure; immediately after the completion of the 12-lead ECG, a Holter monitor will be placed and will remain connected for the following 24 hours.

Patients will undergo physical examinations, assessment of vital signs and an ECG daily during hospitalization; safety blood sampling will be done on the day of discharge.

Patients who have been discharged from the hospital will be contacted by phone on Day 8 to confirm the administration of any concomitant medications, general status of the patient, and any doctor visits since hospital discharge.

Patients will return for follow-up visits on Day 30, Day 90 and Day 180 (End of Study). Additional follow-up safety visits are planned for Months 12, 24, 36, 48 and 60. At each visit, patients will again undergo a physical examination with measurement of vital signs, ECG, blood sampling, echocardiography and completion of the Minnesota Living with Heart Failure questionnaireÒ. At each follow-up visit, the patients will be hooked up to a 24-hour ambulatory Holter monitor, which will be returned the following day. MRIs are to be encouraged through Day 180 as an additional assessment, but are contingent upon the agreement of the patient. MRIs are not to be requested as part of the long term safety visits.

Echocardiograms, ECGs, Holters, angiographies and MRIs, will be evaluated in a core laboratory.

The first 2 patients will be sequentially enrolled; if approved by the ISMB; 3 additional patients will be enrolled. After review and approval of the 30 day safety data from these 3 patients, the balance of patients may be enrolled. Details are provided in Sec. 4.2.

Both female and male patients must agree to use effective contraception (as agreed with the Investigator) for 6 months (180 days) after the procedure.

## 6.2 Outline of study procedures

All study procedures are outlined in the Schedule of Assessments below (Table 6.1). A more detailed description of the study procedures performed at each study stage/visit is given in the following sections.

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#### Table 6.1

#### Schedule of Events

Visits/Week		Hosp	italization		Post discharge follow-up				
Study days	Screening Day (-7) to Day (-1)	Day 1 Day of application <sup>1</sup>	Daily during hospitalization <sup>2</sup>	Day of discharge	Telephone Contact Day 8 (± 1 day)	Day 30 (± 5 days)	Day 90 (± 5 days)	Day 180 (± 7 days) End of Study Visit	Follow-up Safety Visits (Months 12, 24, 36, 48 60, ± 30 days)
AMI	Х								
Hospitalization		X		>					
Coronary angiography, PCI, stent <sup>3</sup>	Х								
Informed consent	Х								
Inclusion/exclusion criteria	X								
Pregnancy test	X								
Demography; medical history; concurrent illnesses	X X	Х	Х	Х		Х	Х	Х	Х
Physical examination Vital signs (temperature, arterial BP, weight)	X	X	X	X		X	X	X	X
12-lead ECG	X	л Х <sup>4</sup>	X	X		X	X	X	X
Laboratory safety parameters	X <sup>5</sup>	л Х <sup>6</sup>	А	X <sup>6</sup>		X	X	X	X
Total CK/CK MB	X	X <sup>7</sup>		A		л	Λ	Λ	Λ
				X6		V	V	V	
NT-proBNP	X	$X^6$		X°		X	X	X	\$7
Echocardiography/MRI <sup>8</sup>	Х	0				Х	Х	Х	Х
Continuous ECG monitoring		X <sup>9</sup>							
Cardiac catheterization; application of BL-1040; coronary angiography		Х							
PTT or ACT measurements		X <sup>10</sup>							
24-hour ambulatory Holter monitoring		Х				Х	Х	Х	Х
Safety contact for discharged patients					Х				
Minnesota Living with Heart FailureO						Х	Х	Х	Х
Serious/Adverse events and concomitant medication	Х	Х	Х	Х		Х	Х	Х	Х

1. Device to be administered within 7 days of AMI

2. Patient must remain hospitalized for at least 48 hours after procedure.

3. Done as treatment of AMI

4. Prior to and after administration of BL-1040

5. Troponin I or T to be measured at Screening only

6. If not done within previous 48 hours

7. Parameters to be assessed prior to, and 8, 16, 24 and 48 hours after administration of BL-1040

8. Echocardiography to be done at each visit. MRIs are to be encouraged as an additional assessment through Day 180, but are contingent upon patient agreement. MRIs are not to be requested as part of the Follow-up Safety visits.

9. Patient to be connected prior to implantation of BL-1040, and for the duration of the procedure

10. Measured prior to implantation of BL-1040, and prior to removal of sheath

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#### 6.2.1 Detailed description of study stages/visits

#### 6.2.1.1 Screening, Day -7 to Day -1

Patients are admitted to the hospital for treatment of an AMI, prior to enrollment into the study. The treatment will include PCI with placement of a stent. After signing of Informed Consent, and prior to initiation of any study-related procedures, the following activities will be carried out:

- · confirmation of inclusion/exclusion criteria
- negative pregnancy test for all women of child-bearing potential (as defined in Inclusion Criteria)
- demographics
- medical history
- physical examination
- vitals signs
- · 12-lead ECG, in supine position
- blood and urine sampling for laboratory safety parameters (biochemistry, hematology and urinalysis)
- · blood sampling for Total CK/CK MB
- · blood sampling for NT-proBNP
- echocardiography
- · MRI, if patient agrees
- concomitant medication record (all currently prescribed and over the counter medications must be recorded in the Case Report Form [CRF], with dose and reason for use)
- · pre-device serious/adverse events

### 6.2.1.2 Day 1

BL-1040 must be implanted within 7 days of the index AMI; the day of implant will be considered Day 1 of the study. Prior to implantation, the following assessments will be carried out:

- physical examination
- vital signs
- · 12-lead ECG
- blood and urine sampling for laboratory safety parameters (biochemistry [excluding troponin I or T], hematology, and urinalysis), if not done within the previous 48 hours
- · Total CK/CK MB
- · NT-proBNP, if not done within the previous 48 hours
- · connection to continuous ECG monitoring

BL-1040 will be implanted in the infarcted tissue via the IRA, distally to the stent as outlined in the separate BL-1040 Instruction Manual. During the procedure the following assessments will be done:

- · continuous ECG monitoring
- · continuous hemodynamic measurements (arterial blood pressure)
- $\cdot$  blood sampling for PTT or ACT, prior to implantation of BL-1040 and prior to removal of sheath

An additional coronary angiography will be done 3 minutes after implantation of the BL-1040, and will include an assessment of TIMI flow and myocardial blush.

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The following assessments will be done after the procedure:

- urinalysis
- · blood sampling at 8 hours, 16 hours and 24 hours after the procedure, for assessment of Total CK/CK MB
- · 12-lead ECG
- · connection to 24 hour Holter monitor

Adverse events and concomitant medications will be monitored continuously during the procedure and recorded on the patient's CRF.

## 6.2.1.3 Daily during hospitalization

The patient must remain hospitalized for at least 48 hours after the procedure. The following assessments and procedures will be carried out during each day of hospitalization, including day of discharge:

- physical examination
- vital signs
- · 12-lead ECG
- blood and urine sampling for laboratory safety parameters (biochemistry [excluding troponin I or T], hematology and urinalysis) on day of discharge and only if not done within the previous 48 hours
- · NT-proBNP on day of discharge and only if not done within the previous 48 hours
- serious/adverse events
- · concomitant medication

## 6.2.1.4 Telephone Contact, Day 8, ±1

Patients who have been discharged from the hospital will be contacted by phone 7 days after application of BL-1040. The patient should be asked the following questions:

- 1. How have you been feeling since your discharge? Have you had any chest pain or experienced any shortness of breath?
- 2. Did you call your doctor for any reason? If so, when, and for what reason?
  - Did you go to the emergency room for any reason? If so, when and for what reason?
- 3. Are you taking any medications? If so, which ones?

The information collected from this phone call is to be recorded in the patient's CRF.

## 6.2.1.5 Day 30, Day 90 and Day 180 (End of Study)

The patient will return to the hospital for the following assessments and procedures on Day 30, Day 90 and Day 180. The visit on Day 180 will be considered the End of Study visit. If a patient is discontinued prior to Day 180 for any reason, the following assessments should be done at the time of discontinuation.

Assessments to be carried out include:

- $\cdot$  physical examination:
- vital signs
- · 12-lead ECG

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- · connection to 24-hour Holter monitor; to be returned on Day 31/Day 91/Day 181
- blood and urine sampling for laboratory safety parameters (biochemistry [excluding troponin I or T], hematology and urinalysis)
- · NT-proBNP
- echocardiography
- · MRI, if patient agrees
- · completion of the Minnesota Living with Heart FailureÒ questionnaire
- · serious/adverse events
- concomitant medication
- 6.2.1.6 Extended safety follow-up (Months 12, 24, 36, 48, 60 ± 30 days)

Patients will return to the hospital yearly for completion of follow-up assessments.

#### Assessments are to include::

- · physical examination
- vital signs
- · 12-lead ECG
- connection to 24-hour Holter monitor; the patient is to be connected at the time of the follow-up visit, and the monitor is to be returned the following day
- · blood and urine sampling for laboratory safety parameters (biochemistry [excluding troponin I or T], hematology and urinalysis)
- echocardiography
- · completion of the Minnesota Living with Heart FailureÒ questionnaire
- · completion of the following questions:
  - How have you been feeling since your last check up?
  - · Have you been hospitalized for any reason? If so, when, and for what reason?
- · serious/adverse events
- concomitant medication

## 6.3 Study evaluations and procedures

Safety will be evaluated by analyzing the results of physical examinations, laboratory examinations and cardiac assessments, as well as AEs (Section 7) and vital signs. Assessments will be carried out at the time points specified in Section 6.2, and as shown in Table 6.1.

All safety related investigations are to be performed by the Principal Investigator or a medically qualified designee, who is responsible for the overall treatment of the patient.

#### 6.3.1 Safety

6.3.1.1 Physical examinations

Physical examinations will include height (Screening only), weight, and a general assessment of overall body systems (cardiovascular, respiratory).

#### 6.3.1.2 Vital signs

The following vital signs will be assessed:

pulse rate

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- · blood pressure (supine, systolic and diastolic)
- body temperature

The actual blood pressure and pulse rate should be recorded in the patient's CRF. Rounding of values is not allowed.

The following ranges will be used to define acceptable blood pressure:

- supine systolic blood pressure: 100 160 mmHg
- supine diastolic blood pressure: 60 95 mmHg
- supine pulse <100 bpm

Body temperature should be measured using the same methodology at each assessment, and should be measured in decimals.

## 6.3.1.3 ECGs

A standard supine 12-lead ECG shall be recorded. ECG morphology and ECG intervals (PR, RR, QRS, QT, and QTc) will be determined; QTc will be calculated using Bazett's formula.

Patients will be connected to a 24-hour ambulatory Holter monitor at each follow-up visit (Day 30, Day 90, Day 180).

Printouts/copies must be placed in the patient's chart, clearly labeled with the patient number, time, date, visit, and study number, and signed by the Investigator. A core laboratory will evaluate the results of both the ECG and Holter.

### 6.3.1.4 Echocardiograms

Echocardiograms will be performed and recorded according to specific criteria established for this study, and provided in a separate Echocardiogram Reference Manual. The same parameters will be measured at each assessment, throughout the study.

A core laboratory will evaluate echocardiograms.

The Principal Investigator, the Sponsor or the ISMB may review echocardiograms at any time if any safety concerns arise. Echocardiograms will be performed at the times indicated on the Schedule of Events and in Sec. 6.2 of the protocol.

#### 6.3.1.5 MRIs

While the MRI is an optional procedure for cardiac assessment at Screening and all follow-up visits (Day 30, Day 90, Day 180/End of Study), patients should be encouraged to undergo the procedure at each relevant visit. Performance of the procedure is always contingent upon patient agreement.

MRIs will be performed according to specific criteria established for this study, and provided in a separate MRI Reference Manual. A core laboratory will evaluate MRIs.

The Principal Investigator, the Sponsor or the ISMB may review MRIs at any time if any safety concerns arise.

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## 6.3.1.6 Clinical safety evaluations

## Safety blood sampling

All laboratory samples will be processed at the local laboratory, except for NT-proBNP, which will be assessed at a core lab.

The Investigator must review the laboratory assessments (initialed and dated) within 24 hours after the receipt of those results. Out of range values will be interpreted by the Investigator with a comment of "not clinically significant" (NCS) or "clinically significant" (CS). Clinically significant abnormal laboratory values must be repeated on the appropriate clinical follow-up arranged by the Investigator and documented on the lab report until the lab value has stabilized or has returned to a clinically acceptable range (regardless of relationship to BL-1040). Any laboratory value that remains abnormal at the End of Study visit and is judged to be clinically significant will be followed according to accepted medical standards for up to 30 days or until resolution of the abnormality.

Approximately 15 mL safety blood samples will be collected at the time points indicated in Sec 6.2 and shown in Table 6.1. Analyses will include:

- biochemistry
  - $\cdot$  total protein
  - · albumin
  - · total bilirubin
  - · ALT
  - · AST
  - · GGT
  - · LDH
  - alk phosphate
  - glucose
  - · sodium
  - potassium
  - · calcium
  - phosphate
  - · urea/BUN
  - · creatinine
  - · PTT or ACT
  - troponin I or T (Screening only)
- hematology
  - · red blood cell count
  - · hemoglobin
  - · hematocrit
  - mean cell hemoglobin
  - · mean cell hemoglobin concentration
  - · mean cell volume
  - · white blood cell count and differential
  - platelet count
  - cardiac biomarkers

- · Total CK/CK MB
- · NT-proBNP

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- urinalysis
  - urine protein
  - urine glucose
  - $\cdot$  urine blood
  - leukocytes
  - nitrites
  - urobilinogen
  - · bilirubin
  - · pH
  - specific gravity
  - ketones

If dipstick analysis reveals any pathological results, a full urine analysis will be conducted and the following should be checked:

- 1. Color
- 2. Appearance
- 3. Leukocytes + erythrocytes per HPF (High Power Field)
- 4. Squamos epithelial cells
- 5. Non squamos epithelial cells
- 6. Yeast in urine
- 7. Amorphous cells
- 8. Mucous in urine
- 9. Casts
- 10. Crystals

### 6.3.2 Core laboratories

Results of echocardiograms, ECGs, Holters, angiographies, and MRIs will be evaluated at Biomedical Systems:

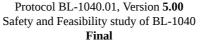
Biomedical Systems 1945 Ch. de Wavre B-1160 Brussels-Belgium phone: +32 2 661 20 70 fax: +32 2 661 20 71 email: sjacobs@biomedsys.com

NT-proBNP samples will be assessed at the central laboratory at the University of Heidelberg:

Universitätsklinikum Heidelberg Zentrallabor Im Neuenheimer Feld 671 69120 Heidelberg, Germany Tel.: 06221-56-8803 Fax: 06221-56-5205

#### 6.4 Minnesota Living with Heart FailureÒ questionnaire

The Minnesota Living with Heart FailureÒ questionnaire (MLHQ) is a standardized and validated questionnaire designed to measure the effects of heart failure and treatments for heart failure on an individual's quality of life (ref. 6-8). The questionnaire measures the effects of symptoms, functional limitations,



and psychological distress on the individual's life. These items are measured using a 6 point Likert scale (0-5) to indicate how much each of 21 items has affected their quality of life.

The scales will be administered by the Investigator or trained/designated personnel, in the local language.

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## 7 Adverse and Serious Adverse Events

## 7.1 Adverse event definition

An adverse event (AE) is any untoward medical occurrence in a clinical trial patient who was administered a medicinal product and/or medical device and which does not necessarily have a causal relationship with this treatment. This includes any noxious, pathological or unintended change in anatomical, physiological or metabolic functions as indicated by physical signs, symptoms and/or laboratory detected changes occurring in any phase of the clinical study whether associated with the study drug/device and whether or not considered related to study intervention. This includes an exacerbation of pre-existing conditions or events, intercurrent illnesses, or drug/device interaction. Anticipated day-to-day fluctuations of pre-existing conditions that do not represent a clinically significant exacerbation need not be considered AEs. Discrete episodes of chronic conditions occurring during a study period should be reported as AEs in order to assess changes in frequency or severity.

AEs should be documented in terms of signs and symptoms observed by the Investigator or reported by the patient at each study visit. A medical diagnosis should be added.

Pre-existing conditions or signs and/or symptoms (including any which are not recognized at study entry but are recognized during the study period) present in a patient prior to the start of the study should be recorded in the Medical History form within the patient's CRF.

#### 7.2 Recording adverse events

All non-serious AEs (serious or non-serious) will be recorded from the time of implantation of BL-1040 on Day 1 until the end of the active study period (Day 180); all serious AEs will be recorded from the time of implantation of BL-1040 until the end of the long term follow-up (Month 60). AEs are to be recorded on the appropriate AE pages in the patient's CRF; if the AE is serious, the appropriate box on the AE page of the CRF should also be ticked. Where possible, a diagnosis rather than a list of symptoms should be recorded. If a diagnosis has not been made then each symptom should be listed individually. The nature, time of onset and cessation, and any treatment provided shall be recorded.

According to "Medical Devices: Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices – GHTF/SG2/N54R8:2006, Study Group 2 Final Document", typical adverse events for medical devices include but are not limited to:

- a malfunction or deterioration in the characteristics or performance
- · an incorrect or out of specification test result
- an inaccuracy in the labeling, instructions for use and/or promotional materials. Inaccuracies include omissions and deficiencies. Omissions do not include the absence of information that should generally be known by the intended users.
- use error

All AEs (serious and non-serious) shall be reported as specified in this section of the Protocol, and the expanded Medical Device Reporting Guidelines, which will be provided to all investigators prior to the start of the study.

#### 7.3 **Pre-device events**

The Investigator will report any pre-device event directly observed or mentioned by the patient from the time of signing Informed Consent until the implantation of BL-1040 on Day 1. Pre-device events are reported in the CRF with at least the nature, the start date and the treatment (if applicable).

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## 7.4 General adverse events

Information on any AE must be recorded when volunteered by the patient, observed by study personnel, or elicited by a non-leading question, such as "How are you feeling?".

## 7.4.1 Assessment of severity of general adverse events

General events should be assessed according to the following scale:

•	mild	the event is easily tolerated and does not interfere with usual activity; disappears without residual effects
	moderate	the event interferes with daily activity, but the patient is still able to function
	severe	the event is incapacitating and the patient is unable to work or complete usual activity; considered as unacceptable by the Investigator

#### 7.4.2 Assessment of causality of adverse events

Every effort should be made by the Investigator to explain each AE, both serious and non-serious, and assess its causal relationship, if any, to implantation of BL-1040.

The relationship of BL-1040 to the event will be determined by how well the event can be understood in terms of one or more of the following

related	there is suspicion of a relationship between BL-1040 and AE (without determining the extent of probability); there are no other more likely causes and administration of BL-1040 is suspected to have contributed to the AE
possible	AE occurs within a reasonable time after the implantation of BL-1040 but can also be reasonably explained by other factors (as mentioned below)
unrelated	there is no suspicion that there is a relationship between BL-1040 and AE, there are other more likely causes and implantation of BL-1040 is not suspected to have contributed to the AE

Non-serious and serious AEs will be evaluated as two distinct types of events given their different medical nature. The Investigator will examine all events assessed as "serious" (Sec. 7.5.1) in order to determine, as far as possible, ALL contributing factors applicable to each serious AE.

Other possible contributors include:

- underlying disease
- other medication
- · protocol required procedure
- other (specify)

#### 7.4.3 Follow-up of adverse events and assessment of outcome

All AEs will be followed to resolution (patient's health has returned to baseline status or all variables have returned to normal); until an outcome has been reached; stabilization (Investigator does not expect any further improvement of worsening of the event); or the event is otherwise explained, regardless of whether the patient is still participating in the study. Where appropriate, medical tests and examinations will be performed to document resolution of the event. All follow-up information will be recorded in the patient's CRF until Day 180.

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#### 7.5 Serious Adverse Events

#### 7.5.1 Definition of Serious Adverse Event (SAE)

A serious adverse event (SAE) is any untoward medical occurrence or effect that led to one of the following outcomes:

- · death of a patient, user or other person
- serious injury of a patient, user or other person

Serious injury (also known as serious deterioration in state of health) is either:

- a life threatening illness or injury \*
- permanent impairment of a body function or permanent damage to a body structure<sup>†</sup>
- a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

The term "permanent" means irreversible impairment or damage to a body structure or function, excluding minor impairment or damage Medical intervention is not in itself a serious injury. It is the reason that motivated the medical intervention that should be used to assess the reportability of an event.

- in-patient hospitalization<sup>‡</sup> or prolongation of existing hospitalization
- an event that might lead to death or serious injury of a patient, user or other person if the event recurs (sometimes called a "near incident")

\*Life threatening: An AE is life threatening if the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

<sup>†</sup>Disabling/incapacitating: An AE is incapacitating or disabling if the event results in a substantial disruption of the patient's ability to carry out normal life functions. This definition is not intended to include experiences of relatively minor medical significance such as headache, nausea, vomiting, diarrhea, influenza, or accidental trauma (e.g. sprained ankle).

<sup>‡</sup>Hospitalization: In general, hospitalization signifies that the patient has been detained (usually involving at least an overnight stay) at the hospital or emergency ward for treatment that would not have been appropriate in the physician's office or out-patient setting.

Hospitalization for either elective surgery related to a pre-existing condition which did not increase in severity or frequency following initiation of the study or for routine clinical procedures<sup>¶</sup> (including hospitalization for "social" reasons) that are not the result of an AE need not be considered as AEs and are therefore not SAEs. When in doubt as to whether 'hospitalization' occurred or was necessary, the AE should be considered serious.

<sup>¶</sup>Routine Clinical Procedure: procedure which may take place during the study period and should not interfere with the implantation of BL-1040 or any of the ongoing protocol specific procedures. If anything untoward is reported during an elective procedure, that occurrence must be reported as an AE, either `serious' or non-serious according to the usual criteria.

For medical devices, typical serious adverse events include but are not limited to:

- use error (e.g. untrained user, incorrect route of administration) related to medical devices, which <u>did</u> result in death or serious injury
- · damage to tissue or tissue function following administration of study device

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- · impairment of an organ or organ function following administration of study device
- · interaction with concomitant treatment (other devices or drugs) that might lead to death or serious injury
- interaction with materials (e.g. catheters, stent), substances or gases entering into contact with the device during normal use that might lead to death or serious injury
- non-biocompatibility leading to serious irritation/allergy that results in in-patient hospitalization or prolongation of existing hospitalization

#### 7.5.2 Pre-defined SAEs

For the purposes of this study, the following events will be defined as serious:

- re-infarction
- · stroke or transient ischemic attack (TIA)
- acute heart failure (decompensation)

The occurrence of any of these events after implantation of BL-1040 will be considered an SAE; they are to be reported and followed up as specified in Sections 7.5.3 and 7.5.4.

#### 7.5.3 Reporting serious adverse events

All Serious Adverse Events (SAEs) must be reported immediately by the Investigator without filtration, whether considered to be associated with BL-1040 and whether or not considered related to BL-1040. The Investigator must report SAEs within one calendar day of becoming aware of the event by telephone, fax or e-mail to the Study Contact for Reporting Serious Adverse Events as indicated below. This initial notification should include minimal, but sufficient information to permit identification of the reporter, the patient, study device, any medications administered, AEs, causality assessment and date of onset. The Investigator should not wait for additional information to fully document the event before providing notification. An acknowledgement letter will confirm the first notification. The report is then to be followed by submission of a completed SAE Report Form provided by Averion International as soon as possible but at latest within 3 calendar days of the initial telephone/fax or e-mail report detailing relevant aspects of the AEs in question. All actions taken by the Investigator and the outcome of the event must also be reported immediately. For documentation of the SAE, any actions taken, outcome and follow-up reports, the SAE Report Forms are to be used. Where applicable, hospital case records and autopsy reports should be obtained.

Investigators must report SAEs to the appropriate ethics committee if requested by the committee and/or according to local legal requirements.

	Study Contact for Reporting Serious Adverse Events.	
	Averion International Gewerbestrasse 24, CH-4123 Allschwil, Switzerland	
F <b>ax:</b> e-mail: Tel:	+ <b>41-61-487-1421</b> SAE@averionintl.com +41-61-487-1681	
	24/24 hour and $7/7$ day availability	

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#### 7.5.4 Follow-up of serious adverse events

All SAEs must be collected and documented until the end of the long term follow-up (Month 60), and followed up until the event either resolved, subsided, stabilized, disappeared or is otherwise explained or the study patient is lost to follow-up. All follow-up activities must be reported, if necessary on one or more consecutive SAE report forms, in a timely manner. All fields with additional or changed information must be completed and the report form should be forwarded to the Study Contact for Reporting Serious Adverse Events as soon as possible but latest within 7 calendar days after receipt of the new information. Clinically significant laboratory abnormalities will be followed up until they have returned to normal, or a satisfactory explanation has been provided. Reports relative to the subsequent course of an AE noted for any patient must be submitted to Averion International.

# 7.6 Treatment of adverse events

Treatment of any AE is at the sole discretion of the Investigator and according to current available best treatment. The applied measures should be recorded in the CRF of the patient.

# 7.7 Pregnancy

The Sponsor must be notified immediately of any pregnancy that occurs during the study. The SAE report form should be used to report the pregnancy, even though the pregnancy is not considered an SAE. Women who become pregnant during the study will be followed up until birth of the child. The health status of the newborn will be reported in the patient's CRF.

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# 8 Data Evaluation and Statistics

In all analyses where a change from baseline is performed, baseline is defined as the last available value before device implantation.

# 8.1 Endpoints

The **primary** endpoints are occurrence of all adverse events including but not limited to:

- · all MIs
- · cardiovascular hospitalization
- · serious ventricular arrhythmias sustained
  - · VT (symptomatic or sustained VT [duration longer than 30 seconds or 100 beats, or associated with hemodynamic collapse]
  - · VF
  - symptomatic bradycardia, pauses of longer than 3.0 seconds, complete atrioventricular block, Mobitz II atrioventricular block
- · symptomatic heart failure (NYHA criteria + physical examination OR hospitalization due to heart failure)
- · renal failure
- stroke
- · death

Secondary Endpoints include the parameters:

- · change from baseline in LV dimensions (end-systolic volume index, end-diastolic volume index, left ventricular mass)
- · change from baseline in regional (infarct related) and global wall motion score
- · change from baseline in ejection fraction
- · cardiac rupture
- · NT-proBNP

#### 8.2 Estimated sample size

No formal sample size calculation was performed. Twenty patients followed up to Day 180 were deemed necessary to meet the objectives of this Phase I study. Taking into account drop-outs after the device implantation, thirty patients will be enrolled.

#### 8.3 Planned methods of analysis

All data recorded will be presented in data listings and summary tables, as appropriate. Missing values will not be replaced. No formal hypothesis testing will be performed.

### 8.3.1 Analysis population

All participants who received the BL-1040 myocardial implant will be included in the safety analysis. Any excluded cases will be documented together with the reason for exclusion. All decisions on exclusions from the analysis will be finalized prior database lock.

# 8.3.2 Analysis of demographics

Continuous demographic variables (age, height, weight) will be summarized using mean, median, standard deviation, minimum, maximum, and number of available observations.

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Qualitative demographic characteristics will be summarized by counts and percentages. Other patient characteristics (medical history, clinical findings, prior medications, inclusion/exclusion criteria) will only be listed.

### 8.3.3 Analysis of safety

AEs will be described in individual listings and frequency tables by system organ class and preferred terms (MedDRA version 10.0 or higher), regardless of relationship as well as for related AEs. The severity of AEs will also be tabulated.

Vital signs will be listed and changes from baseline and raw results will be summarized by means and standard deviations.

Laboratory test values will be presented by individual listings with flagging of values outside the normal ranges. Raw laboratory results and changes from baseline will be summarized by means and standard deviations.

12 lead ECG findings will be presented by listings and frequency tables, as appropriate. Continuous ECG data will be summarized using standard descriptive statistics.

The change from baseline in cardiac parameter (LV dimensions, wall motion score, ejection fraction) as well as the NT-proBNP data will be summarized using standard descriptive statistics.

## 8.4 Interim analysis

An interim safety analysis will be performed after 5 patients have completed the Day 30 visit, on all data collected up to this timepoint.

# 8.5 Final and follow-up reporting

The final clinical study report will be prepared based on data from Day 180, or End of Study, from the final patient. Thereafter, an annual safety report will be prepared after each yearly safety follow-up visit (Months 12, 24, 36, 48, 60).

#### 8.6 Quality assurance

All data collected in the CRF will be double entered into a validated computerized clinical data management system (Clintrial). Laboratory values from the local lab will be entered into the CRF. Analysis of the data will only be performed after all queries have been resolved using an appropriate software for analysis (SAS 8.1).

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## 9 Ethics and regulatory considerations

The study will be conducted according to Good Clinical Practice, the Declaration of Helsinki 2000 (Appendix A), and the rules and regulations of the European Union and Israel.

#### 9.1 Informed Consent

The nature, purpose and potential risk of the study as well as the action of the BL-1040 myocardial implant will be explained to all patients both verbally and in writing. They will be given adequate time to consider the study before signing the consent form. Their questions will be actively encouraged. They will be informed that they may withdraw from the study at any time. This information is documented in the protocol and participants in the study will sign a consent form confirming that they have read and understood it; no study activities will take place until the consent form has been signed. They will also be given a Patient Information Sheet and copy of the consent form.

## 9.2 Authorities

The procedures laid out by the local regulatory authorities must be followed and all documents must be submitted to all concerned authorities, and where needed, approved before a clinical study may commence.

#### 9.3 Protocol Amendments

There will be no alteration to the protocol without the express written approval of the Sponsor.

The local authorities or ethics committees must approve all major protocol amendments prior to implementation.

No protocol amendments should be adopted without prior written approval from the ethics committee except in the following cases:

- · in order to eliminate immediate hazard to the patients,
- · changes involving only logistical or administrative aspects of the trial. Then notification to the relevant authorities should be submitted.

In these cases, the implemented deviation or change should be submitted as soon as possible to the relevant authorities for review and approval.

No protocol deviations are anticipated. However, should any protocol deviations occur, the Principal Investigator must report the matter to the Sponsor as soon as reasonably practical. Details of the deviation and, if possible, the reason for its occurrence must be included in the study report.

Major modifications will need further approval, and will be submitted to the local authorities or ethics committees, according to local regulations, in the form of an Amendment. Minor administrative changes require only that the Chairman of the Ethics Committee be informed in writing without delay.

#### 9.4 Patient confidentiality

Individual patient data obtained as a result of this study is considered confidential. A patient identification number will identify any patient data collected throughout the study only.

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Data generated as a result of this study are to be available for inspection on request by all authorized Sponsor personnel, Averion International personnel, audit personnel and regulatory authorities. The Informed Consent must clearly reflect this access.

## 9.5 Insurance

The compensation of the patient in the event of study related injuries will comply with the applicable obligatory requirements. Details will be included in the Informed Consent.

#### 9.6 Duration of the study

The active study phase for each patient is 180 days. Enrolment is expected to begin in Q1 2008; the study is expected to end Q1 2010.

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# **10** Data Handling and Record Keeping

### 10.1 Documentation

Records must be retained for 15 years after study completion.

# 10.2 Case Report Forms

The Investigator is responsible for maintaining adequate and accurate medical records from which accurate information will be transferred into the study database. Case Report Forms (CRFs) should be completed by the Investigator or delegated personnel.

CRFs will be provided for each patient. All data will be entered in black ink. Data/corrections entered will be signed or initialed by the study personnel undertaking that procedure. Overwriting data or use of liquid correcting fluid is not allowed. Detailed instructions are provided with the CRF.

#### 10.3 Monitoring and quality control

To ensure compliance with relevant regulations, data generated by this study must be available for inspection upon request by representatives of BioLine Innovations Jerusalem, Averion International (CRO), auditing personnel and relevant local regulatory authorities.

Regular on-site visits for monitoring of study activities and data recording will be scheduled. Formal reports of these visits will be generated and copies provided to relevant Sponsor and study personnel.

#### **10.4 Publication policy**

The results of the study are the property of the Sponsor. All manuscripts, abstracts or other modes of presentation arising from the results of the study must be reviewed and approved in writing by the Sponsor, in advance of submission. Co-authorship with any Sponsor personnel will be discussed and mutually agreed upon before submission of a manuscript to a publisher.

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- 8. Rector TS. A conceptual model of the quality of life in relation to heart failure. J Cardiac Failure 2006.

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# **Appendix A: Declaration of Helsinki**

Initiated: 1964 17.C

Original: English

# WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI Ethical Principles for

Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975 35th WMA General Assembly, Venice, Italy, October 1983 41st WMA General Assembly, Hong Kong, September 1989 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996

and the

52nd WMA General Assembly, Edinburgh, Scotland, October 2000 Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002 Note of Clarification on Paragraph 30 added by the WMA General Assembly, Tokyo 2004

# A. INTRODUCTION

- 1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.
- 2. It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.
- 3. The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."
- 4. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.
- 5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.
- 6. The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.

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- 7. In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.
- 8. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognised. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.
- 9. Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

## **B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH**

- 10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.
- 11. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.
- 12. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.
- 13. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the Investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.
- 14. The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.
- 15. Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.
- 16. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.

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- 17. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.
- 18. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.
- 19. Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.
- 20. The subjects must be volunteers and informed participants in the research project.
- 21. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimise the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
- 22. In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.
- 23. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.
- 24. For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the Investigator must obtain informed consent from the legally authorised representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.
- 25. When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the Investigator must obtain that assent in addition to the consent of the legally authorised representative.
- 26. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorised surrogate.
- 27. Both authors and publishers have ethical obligations. In publication of the results of research, the Investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

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# C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

- 28. The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.
- 29. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists.
- 30. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.
- 31. The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.
- 32. In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

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# Appendix B: Minnesota Living with Heart FailureÒ questionnaire

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### LIVING WITH HEART FAILURE QUESTIONNAIRE

#### Instructions for Use

- 1. Patients should respond to the questionnaire prior to other assessments and interactions that may bias responses. You may tell the patient that you would like to get his or her opinion before doing other medical assessments.
- 2. Ample, uninterrupted time should be provided for the patient to complete the questionnaire.
- 3. The following instructions should be given to the patient each time the questionnaire is completed.
  - a. Read the introductory paragraph at the top of the questionnaire to the patient.
  - b. Read the first question to the patient "Did your heart failure prevent you from living as you wanted during the past month by causing swelling in your ankles or legs"? Tell the patient, "If you did not have any ankle or leg swelling during the past month you should circle the zero after this question to indicate that swelling was not a problem during the past month". Explain to the patient that if he or she did have swelling that was caused by a sprained ankle or some other cause that was definitely not related to heart failure he or she should also circle the zero. Tell the patient, "If you are not sure why you had the swelling or think it was related to your heart condition, then rate how much the swelling prevented you from doing things you wanted to do and from feeling the way you would like to feel". In other words, how bothersome was the swelling? Show the patient how to use the 1 to 5 scale to indicate how much the swelling affected his or her life during the past month from very little to very much.
- 4. Let the patient read and respond to the other questions. The entire questionnaire may be read directly to the patient if one is careful not to influence responses by verbal or physical cues.
- 5. Check to make sure the patient has responded to each question and that there is only one answer clearly marked for each question. If a patient elects not to answer a specific question(s) indicate so on the questionnaire.
- 6. Score the questionnaire by summating the responses to all 21 questions. In addition, physical (items 2, 3, 4, 5, 6, 7, 12 and 13) and emotional (items 17, 18, 19, 20, and 21) dimensions of the questionnaire have been identified by factor analysis, and may be examined to further characterize the effect of heart failure on a patient's life.

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# LIVING WITH HEART FAILURE QUESTIONNAIRE

These questions concern how your heart failure (heart condition) has prevented you from living as you wanted during the last month. The items listed below describe different ways some people are affected. If you are sure an item does not apply to you or is not related to your heart failure then circle 0 (No) and go on to the next item. If an item does apply to you, then circle the number rating how much it prevented you from living as you wanted.

## Did your heart failure prevent you from living as you wanted during the last month by:

		No	Verv little				Very much
1			very nue				IIIuCII
1.	Causing swelling in your ankles, legs, etc.?	0	1	2	3	4	5
2.	Making you sit or lie down to rest during the day?	0	1	2	3	4	5
3.	Making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4.	Making your working around the house or yard difficult?	0	1	2	3	4	5
5.	Making your going places away from home difficult?	0	1	2	3	4	5
6.	Making your sleeping well at night difficult?	0	1	2	3	4	5
	Making your relating to or doing things with your						
7.	friends or family difficult?	0	1	2	3	4	5
8.	Making your working to earn a living difficult?	0	1	2	3	4	5
	Making your recreational pastimes, sports or hobbies						
9.	difficult?	0	1	2	3	4	5
10.	Making your sexual activities difficult?	0	1	2	3	4	5
11.	Making you eat less of the foods you like?	0	1	2	3	4	5
12.	Making you short of breath?	0	1	2	3	4	5
13.	Making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14.	Making you stay in a hospital?	0	1	2	3	4	5
15.	Costing you money for medical care?	0	1	2	3	4	5
16.	Giving you side effects from medications?	0	1	2	3	4	5
	Making you feel you are a burden to your family or						
17.	friends?	0	1	2	3	4	5
18.	Making you feel a loss of self-control in your life?	0	1	2	3	4	5
19.	Making you worry?	0	1	2	3	4	5
	Making it difficult for you to concentrate or remember						
20.	things?	0	1	2	3	4	5
21.	Making you feel depressed?	0	1	2	3	4	5
	0,,	J. J	_				-

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Annotated Protocol incorporating Amendment 1, Amendment 2, Amendment 3, and Amendment 4 Appendix B **01 December** 2008

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# SCHEDULE 1.31

# DESCRIPTIONS OF OTHER ON-GOING TRIALS

Name of Study
[\*\*\*]

[\*\*\*] [\*\*\*]

# **Estimated Duration**

9

[\*\*\*] [\*\*\*] [\*\*\*] **Estimated End Date** 

[\*\*\*] [\*\*\*] [\*\*\*]

# SCHEDULE 1.35

# OUTLINE OF STRUCTURE FOR PIVOTAL CLINICAL TRIAL FOR PRIMARY INDICATION

(see Schedule 3.1)

SCHEDULE 1.42(a)

INDEPENDENT SAFETY MONITORING BOARD CHARTER

# **Independent Safety Monitoring Board**

# Charter

# For

# **Bioline Innovations Jerusalem**

# Protocol No. BL-1040

A Phase I, multi-center, open label study designed to assess the safety and feasibility of the injectable BL-1040 implant to provide scaffolding to infarcted myocardial tissue

# APPROVING OFFICIALS

Name	Title	Signature	Date
Lincoff, A. Michael, M.D	Chairman ISMB		
Moti Gal	Sponsor Contact Person		
Andrea Kempf-Müller, M.D	Drug Safety Officer		

# **Contact details ISMB members**

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# ISMB Chairman

#### Contact details BioLine and Averion

Project Manager Averion: Frederic Liegeois, Msc

Senior Drug Development Manager Bioline: Tuvia Shmuel, PhD

ISMB Sponsor Representative Bioline: Adina Porat

Clinical Operations Manager Bioline: Moti Gal

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### 1. PROTOCOL BL-1040

A Phase I, multi-center, open label study designed to assess the safety and feasibility of the injectable BL-1040 implant to provide scaffolding to infarcted myocardial tissue.

Venn Life Sciences AG has been contracted by Bioline Innovations Jerusalem to provide services as the Contract Research Organization (CRO) for the trial.

### 2. SCOPE OF THE ISMB CHARTER

The International Independent Safety Monitoring Board (ISMB) was formed to monitor the safety of patients participating in this trial on an ongoing basis.

The ISMB will evaluate quality, accuracy and timeliness of data flow and assure confidentiality of data.

The ISMB will develop stopping rules for the termination of the study prior to the initiation.

Bioline Innovations Jerusalem will forward the charter to Regulatory Authorities, and/or Ethics Committees as necessary.

The objective of the ISMB Charter is to outline the specific purposes and functions of the ISMB. In addition, it describes the procedures for data abstraction and data delivery conventions to and from the ISMB members for review purposes.

#### 3. COMPOSITION OF THE ISMB

The ISMB is composed of three members, three voting members including the Chairman. In addition a bio-statistician will consult the ISMB however will not attend as a voting member. The members are independent physicians in the field of cardiology and a bio-statistician experienced in evaluating safety data from cardiology clinical studies. Prof. Lincoff will serve as Chairman of the ISMB. All ISMB members have been approved by the sponsor, Bioline Innovations Jerusalem.

By signing the ISMB Charter, voting ISMB members verify that they do not have a vested interest in the outcome of the study, nor do they have a financial conflict of interest. ISMB members are not employees of Bioline Innovations Jerusalem have outside employment and will not be involved in patient recruitment or as investigators in the study.

The ISMB members are expected to serve until the study is completed. Should a member resign, the reason and effective date of resignation must be submitted in writing to Bioline Innovations Jerusalem and the ISMB Chairman. A replacement member will be sought by Bioline Innovations Jerusalem in consultation with the ISMB Chairman.

Except for the initial meeting of the ISMB where the background data on BL-1040 and the study design will be discussed by Bioline Innovations Jerusalem's' representatives, Bioline Innovations Jerusalem will not participate in the ISMB meetings unless requested by the ISMB.

#### **ISMB** Administration

From Venn Life Sciences AG, the ISMB Coordinator will arrange for the provision of the data and narratives required by the ISMB. Bioline Innovations Jerusalem will provide administrative, logistical and coordinating services to the ISMB.

#### **ISMB Contacts & Consultants**

The Chairman will be the representative of the ISMB who will be responsible for timely official communications between the ISMB and Bioline Innovations Jerusalem. The Chairman will provide leadership and oversee that the direction of ISMB meeting operations are in accordance with the ISMB charter.

From the sponsor, Bioline Innovations Jerusalem, an identified representative will serve as the primary contact person for the ISMB. The sponsor primary contact is named on the ISMB charter. This individual is not considered to be a member of the ISMB and will only attend open and final sessions of ISMB Data Review Meetings.

From Venn Life Sciences AG, the ISMB Coordinator will serve as the primary contact person for any questions the ISMB members have regarding the contents of the ISMB Data Reports. This individual is not considered to be a member of the ISMB and will only attend open and final sessions of ISMB Data Review Meetings. Additional individuals may also be invited to attend the open and final sessions of the ISMB Data Review meetings, as deemed appropriate.

The ISMB Chairman will ensure that ISMB contacts are *not* exposed to the ISMB review of the data until the ISMB has arrived at a conclusion. ISMB contacts may *not* be present during closed sessions, when the ISMB Data Report is reviewed, ISMB deliberations are made, ISMB recommendations are discussed and/or ISMB voting procedures are conducted.

# 4. ISMB ROLE & RESPONSIBILITIES

The ISMB is an independent expert advisory group commissioned and charged with the responsibility of evaluating accumulating data at regular intervals and ensuring the safety of the subjects enrolled in the study by monitoring cumulative safety data collected in the clinical program and providing recommendations to Bioline Innovations Jerusalem based on review of this data. The ISMB will contribute to efficient conduct of the trial by providing a fast review of emerging findings from the study. This ISMB will consist of physicians with expertise in cardiovascular disease, particularly in the area of coronary artery disease and with experience monitoring safety of drugs and/or devices for cardiovascular applications, and will have no participation in the trial in any other capacity.

These reviews in subsets of patients will have the objective of searching for signals of clinically important adverse safety findings that may be indicative of risk to currently enrolled patients as well as increased risk for future patients. In these reviews, the ISMB will assume a conservative approach in assessing safety.

The Chairman will be directly responsible for reporting the outcome of all ISMB meetings and be the primary contact for any emergency meetings, as appropriately convened. He will be a voting member of the ISMB. The Chairman will also be responsible for the preparation of the report and/or recommendations to Bioline Innovations Jerusalem.

The three voting members of the ISMB (along with the Chairman) will be responsible for evaluating the safety data and making recommendations on the continuation of the study as set out in the protocol. They may also make other pertinent safety recommendations for the conduct of the study. They will be guided by the ISMB Biostatistician's evaluation of the data, as required.

The bio-statistician will be involved in conducting any analysis that the ISMB recommends. The Bio-statistician will be responsible for designing and maintaining the safety database that the ISMB will use for its analysis. This database may differ from the database by Venn Life Sciences AG and, as such, is meant only for the use of the ISMB. The database will be created in such a way that it is reproducible and can be audited, if necessary. If the ISMB is considering a recommendation of premature termination of the study, the bio-statistician can contact Venn Life Sciences AG for additional data and/or for the performance of confirmatory analysis. The Bio-statistician can also arrange for the necessary ISMB communications to be documented and stored and only to be released after study completion.

The ISMB will ensure that this study meets the highest standards of patient safety. In their analysis of the data from the patients, the ISMB will be focused on determining if there is a signal of clinically significant pattern of change in safety parameters that may lead to termination of study. This may require the ISMB to perform/request additional data/analyses prior to making a decision.

The operating procedures of the ISMB are based on and are in compliance with guidance and definitions of the International Conference on Harmonization and the Food and Drug Administration. The ISMB will conduct all of its operations under the ICH Good Clinical Practices (GCP).

Specifically, the ISMB is authorized and charged to perform the following functions:

- review 30 day safety data patients from the first 2 sequentially enrolled patients to determine whether 3 additional patients may be enrolled; after reviewing the 30 day safety data from these 3 additional patients, will determine whether the rest of patients may be enrolled
- within 30 days of enrolment of each successive group of 5 patients receiving the device, will review all Serious and Severe Adverse Events occurring
  to date and will recommend continuation, discontinuation, or modification of the procedure or protocol, based on a determination of whether the
  occurrence of serious, unexpected, or device-related adverse events (Sec. 7 in protocol) might outweigh the potential benefit achievable with the
  device
- review emerging findings in patients and identify potential safety concerns with BL-1040
- will receive information, on an expedited basis, on all Serious and Severe Adverse Events, clinically significant laboratory values (as defined in the study safety plan), ECG abnormalities and vital signs that are associated with Serious and Severe Adverse Events, and data from patients who decided to withdraw from the study due to Serious and Severe Adverse Events. All Serious and Severe Adverse Events that occur in the catheter lab during the administration of BL-1040 or the hospitalization period after the procedure should be reviewed promptly by the ISMB. The ISMB will review this information and may decide to interrupt, alter, or terminate the trial.

• will adjudicate whether or not an event is unexpected, based on a pre-specified list of expected Serious and Severe Adverse Events as well as clinical judgment within the study population.

All ISMB members will review the safety data provided by the CRO. The members will reach their own individual decision on the relatedness and the potential hazard posed by the event. The ISMB will then collectively discuss the cases. In the event the majority opinion of the Board is that the events do not pose any significant risk then the ISMB will recommend continuing the trial as designed. However, if the Board decides that undue risk could accrue from continuation of the study as designed, the ISMB has the freedom to recommend appropriate changes to the study selection criteria, safety evaluations, etc. In addition, the CRO will provide datasets and listings capturing disposition, AEs, clinically significant Echocardiography, MRI, angiography, Holter, ECG vital signs/laboratory changes, once all patients complete study.

# 5. VENN LIFE SCIENCES AG ROLE & RESPONSIBILITIES

Venn Life Sciences AG will provide coordinating services for the study. The ISMB Coordinator will provide information, on an expedited basis, on all Serious and Severe Adverse Events, clinically significant laboratory values (as defined in the study safety plan, ECG abnormalities and vital signs that are associated with Serious and Severe Adverse Events as required, to the ISMB members. Venn Life Sciences AG will be charged with the following responsibilities:

- To identify a specific individual to interface with the ISMB.
- To provide all required information in advance of the meeting in a mutually agreeable format approved at the initial meeting of the ISMB.
- To provide a standard safety narrative for all patients who withdraw from the study due to Serious or Severe Adverse Events.
- To provide specific meeting issues in advance of the meeting.
- To keep the ISMB Chairman informed of any serious safety issues as the study progresses
- To inform each principal investigator of the ISMB recommendations, as required.
- To notify Bioline Innovations Jerusalem of any issues related to the ISMB which might negatively influence the study.

## 6. BIOLINE INNOVATIONS JERUSALEM'S RESPONSIBILITIES

Bioline Innovations Jerusalem will be responsible for the following:

- To make any necessary changes to the protocol recommended by the ISMB and approved by Bioline Innovations Jerusalem.
- To ensure that the ISMB is operating as needed for the purpose of the study.

# 7. ONGOING COMMUNICATIONS & NOTIFICATIONS

The ISMB Chairman will receive relevant information regarding serious adverse events and Early Terminations on an ongoing basis. The ISMB Chairman will determine whether further distribution of this material to the remaining voting ISMB members is necessary.

#### 8. DATA REVIEW MEETINGS

ISMB Data Review meetings will be held in person or through teleconferences based on the volume of data to be reviewed. The ISMB Coordinator will establish the agenda for each ISMB Data Review meeting, with input from Bioline Innovations Jerusalem and the ISMB Chairman.

It is expected that there will be one initiation and at least three scheduled ISMB Data Review meetings. The initiation meeting will be held via face-to-face format, while the Data Review Meetings may be held via teleconference.

The first 2 patients will be sequentially enrolled into the study. After the 1st patient has completed Day 30 assessments, the Independent Safety Monitoring Board (ISMB, Sec. 4.3) will review the patient's data through Day 30 (first ISMB meeting). The ISMB will then decide whether to give approval to enroll the 2nd patient. After the 2nd patient has completed Day 30 assessments, the ISMB will again review the data and provide approval for enrollment of the next 3 patients (2nd ISMB meeting). After all 3 patients have completed Day 30 assessments, the ISMB will review the data from these patients and provide approval for opening enrollment to the rest of the patients (3rd meeting)

The ISMB may also elect to hold ad hoc meetings outside of the scheduled dates, if deemed necessary. For instance, as the ISMB Chairman will receive information regarding reported serious adverse events on a regular basis, ad-hoc ISMB meetings may also be held on a triggered basis (e.g. in response to a high number of safety events).

#### Voting

Input must be obtained from all three ISMB members, for voting purposes. The ISMB will strive for a consensus opinion regarding the data reviewed. If ISMB consensus is not possible, a majority vote will be required, to determine the final ISMB recommendation. If the ISMB vote does not result in a clear majority, the ISMB Chairman will assemble and present majority and dissenting opinions for all recommendations considered. Meeting Minutes

ISMB Data Review meeting minutes will be divided by session and will reflect the attendance of voting ISMB members, the ISMB Coordinator, ISMB contacts and consultants and other individuals, as well as whether each individual attended in person or via teleconference.

Since all details of ISMB deliberations must be kept strictly confidential among members of the ISMB, portions of the ISMB Data Review meeting minutes must remain confidential until the completion of the final study analysis.

The ISMB Chairman will file all minutes from all sessions, centrally. Once the final study analysis is complete, the ISMB Chairman will forward the central file of all ISMB minutes for all sessions to Bioline Innovations Jerusalem for appropriate filing.

#### 9. **RECORDS RETENTION**

The ISMB Chairman should maintain a record of all ISMB minutes until the investigation of the study device is discontinued. After this period, the ISMB Chairman will forward to the sponsor all records to the sponsor to determine if further retention and/or archiving is necessary.

Data Source and Content

#### 10. ISMB COMMUNICATION OF FINAL CONCLUSIONS

The ISMB Chairman will contact Bioline Innovations Jerusalem within two working days after an ISMB meeting (via facsimile or telephone) to notify them of recommendations forthcoming from that meeting. Bioline Innovations Jerusalem will act upon these recommendations as appropriate, i.e., the final decision will rest with Bioline Innovations Jerusalem. Bioline Innovations Jerusalem's VP of Medical Affairs or designee will notify the project team and the CRO of the ISMB recommendations.

Bioline Innovations Jerusalem's VP of Medical Affairs will also write a memo to the files documenting the recommendations of the ISMB and convey to all investigators the decision to continue/discontinue the study.

# 11. IMPLEMENTATION OF THE ISMB RECOMMENDATIONS

The decision to implement the recommendations of the ISMB will be made by Bioline Innovations Jerusalem. Bioline Innovations Jerusalem will notify the ISMB of the actual action taken, in response to all recommendations.

If the ISMB recommends early study termination or protocol modification and such action is not accepted or implemented, Bioline Innovations Jerusalem will address this decision with the ISMB in writing.

# 12. CONFIDENTIALITY

The ISMB will maintain a strictly confidential relationship to the study data. The ISMB will only reveal specific details and information associated with ISMB data review to appropriate parties, as specified by this ISMB Charter.

SCHEDULE 2.3

# EXISTING PRODUCT AGREEMENTS



#### SCHEDULE 3.1

### INITIAL DEVELOPMENT PLAN

#### **Project Boston Clinical Development Plan**

#### Objective

This product is a unique concept, and will require a unique and sophisticated development plan to satisfy all stakeholders.

This product has been given a regulatory designation as a device (rather than drug). The objective of this development plan is to leverage that designation for a rapid and efficient regulatory approval, while providing adequate evidence for safety within the intended patient population.

#### Strategy

The strategy is to complete a minimal additional amount of preclinical safety in parallel with the clinical development program. [\*\*\*]

The filing will be based on a [\*\*\*] note that the current phase 2 study has no control group, and can give only general information about safety and tolerability, and no real information on efficacy in humans. For this reason the [\*\*\*] will be designed with a 'vanguard' cohort of approximately [\*\*\*] patients. Once the vanguard has completed 6 months of follow up, and interim analysis will be performed, assessing the study for 1) safety, 2) efficacy or futility and 3) performance of the endpoint. Specific, detailed and comprehensive criteria will be established to allow for stopping or continuation, or adjustments in sample size or inclusion criteria. The rules for the interim analysis will be agreed with regulatory authorities in advance of any unblinding, and appropriate adjustments will be made for type 1 error.

Following the interim analysis the number of participating centers will be increased to speed enrollment, and the study will continue to completion.

#### Endpoint and sample size

We will define [\*\*\*], and then power the study to show at least a [\*\*\*] with BL-1040 compared to placebo. This difference is clinically meaningful.

To give maximum power we want to define an endpoint that has a [\*\*\*] after treatment, which would be reduced to [\*\*\*]. We will design a [\*\*\*] that ensures an event rate that is [\*\*\*] in the control arm.

Failure could include [\*\*\*] Any <u>one</u> of these events and the patient is [\*\*\*]'; <u>none</u> of these events and the patient is considered [\*\*\*]. It is possible that other clinically relevant events may be added to the composite.

Next we will estimate how often each of these events will happen. [\*\*\*]

Control Group Event Rate	Treatment Group Event Rate	Sample size per arm 90% power and type 1 error < 5%	Total
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Although not required under device approval regulations, approximately [\*\*\*] patients would be desirable for a safety database. If we assume that the placebo event rate will be approximately [\*\*\*], we would estimate the sample size of the pivotal study to be approximately [\*\*\*] patients, including the [\*\*\*] patients in the vanguard cohort.

# Budget

	2009	2010	2011	2012	2013	2014	2015	2016	TOTAL
[***]	[***]	[***]	[***]	[***]	[***]	[***]			
[***]						[***]			
[***]							[***]		
[***]							[***]	[***]	
[***]								[***]	
TOTAL	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]

# Phase III Study

Budget will assume [\*\*\*] of [\*\*\*] patients, with a primary endpoint at [\*\*\*], major adverse cardiac outcomes at [\*\*\*], and a safety follow up annually for [\*\*\*].

# **Clinical:**

Monitoring: Per Patient total:	[***]		[***] [***]
Pre Clinical	[***]	[***]	

# Total

[\*\*\*]

Given that 15-20% of the total clinical costs are committed before the first patient is enrolled, we estimate that <u>cost to decision point is approximately</u> [\*\*\*]. It may be possible to reduce cost to the decision point by [\*\*\*], trading off for time-to-launch. This alternative scenario has not been modeled.

# Cost by Year (\$M)

[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]

# [\*\*\*] <u>Study</u>

Budget will assume a [\*\*\*] (including ethnicity) of [\*\*\*] patients. Study will start in [\*\*\*] and end [\*\*\*].

# Cost by Year (\$M)

[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]

# Timeline

# Phase III Study

Enrollment			
w/ [***]per site per month	Part 1	Part 2	
Total Enrollment	[***]	[***]	
Active Sites	[***]	[***]	
Enrollment/Site/Month (on average)	[***]	[***]	
Monthly Study Enrollment	[***]	[***]	
Time to Enroll Patient per Part (months)	[***]	[***]	
TOTAL ENROLLMENT TIME (months)	[***]		

Trial Task	End Date
Initiate Project	[***]
FPI	[***]
[***]	[***]
LPI	[***]
DB Lock	[***]
CSR	[***]
Submit PMA	[***]

# **Probability of success**

Based on the available preclinical data it is not possible to come to a firm estimate of POS at this time. However, there is evidence of efficacy in preclinical models, and a consensus among experts that the mechanism is plausible. Given the existing data on the prior use of this class of compounds in humans, the likelihood of adequate safety and tolerability seems higher than would otherwise be possible at this stage, and given the device designation, the probability of clinical and regulatory success is likewise higher than it might otherwise be. Assuming the likelihood of adequate safety at [\*\*\*] and the likelihood of adequate efficacy at [\*\*\*], the overall POS to filing is in the range of [\*\*\*].

#### SCHEDULE 3.7

# PRELIMINARY COMMERCIALIZATION PLAN

#### **Preface:**

This document is prepared for the management of BioLineRx as a basis for discussion only, and is intended to be indicative of Ikaria's current intent with respect to global commercialization of BL-1040. Actual launch plans will continue to evolve over time, in accordance with the evolution of market dynamics, the global environment for cardiovascular drugs and devices, and the emerging product profile of BL-1040.

#### I. Situation Analysis

#### a. Unmet Medical Need

Each year cardiovascular disease (CVD) causes over 4.3 million deaths in Europe. CVD is estimated to cost the European Union (EU) economy €192 billion a year. The main forms of CVD are coronary heart disease (CHD) and stroke. Just under half of all deaths from CVD are from CHD. CV is also a large problem in Japan, and is emerging as a public health issue even in the developing countries.

Each year smoking kills over 1.2 million people in Europe (450,000 from CVD)). Dietary patterns across Europe are playing an increasing role in CVD. Levels of physical inactivity are high in many European countries and levels of obesity are increasing across Europe in both adults and children. Over 48 million adults in Europe have diabetes and the prevalence is increasing.

Estimates for population and cardiovascular statistics are presented in Table 1

Table 1
---------

		<b></b>		
		Est.		
		Annual		
		non-fatal		
	Population	Ml	Interventional	Annual PCI
Country	(000,000)	(000)	Cardiologist	Procedures
[***]	10.4	34.7	230	28
[***]	5.5	18.3	85	15
[***]	5.3	17.7	80	14
[***]	64.4	214.7	1,772	172
[***]	82.3	274.3	1,500	219
[***]	16.7	55.7	266	45
[***]	0.3	1.0	14	1
[***]	58.1	193.7	1,879	155
[***]	40.5	135.0	730	108
[***]	7.6	25.3	124	20
[***]	61.1	203.7	1,000	163
Total Europe	352.2	1,174.0	7,682	939
[***]	127.0	423.3	2,500	339
[***]	21	70	373	56
Grand Total	479.2	1,597.3	10,182	1,278

# b. Product

BL-1040, a novel, injectable, biodegradable polymer designed to be used in conjunction with Percutaneous coronary intervention (PCI) to provide mechanical scaffolding and reduce the risk of structural remodeling and heart failure in post-myocardial infarction (post-MI) patients, is currently in development and could be on the market as early as [\*\*\*] If successful, BL-1040 could be a breakthrough in the management of patients with cardiovascular disease and could represent a large commercial opportunity for Ikaria and BioLineRx.

#### c. Assessment of current level of CV practice

There is significant variability around the medical management of CHD across Europe. Theses groupings give a high level overview of the most common interventions:

#### Hospital admissions

Rates of admission for CVD vary considerably across Europe. In general, higher admission rates are found in Eastern European and Scandinavian countries. Similar geographical trends are seen for CHD.

#### Coronary revascularization and other procedures for CVD

While rates of revascularization vary widely across Europe, all countries have seen rates increase significantly since the 1990s. For example, since 1990 rates of PCI have increased fifteen-fold in Italy and twelve-fold in Finland. We expect that advances in medical technique and continued development of medical infrastructure around the world will drive continued growth in the coronary revascularization market.

#### <u>Drugs</u>

The use of drugs for secondary prevention in CHD patients varies considerably across populations, except in the case of anti-platelet drugs. Over 80% of patients took this form of drug (mostly aspirin). The use of beta blockers, lipid-lowering drugs and ACE inhibitors varies throughout the EU.

#### d. Pricing and reimbursement environment

The global market for cardiovascular drugs and devices is highly variable in terms of pricing and reimbursement climates.

#### **Pricing**

Pricing in the developed markets of western Europe tends to be similar to U.S. pricing, although prices can vary significantly by market, with Northern European markets having higher prices than southern European markets. By contrast, pricing in less developed markets (Eastern Europe, Latin America and the Far East) is highly variable, and will require careful study to ensure an appropriate price is selected in order to maximize penetration and profitability. A clear target product profile will be critical to assessment of pricing strategy in all markets.

Reference pricing is common practice in Europe, so timing of local launches must be carefully coordinated to ensure optimized pricing across the territory.

[\*\*\*]

[\*\*\*].

# Reimbursement

With the exception of regulatory approval, reimbursement will be the single most important driver of commercial success.

The process by which products gain reimbursement can vary greatly from country to country, and may take a considerable amount of time. A recent study by IMS suggested that it was common for newly approved drugs to take between one and three years to gain widespread reimbursement coverage in the top 16 EU markets. Because most European countries operate centralized, government-financed health systems, it is not typical for patients to pay for treatments privately. In many countries where there is virtually no habit of citizens paying for their own healthcare, initiating selling activity without reimbursement would be virtually impossible, while inhabitants of some other countries may have no problem paying for healthcare out of their own disposable income.

Expected timing of reimbursement will, therefore, be a major driver of the timetable for building out sales infrastructure, and commencing selling activities. Ikaria will conduct extensive research between deal closing and launch to ensure that reimbursement conditions are clearly understood and that plans are in place to ensure broad and favorable access to major commercial markets.

# II. Commercialization Plan

# Product Positioning Strategy

Given the current expectations of the product profile, we aspire to – and expect that – BL-1040 will be positioned as the de facto standard for prevention of post-MI remodeling.

While this depends on the specific results of the clinical trials, the market conditions, including competitive scenario, and prevailing clinical practice standards, the goal will be to make BL-1040 use prevalent across a range of patient sub-groups that are at risk for remodeling. Specifically, the following patient groups will be addressed in the marketing plan:

- <u>High-risk STEMI</u> (includes patients with large myocardial Infarctions (MIs), anterior wall MIs and long lead time to PCI): [\*\*\*]
- Other STEMI (includes all STEMI patients not considered of the highest risk): [\*\*\*]

- [\*\*\*]
- <u>NSTEMI</u> [\*\*\*]

In addition to the market development efforts listed above, the focus of marketing strategy will be on creating broad awareness of the significant long-term effects of remodeling as well as discussing the risks of myocardial damage and resulting negative consequences for all patients with MIs. In Europe, this will also require resetting of the current paradigm of treating non-primary PCI patients with medical therapy alone, and illustrating the benefits of treatment with a mechanical scaffolding device such as BL-1040.

#### **Organization Size and Structure**

As an experienced critical care company, Ikaria is committed to providing doctors and other medical professionals with a high level of customer service. Operating in a highly specialized, life-or-death environment Ikaria strives to match our customers own urgency and commitment to patient care.

To be successful in the area of post-MI care we anticipate creating an organization capable of delivering both the commercial and medical support desired by our target customer base. Ikaria intends to establish itself as the leader in critical care globally, and will use BL-1040 as the platform on which to establish its international presence. As such, we intend to build a robust but flexible organization with all the competencies necessary to achieve leadership of the field. Although BL-1040 will likely be Ikaria's first global product, we anticipate that our own internal pipeline candidates IK-1001 and Covox will not be far behind. The infrastructure envisioned by Ikaria and described in this document will therefore be sufficient to successfully commercialize all of Ikaria's present and future pipeline compounds.

Ikaria proposed to use a "hub and spoke" approach to commercializing BL-1040 in Europe—the "hub" being a European headquarters and the "spokes" representing local operating companies (LOCs) in major markets. The headquarters will provide overall strategic leadership and will spearhead European product development and commercial strategy, while local operating companies will be responsible for selling activity and local tactic implementation.

In addition to strategic marketing and leadership support, the European headquarters will be responsible for financial management and reporting of regional results, management of European regulatory affairs functions, development of a European clinical development program, development of effective key opinion leadership, development of compelling health economic data and development of HR strategies to maintain a strong and vibrant European organization.

The primary role of LOCs is to provide the necessary local sales and marketing efforts necessary to achieve financial objectives for BL-1040. In addition to the necessary commercial infrastructure, the local operating companies would also be staffed with the support functions essential to commercial success. This would include a small local finance team, medical affairs, regulatory affairs and human resource functions. The role of the local support staff is to implement strategic initiatives conceived at headquarters level, and support local initiatives as necessary. The medical affairs staff will be particularly important in supporting marketing in disseminating the full medical information on BL-1040 and the clinical specialists will also lead the training of physicians in using this product appropriately.

The LOC staffing level will be determined as a function of country population, disease prevalence and target doctor population. Sales Representatives will be recruited from companies with a depth of experience in cardiovascular drug and device sales to ensure we gain rapid access to the necessary prescriber base. Representatives will be compensated through a blend of base salary and sales incentive bonus, according to Ikaria's existing sales force incentive plan. (See Table 2)

Table 2							
Country	Population (000,000)	Est. Annual non-fatal Ml (000)	Interventional Cardiologist	Annual PCI Procedures (000)	Sales Reps		
[***]	10.4	34.7	230	28	[***]		
[***]	5.5	18.3	85	15	[***]		
[***]	5.3	17.7	80	14	[***]		
[***]	64.4	214.7	1,772	172	[***]		
[***]	82.3	274.3	1,500	219	[***]		
[***]	16.7	55.7	266	45	[***]		
[***]	0.3	1.0	14	1	[***]		
[***]	58.1	193.7	1,879	155	[***]		
[***]	40.5	135.0	730	108	[***]		
[***]	7.6	25.3	124	20	[***]		
[***]	61.1	203.7	1,000	163	[***]		
Total Europe	352.2	1,174.0	7,682	939	[***]		
[***]	127.0	423.3	2,500	339	[***]		
[***]	21.0	70.0	373	56	[***]		
Grand Total	479.2	1,597.3	10,182	1,278	[***]		

NB: The number of sales reps anticipated to be needed in each market has been estimated as a function of [\*\*\*].

# Launch Timelines

To maximize the value of BL-1040 Ikaria intends to be ready to launch at the earliest possible opportunity. As described above, a key driver of launch readiness in any given market will be the ability to access reimbursement for BL-1040. Without appropriate reimbursement in place, attempting to launch BL-1040 would be at best un-productive, and at worst, damaging to the long-term perception of the product.

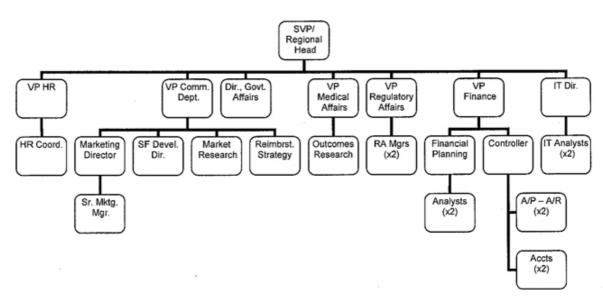
Ikaria proposes to immediately undertake a battery of research and analysis to understand the market-specific reimbursement environments across major target markets. Results of this research would guide future launch plans, and help inform the timing of key investments in people and infrastructure.

Development of Ikaria's ex-US presence will occur differently throughout the world:

- Ikaria already has management structures in place in Canada, Japan and Australia. These budding organizations would be expanded in the near term to allow essential market preparation activities to begin as soon as possible. As the product profile of BL-1040 becomes clearer, and the expectations for launch timing crystallize, this existing in-country leadership infrastructure will be expanded to include all the local sales and medical affairs capability necessary to a successful launch.
- 2) Establishment of a European Headquarters function would be a high priority. We anticipate filling key leadership positions as early as [\*\*\*], so that high-level reimbursement, medical affairs and commercial strategic planning can commence. As a clearer view of the likely launch timeline for BL-1040 emerges, remaining HQ infrastructure will be built out to ensure a fully operational European headquarters well in advance of launch. In the event that a positive result emerges from the interim analysis and a decision is made to move up the commercial launch of the product, the development of the launch plans including execution of reimbursement strategy and creation of marketing materials will occur in parallel to the ramp up of the LOCs.
- 3) Additional, 2<sup>nd</sup>-tier markets will be evaluated in parallel with [\*\*\*] commercial infrastructure development. Ikaria believes that there will be great potential for BL-1040 in markets such as [\*\*\*], but will need more time to evaluate the optimal way to maximize sales in those territories.

[\*\*\*]

#### Headquarters



#### **Human Resources**

Human Resources will oversee European benefits programs, ensure compliance with local employment law, promote employee development and succession planning, and all functions necessary to building a world-class critical care business in Europe. The European HQ team will work closely with LOC country managers to ensure local employee needs are met and compliance with local laws is maintained. Local in-country contractors may be employed to deliver HR services at the local level.

Anticipated headcount:

2

1

#### **Government Affairs**

Appropriate reimbursement will be critical to the success of BL-1040. As described above, reimbursement can be highly variable across Europe. Development of a skilled government affairs capability within Ikaria Europe will be critical to our success, for BL-1040 as well as future Ikaria pipeline products.

Anticipated headcount:

### **Commercial Development**

The European Commercial Development team is responsible for commercial strategy formulation across the European area, including both product and sales force strategy. The HQ marketing team will work closely with the Clinton, NJ-based marketing team to develop a cohesive global strategy suitable for implementation in European markets. The European team will have responsibility to ensure that brand strategies are implemented consistently across the area, and will perform market research to monitor performance and adjust strategy as appropriate. The team will also work in concert with country GMs and local marketing management to implement large-scale promotional and educations programs.

The European HQ team will also develop and implement European sales force strategies including development and maintenance of a customer relationship management system, sales skills training programs, and sales leadership development. The HQ team will work closely with LOC commercial management to ensure a top-class sales effort in each country.

Anticipated headcount: 5

#### **Medical Affairs**

Development of a strong base of key opinion leaders will be critical to the success of BL-1040. Cardiology is a fast moving, highly technical field, and for Ikaria to be a credible player we will need to make a significant commitment to supporting the medical community through education, research support, etc. The European Medical Affairs team will take the lead in formulating strategy for the engagement of key opinion leaders in the formulation of brand development strategy, the development of brand champions and building high-level relationships between Ikaria and the medical community. The HQ

Medical Affairs team will work closely with LOC Medical Affairs teams to align strategy across Europe and ensure a consistent medical approach.

The HQ Medical Affairs team will also be responsible for development of health outcome data to support cost-effectiveness arguments. The HQ team will work closely with LOC commercial teams to package health outcome data for effective presentation to in-country prescribers and reimbursement decision makers.

The HQ Medical Affairs team will also take responsibility for developing responses to requests for medical information about Ikaria products. The team will work with LOC Commercial and Medical Affairs teams to ensure a high level of customer support and satisfaction.

Anticipated headcount: 3

#### **Regulatory Affairs**

The European Regulatory Affairs (RA) team will lead all regulatory efforts on behalf of Ikaria's European operations. The HQ RA team will work closely with the Medical Affairs team to ensure development programs have maximal likelihood of success and that regulatory compliance is maintained at all times. The RA team will work in concert with in-country RA teams to execute on regulatory strategies and maintain product registrations with local authorities.

Anticipated headcount:

2

3

# Finance

The European Finance team will support all local operating companies with financial reporting and planning functions as well as accounts payable and accounts receivable activities. The HQ team will consolidate European results and maintain a full European operating P&L. The HQ team will perform most of the finance functions on behalf of the European Area, with LOCs having minimal local requirement for finance headcount.

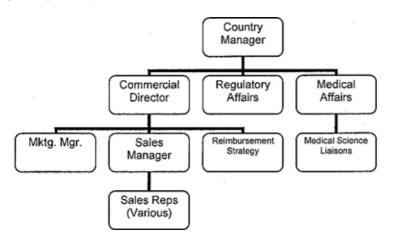
Anticipated headcount: 9

# **Information Technology**

Ikaria's European IT requirements will be delivered by the European HQ team, with local support from 3<sup>rd</sup>-party contract services. The HQ team will liaise with Ikaria's corporate headquarters IT function in Clinton, NJ to ensure reliable systems functionality and robust customer support.

Anticipated headcount:

# Local Operating Country (LOC) Structure



#### **Human Resources**

Human Resources support will be provided from HQ as described above. Specific local needs will be coordinated with HQ HR and delivered by local 3<sup>rd</sup> party providers

Anticipated headcount: None

#### **Commercial Development**

The LOC Commercial Development team is responsible for implementation of commercial strategy at the local level. The marketing team is responsible for implementation of European product strategy and for directing local tactical marketing in support of BL-1040. The LOC commercial director is also responsible for the development of a skilled critical care sales organization, including recruitment, training and management of reps and managers.

The number of sales reps required to promote BL-1040 will vary from country to country according to the market opportunity, the number of prescribing doctors, and the incidence of PCI procedures. (See Appendix A)

Anticipated headcount: Various

#### **Medical Affairs**

Maintenance of a strong relationships and robust medical affairs response capability will be essential for success at the local level. The LOC medical director will take responsibility for development of strong local relationships, coordination of company response to medical information requests. Clinical Specialists in each LOC will be responsible for training of physicians on use of product and for customer service.

Anticipated headcount: 1-2

# **Regulatory Affairs (RA)**

The LOC RA team will work together with HQ RA teams to execute on regulatory strategies and maintain product registrations with local authorities.

Anticipated headcount: 1 -2

# Finance

The HQ team will perform most of the finance functions on behalf of the European Area, with LOCs having minimal local requirement for finance headcount.

Anticipated headcount: None

# Information Technology

Ikaria's European IT requirements will be delivered by the European HQ team, with local support from 3<sup>rd</sup>-party contract services.

Anticipated headcount: None

# SCHEDULE 4.3(a)

# BIOLINERX WIRE TRANSFER INFORMATION

# [\*\*\*]

# EXHIBIT A

# TECHNOLOGY EXCHANGE PLAN

Upon Ikaria's request, the following will be provided by BioLineRx to Ikaria or its designee:

- 10. All materials (original or copies as appropriate) in BioLineRx's possession and Control relating to Product, including documentation relating to Development and all regulatory filings, clinical information, and data and other documents relating to the On-Going Phase I/II Trial and the Other On-Going Trials.
- 11. Copies of all documents and available information in BioLineRx's possession and Control necessary for Manufacturing of Product at the time of technology exchange. These documents will include information necessary to assist Ikaria or its designee in setting up Manufacturing operations for such things as:
  - raw material test methods, specifications, qualification and justification for use
  - raw material vendor lists with part numbers
  - analytical methods stated purpose, development, qualification and validation reports
  - process development reports, laboratory notebooks and associated electronically stored data
  - Manufacturing summary including
    - o detailed process description with process schematics, operating parameters and target ranges, flow charts outlining critical process controls and steps, cartoons, verbal description including abbreviations, process scale, yield, and standard process instructions
    - o in-process controls/tests and acceptance criteria including stated purpose of in-process tests
    - o master batch record(s)
    - o filling/packaging process
    - o aseptic and process development and validation documents
    - o facility and equipment requirements and design documents
    - o descriptions of process equipment, including suppliers, part numbers, and historic invoices
    - o product test methods, specifications and justification of specifications
    - o product stability, test methods and qualification/validation reports, stability reports, shelf life recommendations

As available and agreed upon by the JDC at the time of a technology exchange, BioLineRx will provide requested technical manufacturing or engineering advice to Ikaria or its designee. Ikaria will ensure designee has necessary expertise in place to exchange the documentation and expertise in an orderly fashion.

# <u>EXHIBIT B</u>

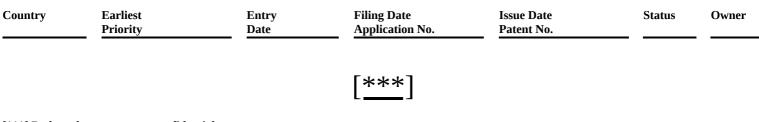
# BIOLINERX PATENT RIGHTS

Family 1

INJECTABLE	<b>CROSS-LINKED POLYM</b>	IER PREPARATIONS	AND USES THEREOF			
Country	Earliest Priority	Entry Date	Filing Date	Issue Date	Status	Owner
			Application No.	Patent No.		
			[***]			
[***] Redacted	pursuant to a confidential	treatment request.				

Family 2

# A METHOD OF TREATING MUSCLE TISSUES



# BioLineRx Ltd.

# 2003 Share Incentive Plan

# (\*In compliance with Amendment No. 132 of the Israeli Tax Ordinance, 2002)

# 1. <u>Name</u>

This plan, as amended from time to time, shall be known as the "BioLineRx Ltd. 2003 Share Incentive Plan" (the "Plan").

# 2. <u>Purpose</u>

The purpose and intent of the Plan is to provide incentive: (i) to retain, in the employ of the Company and its Affiliates (as defined below), persons of training, experience and ability, (ii) to attract new employees, directors, consultants, service providers and other entities, the services of which shall be considered valuable to the Company by the Board of Directors of the Company, (iii) to encourage the sense of proprietorship of such persons, and (iv) to stimulate the active interest of such persons in the development and financial success of the Company by providing them with opportunities to purchase shares in the Company, pursuant to the Plan.

# 3. **Definitions**

For purposes of the Plan and related documents, including the Incentive Agreement, the following definitions shall apply:

3.1.	"Affiliate" means any "employing company" within the meaning of Section 102(a) of the Ordinance.
3.2.	" <b>Approved 102 Option</b> " means an Option granted pursuant to Section 102(b) of the Ordinance and held in trust by a Trustee (as defined in Section 7) for the benefit of Grantee.
3.3.	"Approved 102 Security" means an Approved 102 Option and/or an Approved 102 Share.
3.4.	" <b>Approved 102 Share</b> " means a Share issued pursuant to Section 102(b) of the Ordinance or a Share issued upon the exercise of an Approved 102 Option, and held in trust by a Trustee (as defined in Section 7) for the benefit of a Grantee.
3.5.	"Board" means the Board of Directors of the Company.
3.6.	"Capital Gain Security (CGS)" as defined in Section 6.4.
3.7.	" <b>Cause</b> " means (i) commitment of a serious breach of trust, including, but not limited to, theft, embezzlement, self-dealing; (ii) prohibited disclosure to unauthorized persons or entities of confidential or proprietary information of, or relating to, the Company and/or its Affiliates; (iii) the engaging by Grantee in any prohibited business or activities competitive to the business of the Company and/or its Affiliates; or (iv) any other action or omission which may be defined as Cause "justifiable cause" or the like in the respective Grantee's employment, consulting or service agreement with the Company or an Affiliate, as applicable.

3.8. "Chairman" means the chairman of the Committee.

- 3.9. "**Committee**" means a share option / share incentive compensation committee appointed by the Board, as may be fixed from time to time by the Board.
- 3.10. "Companies Law" means the Israeli Companies Law 5759-1999, as now in effect or as hereafter amended.
- 3.11. "**Company**" means BioLineRx Ltd.
- 3.12. "Controlling Shareholder" shall have the meaning ascribed to it in Section 32(9) of the Ordinance.
- 3.13. "Date of Grant" means, the date of grant of a Security, as determined by the Board and set forth in Grantee's Incentive Agreement.
- 3.14. "**Employee**" means a person who is employed by the Company or its Affiliates, including an individual who is serving as a director or an office holder, but excluding Controlling Shareholder(s).
- 3.15. "Exercise Price" means the price for each Share subject to an Option.
- 3.16. **"Expiration Date**" means the date upon which an Option shall expire, as set forth in Section 10.2.
- 3.17. **"Fair Market Value**" means as of any date, the value of a Share determined as follows:
  - (i) If the Shares are listed on any established stock exchange or a national market system, including without limitation the NASDAQ National Market system, or the NASDAQ SmallCap Market of the NASDAQ Stock Market, the Fair Market Value shall be the closing sales price for such Shares (or the closing bid, if no sales were reported), as quoted on such exchange or system for the last market trading day prior to time of determination, as reported in the Wall Street Journal, or such other source as the Board or the Committee deems reliable. Without derogating from the above, solely for the purpose of determining the tax liability pursuant to Section 102(b)(3) of the Ordinance, if at the Date of Grant the Company's shares are listed on any established stock exchange or a national market system or if the Company's shares will be registered for trading within ninety (90) days following the Date of Grant, the Fair Market Value of a Share at the Date of Grant shall be determined in accordance with the average value of the Company's shares on the thirty (30) trading days preceding the Date of Grant or on the thirty (30) trading days following the date of registration for trading, as the case may be;
  - (ii) If the Shares are regularly quoted by a recognized securities dealer but selling prices are not reported, the Fair Market Value shall be the mean between the high bid and low asked prices for the Shares on the last market trading day prior to the day of determination, or;
  - (iii) In the absence of an established market for the Shares, the Fair Market Value thereof shall be determined in good faith by the Board or the Committee.
- 3.18. "Grantee" means a person who receives or holds a Security under the Plan.
- 3.19. **"IPO**" means the initial public offering of the Company's shares.
- 3.20. "Issuance Price" means the price for each share issued to a Grantee.
- 3.21. "**Non-Employee**" means a consultant, adviser, service provider, Controlling Shareholder or any other person who is not an Employee.
- 3.22. "Ordinary Income Security (OIS)" as defined in Section 6.5.

- 2 - -

- 3.23. "**Option**" means an option to purchase one or more Shares of the Company pursuant to the Plan.
- 3.24. "**102 Option**" means any Option granted pursuant to Section 102 of the Ordinance to any person who is an Employee.
- 3.25. "102 Security" means a 102 Option and/or a 102 Share.
- 3.26. "**102 Share**" means a Share issued pursuant to Section 102 of the Ordinance or a Share issued upon the exercise of a 102 Option, to any person who is an Employee.
- 3.27. "3(i) Option" means an Option granted pursuant to Section 3(i) of the Ordinance to any person who is a Non-Employee.
- 3.28. "3(i) Security" means a 3(i) Option and/or a 3(i) Share.
- 3.29. "**3(i) Share**" means a Share issued pursuant to Section 3(i) of the Ordinance or a Share issued upon the exercise of a 3(i) Option, to any person who is an Non-Employee.
- 3.30. **"Incentive Agreement**" means the share option agreement or share incentive agreement between the Company and a Grantee that sets out the terms and conditions of a Security.
- 3.31. "Ordinance" means the Israeli Income Tax Ordinance [New Version] 1961, as now in effect or as hereafter amended.
- 3.32. "Plan" means this BioLineRx Ltd. 2003 Share Incentive Plan.
- 3.33. "Section 102" means section 102 of the Ordinance as now in effect or as hereafter amended.
- 3.34. "Security" means an Option or a Share.
- 3.35. "Share" means an Ordinary Share, NIS 0.01 par value, of the Company.
- 3.36. "**Transaction**" means (i) a merger, consolidation or reorganization of the Company with or into any other corporation, or (ii) the sale or transfer of all or substantially all of the outstanding shares of the Company, (iii) or the sale or transfer of all or substantially all of the assets of the Company.
- 3.37. "**Unapproved 102 Option**" means an Option granted pursuant to Section 102(c) of the Ordinance.
- 3.38. "Unapproved 102 Security" means an Unapproved 102 Option and/or an Unapproved 102 Share.
- 3.39. "**Unapproved 102 Share**" means a Share issued pursuant to Section 102(c) of the Ordinance or a Share issued upon the exercise of an Unapproved 102 Option.
- 3.40. "Vesting Dates" means, as determined by the Board or by the Committee, the date as of which Grantee shall be entitled to exercise the Options or part of the Options.

# 4. <u>Administration</u>

4.1. The Plan will be administered by the Board or by a Committee. If a Committee is not appointed, the term Committee, whenever used herein, shall mean the Board. The Board shall appoint the members of the Committee and may, from time to time, remove members from, or add members to, the Committee and shall fill vacancies in the Committee however caused.

- 4.2. The Committee shall select one of its members as its Chairman and shall hold its meetings at such times and places as it shall determine. Actions taken by a majority of the members of the Committee, at a meeting at which a majority of its members is present, or acts reduced to or approved in writing by all members of the Committee, shall be the valid acts of the Committee. The Committee may appoint a Secretary, who shall keep records of its meetings and shall make such rules and regulations for the conduct of its business as it shall deem advisable.
- 4.3. Subject to the general terms and conditions of the Plan, the Committee shall have the full authority in its discretion, from time to time and at any time to: (i) designate Grantees to whom Securities shall be granted; (ii) determine the number of Shares to be covered by each Option; (iii) determine the time or times at which the same shall be granted; (iv) determine the Exercise Price of the Options and the Vesting Dates; (v) determine the Fair Market Value of the Shares; (vi) make an election as to the type of Approved 102 Securities; (vii) designate the type of Securities; (viii) determine any conditions on which the Options may be exercised and on which such Shares shall be paid for; and (ix) make all other determinations necessary or desirable for, or incidental to, the administration of the Plan.
- 4.4. Notwithstanding the above, the Committee shall not be entitled to grant Options or issue Shares that are not underlying Options to Grantees, however, it will be authorized to issue Shares underlying Options which have been granted by the Board and duly exercised pursuant to the provisions herein in accordance with section 112(a)(5) of the Companies Law.
- 4.5. The Committee may, from time to time, adopt such rules and regulations for carrying out the Plan as it may deem necessary. No member of the Board or of the Committee shall be liable for any act or determination made in good faith with respect to the Plan or any Security granted thereunder.
- 4.6. The interpretation and construction by the Committee of any provision of the Plan or of any Security thereunder shall be final and conclusive unless otherwise determined by the Board.

# 5. Eligible Grantees

- 5.1. The persons eligible for participation in the Plan as Grantees shall include any Employees and/or Non-Employees of the Company or of any Affiliate; provided, however, that (i) Employees may only be granted 102 Securities; (ii) Non-Employees may only be granted 3(i) Securities; and (iii) Controlling Shareholders may only be granted 3(i) Securities.
- 5.2. The grant of a Security to a Grantee hereunder, shall neither entitle such Grantee to participate, nor disqualify her/him from participating, in any other grant of Securities pursuant to the Plan or any other Share incentive plan of the Company.

# 6. Designation of Securities Pursuant to Section 102

- 6.1. The Company may designate Securities granted to Employees pursuant to Section 102 as Unapproved 102 Securities or as Approved 102 Securities.
- 6.2. The grant of Approved 102 Securities may be made under the Plan only following its adoption by the Board as described in Section 18, and shall be conditioned upon the approval of the Plan by the Israeli Tax Authorities.

- 6.3. Approved 102 Securities may either be classified as Capital Gain Securities ("CGS") or Ordinary Income Securities ("OIS").
- 6.4. Approved 102 Securities elected and designated by the Company to qualify under the capital gain tax treatment in accordance with the provisions of Section 102(b)(2) shall be referred to herein as **CGS**.
- 6.5. Approved 102 Securities elected and designated by the Company to qualify under the ordinary income tax treatment in accordance with the provisions of Section 102(b)(1) shall be referred to herein as **OIS**.
- 6.6. The Company's election of the type of Approved 102 Securities as CGS or OIS granted to Employees (the "**Election**"), shall be appropriately filed with the Israeli Tax Authorities before the Date of Grant of any Approved 102 Securities.

Such Election shall become effective beginning the first Date of Grant of an Approved 102 Security under the Plan and shall remain in effect until at least the end of the year following the year during which the Company first granted Approved 102 Securities. The Election shall obligate the Company to grant *only* the type of Approved 102 Security it has elected, and shall apply to all Approved 102 Security granted during the period indicated herein, all in accordance with the provisions of Section 102(g) of the Ordinance. For the avoidance of doubt, such Election shall not prevent the Company from granting Unapproved 102 Securities simultaneously.

- 6.7. All Approved 102 Securities must be held in trust by a Trustee, as described in Section 7.
- 6.8. For the avoidance of doubt, the designation of Unapproved 102 Securities and Approved 102 Securities shall be subject to the terms and conditions set forth in Section 102 of the Ordinance and the regulations promulgated thereunder.
- 6.9. With regards to Approved 102 Securities, the provisions of the Plan and/or the Incentive Agreement shall be subject to the provisions of Section 102 and the Tax Assessing Officer's permit, and the said provisions and permit shall be deemed an integral part of the Plan and of the Incentive Agreement. Any provision of Section 102 and/or the said permit which is necessary in order to receive and/or to keep any tax benefit pursuant to Section 102, which is not expressly specified in the Plan or the Incentive Agreement, shall be considered binding upon the Company and the Grantees.

# 7. <u>Trustee</u>

- 7.1. Anything herein to the contrary notwithstanding, Approved 102 Securities granted under the Plan and/or other shares received subsequently following any realization of rights with respect to such Securities, including without limitation bonus shares, shall be granted by the Company to a trustee designated by the Board and approved by the Israeli Tax Authorities in accordance with the provisions of Section 102(a) of the Ordinance (the "**Trustee**"), and held for the benefit of the Grantees for such period of time as required by Section 102 or any regulations, rules or orders or procedures promulgated thereunder (the "**Holding Period**"). In the event that the requirements for Approved 102 Securities are not met, then the Approved 102 Securities may be treated as Unapproved 102 Securities, all in accordance with the provisions of Section 102 and regulations promulgated thereunder.
- 7.2. Notwithstanding anything to the contrary, the Trustee shall not release any Approved 102 Shares prior to the full payment of Grantee's tax liabilities arising from Approved 102 Securities which were granted to Grantee.



- 7.3. With respect to any Approved 102 Securities, subject to the provisions of Section 102 and any rules or regulation or orders or procedures promulgated thereunder, a Grantee shall not sell or release from trust any Approved 102 Share and/or any share received subsequently following any realization of rights, including without limitation, bonus shares, until the lapse of the Holding Period required under Section 102 of the Ordinance. Notwithstanding the above, if any such sale or release occurs during the Holding Period, the sanctions under Section 102 of the Ordinance and under any rules or regulation or orders or procedures promulgated thereunder shall apply to and shall be borne by such Grantee.
- 7.4. Upon receipt of Approved 102 Securities, Grantee will sign and undertaking to release the Trustee from any liability in respect of any action or decision duly taken and bona fide executed in relation with the Plan, or any Approved 102 Security granted to Grantee thereunder.
- 7.5. For the avoidance of doubt, nothing contained herein shall prevent the Company from granting Unapproved 102 Securities and/or 3(i) Securities to a trustee designated by the Board, to be held for the benefit of Grantees, all in accordance with the terms and conditions specified by the Board.

# 8. Reserved Shares

The Company has reserved 2,285,022 authorized but unissued Shares for purposes of the Plan and any other present or future share incentive plans of the Company, subject to adjustments as provided in Section 14 (such number is based on a contemplated 1:20 split of the share capital of the Company, by way of division of the share capital and/or issuance of bonus shares). All Shares under the Plan or under any other present or future share incentive plans, in respect of which the right of a Grantee hereunder or thereunder to hold or purchase the same shall, for any reason, terminate, expire or otherwise cease to exist, shall again be available for issuance and/or grant through Options under the Plan and such other share incentive plans.

# 9. <u>Grant of Securities</u>

Each Security granted pursuant to the Plan shall be evidenced by a written Incentive Agreement between the Company and Grantee, in such form as the Board or the Committee shall from time to time approve. Each Incentive Agreement shall state, inter alia, the number of Shares covered thereby, the type of Security granted thereunder (whether a CGS, OIS, Unapproved 102 Security or a 3(i) Security), the dates when the Option may be exercised (if applicable), the Exercise Price (if applicable), and such other terms and conditions as the Committee at its discretion may prescribe, such as, without limitation, vesting or reverse vesting dates, provided that they are consistent with the Plan.

# 10. <u>Term and Vesting of Securities</u>

10.1. Subject to the provisions of this Plan, Options granted to a Grantee under the Plan shall vest and become exercisable following the vesting dates and for such number of Shares as set forth in such Grantee's Incentive Agreement, as determined by the Committee. As well, subject to the Plan, Shares issued to a Grantee shall be released from reverse vesting as set forth in the Grantee's Incentive Agreement, as determined by the Committee. A Security may be subject to such other terms and conditions on the time or times when it may be exercised or released from reverse vesting, as applicable, as the Committee may deem appropriate. The vesting or reverse vesting provisions of individual Securities may vary.

10.2. Options, to the extent not previously exercised, shall terminate forthwith upon the earlier of: (i) ten (10) years from the Date of Grant (unless otherwise specified in the Option Agreement); (ii) the expiration in accordance with Section 15; and (ii) the expiration of any extended period in any of the events set forth in section 13.

# 11. Issuance Price and Exercise Price

The Issuance Price or Exercise Price per Share issued or covered by each Option, as applicable, shall be determined by the Committee in its sole and absolute discretion; provided, however, that such Issuance Price or Exercise Price shall not be less than the par value of the Shares issued or of the Shares into which such Option is exercisable, as applicable. Each Incentive Agreement will contain the Issuance Price or Exercise Price determined for each Grantee.

# 12. Exercise of Options

- 12.1. Options shall be exercisable pursuant to the terms under which they were awarded and subject to the terms and conditions of the Plan.
- 12.2. The exercise of an Option shall be made by a written notice of exercise (the "**Notice of Exercise**") delivered by Grantee to the Company at its principal executive office, specifying the number of Shares to be purchased and accompanied by the payment of the Exercise Price, and containing such other terms and conditions as the Committee shall prescribe from time to time.
- 12.3. Anything herein to the contrary notwithstanding, but without derogating from the provisions of Section 13, if any Option has not been exercised and the Shares covered thereby not paid for until the Expiration Date, the Grantee's right to such Option and his/her right to acquire the underlying Shares of such Option shall terminate, all interests and rights of the Grantee in and to the same shall ipso facto expire, and, in the event that in connection therewith any Approved 102 Options are still held by the Trustee as aforesaid, the trust with respect thereto shall ipso facto expire and all of such Approved 102 Options shall again be subject for grant as provided in Section 8.
- 12.4. Each payment for Shares shall be in respect of a whole number of Shares, and shall be effected in cash or by a cashier's check payable to the order of the Company, or such other method of payment acceptable to the Company.
- 12.5. For the avoidance of doubt, Grantees shall not have any of the rights or privileges of shareholders of the Company in respect of any Shares purchasable upon the exercise of any Option, nor shall they be deemed to be a class of shareholders or creditors of the Company for purpose of the operation of sections 350 and 351 of the Companies Law or any successor to such section, until registration of Grantee as holder of such Shares in the Company's register of shareholders upon exercise of the Option in accordance with the provisions of the Plan, but in case of Options and Shares held by the Trustee, subject to the provisions of Section 7.

# 13. Termination of Engagement

13.1. Subject to the provisions of Section 13.2, unless otherwise provided in the Grantee's Incentive Agreement, in the event that a Grantee ceases, for any reason, to be employed by or to provide services to the Company or an Affiliate, all Options granted to such Grantee will immediately expire upon such cessation. For the avoidance of doubt, unless expressly stated otherwise in the Grantee's Incentive Agreement, in case of such cessation of employment or service, the unvested portion of the Grantee's Option shall not continue to vest and shall immediately expire.

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13.2. Notwithstanding anything to the contrary hereinabove and unless otherwise determined in the Grantee's Incentive Agreement, an Option may be exercised after the date of cessation of Optionee's employment or service with the Company or any Affiliates during an additional period of time beyond the date of such cessation, but only with respect to its vested portion at the time of such termination, as follows:

13.2.1. If the Grantee's termination of employment or service is due to such Grantee's death or "Disability" (as hereinafter defined), then any of such Grantee's vested Options (to the extent exercisable at the time of the Grantee's termination of employment or service) shall be exercisable by the Grantee's legal representative, estate of other person to whom the Grantee's rights are transferred by will or by laws of descent of distribution for a period of twelve (12) months following such death or termination of employment or service due to "Disability" (but in no event after the expiration of the Option Term), and shall thereafter terminate.

For purposes hereof, "**Disability**" shall mean the inability, due to illness or injury, to engage in any gainful occupation for which the individual is suited by education, training or experience, which condition continues for at least six (6) consecutive months or an aggregate of six (6) months in any twelve (12)-month period.

- 13.2.2. If the Grantee's termination of employment or service is for any reason other than for Cause, then any of such Grantee's vested Options (to the extent exercisable at the time of the Grantee's termination of employment or service) shall be exercisable for a period of ninety (90) days following such termination of employment or service, and shall thereafter terminate; provided, however, that if the Grantee dies within such ninety-day period, such Options shall be exercisable by the Grantee's legal representative, estate or other person to whom the Grantee's rights are transferred by will or by laws of descent of distribution for a period of twelve (12) months following the Grantee's death (but in no event after the expiration of the Option Term), and shall thereafter terminate.
- 13.2.3. In the event of termination for Cause, any Option held by such Grantee (whether or not vested) shall terminate immediately and the Grantee shall have no further rights to purchase Shares pursuant to such Option.
- 13.3. With respect to Unapproved 102 Securities, if the Grantee ceases to be employed by the Company or any Affiliate, the Grantee shall extend to the Company and/or its Affiliate a security or guarantee for the payment of tax due at the time of sale of Shares, all in accordance with the provisions of Section 102 and the rules, regulation or orders promulgated thereunder.

# 14. Adjustment Upon Changes in Capitalization

Subject to any required action by the shareholders of the Company, the number and type of Shares covered by each outstanding Option, and the number of Shares which have been authorized for issuance under the Plan but which have not been issued or as to which no Options have yet been granted or which have been returned to the Plan upon cancellation or expiration of an Option or otherwise, as well as the Exercise Price, shall be proportionately adjusted for any increase or decrease in the number of issued Shares resulting from a stock split, stock dividend, combination, exchange of shares or reclassification of the Shares, all only if such triggering event generally applies to all Shares.

Such adjustment shall be made by the Committee, whose determination in that respect shall be final, binding and conclusive. Except as expressly provided herein, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number or price of Shares subject to the Plan.

# 15. <u>Consequences of a Transaction or Dissolution</u>

- 15.1. Upon the occurrence of any kind of Transaction or voluntarily liquidation or dissolution of the Company ("**Dissolution**"), any unexercised vested Options and any unvested Options existing at that time shall be automatically terminated.
- 15.2. Notwithstanding the aforesaid, in case of a Transaction that involves sale, transfer or disposal of the securities of the Company, the Grantee's Options then outstanding may be assumed or substituted for an appropriate number of shares of each class of shares or other securities and/or assets of the successor company in such Transaction (or a parent or subsidiary or another affiliate of such successor company) (the "**Successor Company**") as were distributed to the shareholders of the Company in respect of the Transaction. Furthermore, if the consideration received by the shareholders of the Company in respect of the Transaction to be received upon the exercise of Options shall be solely common stock (or its equivalent) of the Successor Company, then the Committee may stipulate that in lieu of any assumption of Options for shares or other securities of the Successor Company, such Options will be substituted for any other type of asset of the Successor Company as may be fair under the circumstances, including, but not limited to, cash amounts. In the case of such assumption and/or substitution of shares, appropriate adjustments shall be made to the Exercise Price of the Options to reflect such action, and all other terms and conditions of the Options, such as the vesting periods, shall remain in force.
- 15.3. The Company may notify all holders of vested but unexercised Options, at least 10 (ten) business days before the estimated day of closing of a Transaction or of Dissolution (as shall be determined by the Committee) of such expected event, and such holders shall be required to advise the Company within 7 (seven) days of such notice, whether they wish to exercise their vested Options, in accordance with the procedures set forth in this Plan (regardless of whether or not actual closing of the Transaction or the Dissolution occurs after more than such 7-day period). Such exercise may be contingent on actual closing of the Transaction or actual occurrence of the Dissolution. Upon the expiration of such 7-day period, no exercise of the Options shall be allowed unless specifically authorized by the Committee. With respect to a Transaction, the provisions of this Section 15.3 shall not apply in the event of an assumption or substitution under Section 15.2 apply.

# 16. <u>Transferability; Restrictions</u>

16.1. No Option shall be assignable or transferable by the Grantee to whom granted otherwise than by will or the laws of descent and distribution, and an Option may be exercised during the lifetime of the Grantee only by such Grantee or by such Grantee's guardian or legal representative. The terms of such Option shall be binding upon the beneficiaries, executors, administrators, heirs and successors of such Grantee. The provisions of this Section 16.1 applying to Options shall apply to any Shares subject to reverse vesting, *mutatis mutandis*.

- 16.2. Unless otherwise determined by the Committee, until the consummation of an IPO, the Shares issued under the Plan shall be subject to all restrictions on transfer applicable to the Shares of the Company (including without limitation, rights of first refusal, bring along rights, no-sale, market stand-off and tag-along rights), as stated in the Articles and in any shareholders agreement applicable to all or substantially all of the Company's shareholders, regardless of whether or not the Grantee is party to such shareholders agreement.
- 16.3. Anything herein to the contrary notwithstanding, if, prior to the closing of an IPO, all or substantially all of the shares of the Company are to be sold, or upon a Transaction, all or substantially all of the shares of the Company are to be exchanged for securities of another company, then Grantee shall be obliged to sell or exchange, as the case may be, all Shares such Grantee was issued or purchased under the Plan, in accordance with the instructions then issued by the Board, whose determination shall be final.
- 16.4. Grantee acknowledges that in the event that Company's shares shall be registered for trading on any public market, Grantee's right to sell the Shares may be subject to certain limitations (including a lock-up period), as will be required by the Company or its underwriters; and Grantee unconditionally agrees and accepts any such limitations.
- 16.5. By exercising an Option and/or by being issued a Share hereunder, Grantee agrees not to sell, transfer or otherwise dispose any of the Shares so purchased by him except in compliance with the United States Securities Act of 1933, as amended, and the rules and regulations thereunder or any other applicable law, and Grantee further agrees that all certificates evidencing any of such shares shall be appropriately legended to reflect such restriction. Nothing herein shall be deemed to require the Company to register the Shares under the securities laws of any jurisdiction. The Company shall not register any transfer of Shares not made in accordance with the provisions of the Plan, the Company's Articles of Association and any applicable law.

### 17. Shareholders Rights

- 17.1. The Grantee shall have no rights of a shareholder with respect to the Shares subject to the Plan until the Grantee shall have exercised the Option (if applicable), paid the Exercise Price thereof (if applicable) and become the record holder of the Shares.
- 17.2. With respect to all exercised Options or Shares issued under the Plan, the Grantee shall be entitled to receive dividends in accordance with the number of such Shares, and subject to any applicable taxation on distribution of dividends, and when applicable subject to the provisions of Section 102 and the rules, regulations or orders promulgated thereunder.

#### 18. Term and Amendment of the Plan

- 18.1. The Plan shall be effective as of the day it was adopted by the Board, and shall expire on such date that is ten (10) years following the Board adoption of the Plan.
- 18.2. Subject to applicable laws, the Board may, at any time and from time to time, but when applicable, after consultation with the Trustee, terminate or amend the Plan in any respect. In no event, unless allowed under this Plan, may any action of the Company alter or impair the rights of a Grantee, without his consent, under any Security previously granted to him. Termination of the Plan shall not affect the Committee's ability to exercise the powers granted to it hereunder with respect to Securities granted under the Plan prior to the date of such termination.

# 19. Tax Consequences

- 19.1. All tax consequences and/or obligations regarding other compulsory payments arising from the issuance of Shares, the grant or exercise of any Option, from the payment for, or the subsequent disposition of, Shares covered thereby or from any other event or act (of the Company, its Affiliates, the Trustee or the Grantee) hereunder, shall be borne solely by the Grantee, and the Grantee shall indemnify the Company and/or its Affiliates and/or the Trustee, as applicable, and hold them harmless against and from any and all liability for any such tax (and compulsory payment, if any) or interest or penalty thereon, including without limitation, in respect of Approved 102 Securities, liabilities relating to the necessity to withhold, or to have withheld, any such tax (and compulsory payment, if any) from any payment made to the Grantee.
- 19.2. The Company and/or, when applicable, the Trustee, shall not be required to release any Share certificate to a Grantee until all required payments have been fully made.

# 20. <u>Miscellaneous</u>

- 20.1. <u>Continuance of Employment or Hired Services</u>: Neither the Plan nor the grant of a Security hereunder shall impose any obligation on the Company or any Affiliate thereof to continue the employment or service of any Grantee, and nothing in the Plan or in any Security granted pursuant hereto shall confer upon any Grantee any right to continue in the employ or service of the Company or an Affiliate thereof, or restrict the right of the Company or an Affiliate to terminate such employment or service at any time.
- 20.2. Lock up: The Grantee will be subject to a lock-up period of: (i) not less than one hundred and eighty (180) days beginning on the effective date of the registration statement pursuant to which an IPO was effected, or any longer period of time which may be required by the underwriters of such IPO, or as shall be binding on all other shareholders of the Company; and (ii) up to ninety (90) days beginning on the effective date of any subsequent underwritten registration of the Company's securities (except to the extent that the relevant shares of the Grantee are part of such underwritten registration), or any longer period of time which may be required by the underwriters of such subsequent underwritten registration, or as shall be binding on all other shareholders of the Company.
- 20.3. <u>Governing Law and Jurisdiction</u>: The Plan and all instruments issued hereunder or in connection herewith, shall be governed by, and interpreted in accordance with, the laws of the State of Israel. The competent courts in Tel Aviv shall have sole and exclusive jurisdiction over any matters pertaining to the Plan.
- 20.4. <u>Multiple Agreements</u>: The terms of each Security may differ from other Securities granted under the Plan at the same time, or at any other time. The Committee may also grant more than one Security to a given Grantee during the term of the Plan, either in addition to, or in substitution for, one or more Securities previously granted to that Grantee. The grant of multiple Securities may be evidenced by a single Incentive Agreement or multiple Incentive Agreements, as determined by the Committee.
- 20.5. <u>Non-Exclusivity of the Plan</u>: The adoption of the Plan by the Board shall not be construed as amending, modifying or rescinding any previously approved incentive arrangement or as creating any limitations on the power of the Board to adopt such other incentive arrangements as it may deem desirable, including, without limitation, the granting of stock options otherwise than under the Plan, and such arrangements may be either applicable generally or only in specific cases.

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# TRANSLATION FROM HEBREW

# **Unprotected Lease Agreement**

### Made and executed in Jerusalem on the 10<sup>th</sup> day of July, 2005

Between

Kapps-Pharma Ltd. Of 24 Raul Wallenberg Street, Tel Aviv

(Hereinafter: "the Lessor")

Of the first part

And

Bioline Innovations Jerusalem, Limited Partnership Partnership No. 55-021885-3 Of 19 Hartum St., Har Hotzvim, Jerusalem

(Hereinafter: "the Lessee")

Of the second part

- WHEREAS The Lessor declares that it is entitled to be registered as the owner of lease rights in the land known as bloc 30243, parcel 62, lot 5 according to Urban Building Plan / Jerusalem / 2787, which constitute a lot with an area of 7,863 square meters located in the Har Hotzvim industrial area of Jerusalem (hereinafter: "the Lot"), whereon is constructed "the building" as defined herein below:
- **WHEREAS** The Lessor declares that there is no preclusion on his part pursuant to any law and/or agreement for it to enter into this agreement and perform all the undertakings thereof pursuant thereto and the signature thereof of this agreement and the performance of the undertakings thereof pursuant thereto fail to constitute any breach of any undertaking whatsoever vis-à-vis any third parties;
- **WHEREAS** The Lessee would like to rent from the Lessor and the Lessor would like to rent to the Lessee the parts of "the building" as defined herein below, described and defined herein below as the "rented premises," all in accordance with and subject to the provisions of this agreement;

# Accordingly, the parties have agreed, declared and stipulated the following:

- 1. The Preamble to this agreement constitutes a binding and integral part thereof.
- 2. Definitions

In this agreement, the terms specified herein below shall have the meaning that appears alongside them:

"The Agreement" – This agreement including all appendices thereto

"The Building" – The 9-story building for light industry and offices and 2 basement parking lots that exists on the lot

"**The Rented Premises**" – An area of 1,419 square meters (gross), all as delineated and marked in red on the sketch attached hereto as Appendix A to this agreement and the provisions as specified in section 7 herein below. It is hereby clarified that the area, as aforesaid, is divided as follows:

751 square meters (gross) in the new wing of the building (hereinafter: "the New Wing Area")

623 square meters (gross) in the old wing of the building (hereinafter: "the Old Wing Area")

31 square meters (gross) in the old wing of the building, wherein the generator, the bellows and chiller shall be placed, as specified further on in the agreement (hereinafter: "the Machinery Area")

14 square meters (gross) – a gallery in the new wing, wherein the Lessee may place an additional bellows (hereinafter: "the Gallery Area")

For the avoidance of doubt, it is hereby clarified that for all intents and purposes the rented premises shall be deemed, pursuant to this agreement, as the gross area of the rented premises, i.e., 1,419 square meters, and this area shall be final and not given to appeal even if by way of any measurement it becomes clear that it differs from the particulars above.

"Gross Area" in this agreement: the net area with the addition of 15% in respect of the area of walls, hallways and public areas.

"Project Manager" – Mr. Avi Kirschenberg or anyone to be authorized by the Lessor in writing by way of notice to be delivered to the Lessee

"Index" – The Consumer Price Index (including fruits and vegetables) that is publicized by the Central Bureau of Statistics

"**Basic Index**" – The known index on the date of signature of this agreement, i.e., the index for the month of May, publicized on the 15<sup>th</sup> of June, 2005, which stood at \_\_\_\_\_\_ points

"**Interest for Delay**" – The total interest for delay at the highest customary rate during the period of delay pertinent to the matter at the Israel Discount Bank Ltd. in respect of unauthorized overdrafts in current loan accounts. Written authorization of one of the managers of a bank branch with respect to the rate of interest as aforesaid shall be proof positive for the interest rate

### 3. Non-application of the Tenancy Protection Law

- a. It is hereby explicitly declared that the rented premises are situated in a building, the construction whereof shall be completed following the date of August 20, 1968 and this rental has been made with the explicit condition that the Tenancy Protection (Consolidated Version) Law 5732-1972 as well as the other tenancy protection laws, including the regulations and orders thereof (hereinafter: "the Tenancy Protection Law") and any law that grants the Lessee the status of a protected tenant fail to apply to the rental.
- b. The Lessee declares that it has not paid and shall not pay the Lessor any key money or other proceeds for the rental, which do not comprise rent and the Lessee or anyone on behalf thereof shall not be a protected tenant in the rented premises according to law.
- c. The Lessee declares that all investments that it makes in the rented premises, including equipment and devices, shall be made solely for its needs and it shall be precluded from contending that such investments comprise any key money or payment pursuant to section 82 of the Tenancy Protection (Consolidated Version) Law 5732-1972 or any payment that grants it any rights whatsoever in the rented premises apart from the contents of this agreement. It shall also be precluded from demanding from the Lessor participation or a refund, in full or in part, in respect of the aforesaid investments.
- d. The Lessee is aware that the rented premises are rented to the Lessee, *inter alia*, based on the declarations thereof above and it shall be precluded from raising any claims or contentions whatsoever in connection with being a protected tenant or that it has further rights in the rented premises apart from those granted thereto explicitly herein in this agreement.

# 4. <u>The Tenancy</u>

- a. The Lessor hereby rents to the Lessee and the Lessee hereby rents from the Lessor the rented premises in a tenancy that is unprotected by the Tenancy Protection Law for the sole purposes of the tenancy for a period and under the conditions as specified herein in this agreement above and below.
- b. The Lessee declares that it has seen the rented premises and/or the plans thereof and/or the blueprint of the rented premises and examined the legal state thereof and subject to the accuracy of the declarations and representations of the Lessor, it has found the premises to be suitable for the purposes thereof and the Lessee is hereby precluded from contending any contention in connection with the suitability of the rented premises for its needs and/or any other contention, save for a contention with respect to a concealed fault and/or flaw and/or damage.
- c. The Lessee shall act to the best of its ability and subject to the plans thereof to obtain authorization of an authorized concern as defined in the Encouragement of Capital Investments Law. The Lessee shall present this authorization to the Lessor forthwith upon receiving it and from this date an authorized enterprise shall be run throughout the period of the tenancy (including the extension periods). It is clarified that in the event that the Lessee loses the status of an authorized concern, at any time and for any reason, the Lessee shall inform the Lessor thereof forthwith and in writing.

# 5. Adapting the Rented Premises

The Lessee has prepared and shall prepare, at its expense, by way of planners to be authorized by the Lessor in advance and in writing, all plans a. for the performance of the initial adaptation works in the premises, as they are defined herein below, including interior plans, statements of quantities, specifications, and the plans of the rented premises and of all the systems in the premises, including air-conditioning, electricity, plumbing, fire-extinguishing, smoke detectors, and security systems (all the aforesaid together hereinafter: "the Plans") and shall submit such for authorization of the Lessor. The parties agree that up to the date of signature of the agreement, solely the plans for the performance of the initial adaptation works in the area of the new wing of the rented premises have been authorized and these are attached hereto as Appendix B 1 to this agreement. The Lessee has submitted to the Lessor solely initial interior division plans for the performance of the adaptation works in the area of the old wing in the rented premises, which have been authorized as such by the Lessor. Subsequently, the parties hereby agree that the Lessee shall transmit for the Lessor's authorization the plans (as defined above), including the specific plans for the performance of the initial adaptation works in the area of the old wing, including plans of the systems in accordance with the schedules attached hereto as Appendix B to this agreement. With respect to these plans, the Lessee shall perform any amendment and/or alteration, as required by the Lessor, until it receives authorization of the Lessor for the plans and all this at the earliest possible time, and, in any case, in accordance with the schedules attached hereto to this agreement, as aforesaid. From the moment of final authorization of the plans for the performance of the initial adaptation works in the area of the old wing by the Lessor, as aforesaid, these shall be attached to the agreement as **Appendix B2**. The Lessee hereby undertakes that the plans shall be adapted by the various consultants on behalf of the Lessee and Lessor, insofar as required by the Lessor, including a safety consultant on behalf of the Lessor, and the Lessee shall act, at its expense, insofar as required, to carry out all the aforesaid.

b. The Lessee shall receive possession of the rented premises, in its present state, "as is" on the date of delivery as defined in section 6 herein below.

The Lessee shall perform, at its sole liability and expense, all the adaptation works in the rented premises, all subject to the provisions of this agreement, including section 14 of this agreement and including the undertaking of the Lessor to participate in the costs of performance of the initial permanent adaptation works, as defined herein below, in accordance with the provisions of this agreement.

Without derogating from the other provisions of this agreement, the parties hereby agree that the adaptation works that the Lessee shall perform in the rented premises in accordance with the final authorized plans, as aforesaid and as specified in section 5(a) above, shall be performed thereby solely from the date of delivery of the rented premises to the Lessee until the date February 1, 2006 (hereinafter: "the Initial Adaptation Works"). The initial adaptation works shall be performed solely by registered contractors, provided that the Lessor shall be partner to the procedure of choosing the performing contractors and the process of conducting negotiations therewith. Any conclusion with respect to selecting any performing contractor and the cost of the works to be performed shall be subject to the prior authorization of the Lessor shall refuse to give its agreement, as aforesaid, solely on reasonable grounds. In addition, the Lessee hereby agrees that the Lessor shall propose to the Lessee, if it chooses to do so, names of contractors to obtain price offers from them and the Lessee shall contact the contractors, as aforesaid, with a request to obtain a price proposal for the performance of the initial adaptation works or any part thereof. In the event that the Lessor fails to give the Lessee its decision in connection with the price proposal of the contractor that was authorized by the Lessor in advance, as aforesaid, within 10 days of the date the Lessee submits the price proposal in writing to the Lessor, the matter shall be deemed as implied consent of the Lessor, and the Lessee may decide, according to its sole discretion, whether or not the contractor's proposal is acceptable.

The parties hereby clarify and agree that the Lessor may determine on reasonable grounds in connection with the initial adaptation works that the price proposal and/or the contractor are unacceptable thereto and the Lessee shall act in accordance therewith.

In addition, the Lessee hereby undertakes to cooperate and instruct each contractor and/or anyone on behalf thereof to cooperate with the Lessor and/or anyone on behalf thereof concerning all that is connected to the performance of the initial adaptation works, including in connection with the manner of the performance thereof in the building and in general the fulfillment of the provisions and directions for safety, etc.

The parties hereby agree that on behalf of the Lessee Mr. Yoav Avichai shall supervise the performance of the initial adaptation works, pursuant to the provisions of this agreement.

The Lessor shall finance part of the cost of the initial permanent adaptation works, as to be defined herein below, solely in the amount of \$250 per square meter of the rented premises with the addition of Value Added Tax (hereinafter: "the Lessor's Contribution") and all subject to the performance thereof pursuant to the provisions of this agreement, in full and on time and in accordance with the provisions of this section.

For the avoidance of doubt, it is hereby clarified that the Lessor's contribution to the cost of the initial adaptation works, as specified above, shall apply solely to the initial adaptation works in the rented premises, which shall remain in the rented premises on the date of evacuation thereof by the Lessee and which constitute an alteration and/or addition to the infrastructures, to the division or systems of the rented premises, including the form thereof, the nature thereof, the style thereof, the quality thereof, the kind thereof, the size thereof or the quantity thereof and, *inter alia*, the Lessor's contribution, as aforesaid, shall not apply to the purchase of movable equipment, such as furniture, computers, etc. (above and herein below: "the Initial Permanent Adaptation Works").

The parties agree that following the parties' and various contractors' conclusion regarding the estimated comprehensive price of the initial permanent adaptation works, the parties shall prepare a revaluation of the amount of the Lessor's contribution, as defined and specified above, in relation to the total cost of the initial permanent adaptation works (i.e., a revaluation according whereto the Lessor's contribution reaches a certain percentage [revaluated] of the sum total of revaluated costs of the initial permanent adaptation works) (hereinafter: "the Proportion of the Lessor's Contribution").

The Lessor shall pay the Lessee the sum of the Lessor's contribution in respect of the performance of the initial permanent adaptation works, or any part thereof, according to the amount of the Lessor's contribution in connection with each and every invoice within 21 days of any date whereon the Lessee issues to the Lessor demands to pay in connection with the performance of such works, against the presentation of the contractors' invoices in connection with the same works, provided that prior to the performance of the works subject of any invoice, as aforesaid, the Lessee shall receive the authorization of the Lessor in advance and in writing for the price proposal of the contractor selected for the performance of the same works and the selection of the contractor for the performance thereof, and, likewise, the Lessor has authorized that this concerns the initial permanent adaptation works, subject to the fact that the Lessor has authorized the same invoices following the performance of doubt and solely for purposes of illustration, it is hereby clarified that if following the aforesaid revaluation, the parties agree that the Lessor's contribution to the costs of the initial permanent adaptation works, as aforesaid, amount to (for example) the sum of 35% of the revaluated value thereof (i.e., the amount of the Lessor's contribution in this case), the Lessor shall pay the Lessee, in accordance with the aforesaid, the value of 35% of the entire invoice to be presented thereto, as aforesaid, in any event up to an upper comprehensive and final limit of \$250 per square meter of the rented premises).

The parties hereby further clarify and agree that insofar as the cost of the initial permanent adaptation works shall exceed the sum of the Lessor's contribution, as defined above, such works shall be performed at the expense of the Lessee, as specified above, and the addition of the surplus price shall be paid by the Lessee. And, in any event where the cost of the initial permanent adaptation works shall be less than the amount of the Lessor's contribution, as defined above, the Lessee shall not be entitled to any compensation and/or payment and/or refund of the difference between the actual cost of the initial permanent adaptation works and the amount of the Lessor's contribution, as specified above, and/or to financing for the works and /or any equipment whatsoever, in the amount of the aforesaid difference, at any time whatsoever.

# 6. Date of Delivery

- a. If the Lessee has conveyed to the Lessor the securities as specified in section 22 herein below, and all remaining payments in accordance with section 11 (c), the Lessor shall deliver to the Lessee possession of the rented premises at the time of signature of the agreement by the Lessee and the submission thereof signed, with all appendices agreed thereto, to the Lessor (hereinafter: "the Date of Delivery").
- b. Without derogating from the generality of the aforesaid, a delay of up to 14 days in the date of delivery as a result of any delay whatsoever, for any reason whatsoever, shall not be deemed a breach of the agreement and shall not entitle the Lessee to any relief whatsoever. It is clarified that termination of the tenancy period shall not be deferred in accordance with a delay in delivery.
- c. Without derogating from the aforesaid in sub-section b above, the parties hereby agree that the date of delivery and/or date of completion of the initial adaptation works shall be deferred in cases of force majeure, strikes or lockdowns in the construction industry, situations of war or mobilization of reserves, an unanticipated shortage in materials or laborers, the failure to supply electricity and/or if the rented premises fail to be connected to the electricity grid, provided that liability for such is not exclusively the Lessor's or any other reason or cause not under the control of or within the reasonable anticipation of the Lessor. The project manager shall determine, according to his discretion, the duration of time wherein the circumstances as specified above occurred and the date of delivery shall be deferred accordingly. A delay as aforesaid shall not be deemed a breach of the agreement and shall not entitle the Lessee to any relief whatsoever. Termination of the tenancy period shall be deferred in accordance with a delay in the delivery of possession thereof.

In the event that completion of the initial adaptation works by the Lessee is delayed due to force majeure and this precludes the entry of the Lessee into the rented premises and its reasonable use thereof for the objective of the tenancy, pursuant to the agreement, all dates pursuant to the agreement shall be deferred for the period wherein the force majeure occurred, provided that the Lessee acted insofar as possible and took all possible means to complete the works as soon as possible and curtail the aforesaid delay.

- d. The date of delivery or deferred date of delivery in accordance with sub-sections b or c above, shall be called hereinafter: "the Date of Delivery."
- e. The Lessee shall be obligated to accept possession of the rented premises on the date of delivery and the Lessor shall perform the delivery of the rented premises with the participation of the Lessee's representative, if he is present, subsequent to receiving notice of at least two business days in advance.

E1. The parties hereby agree and clarify that a principal and fundamental condition of this agreement is that the Lessee shall evacuate an area of 430 square meters on the first floor of the building, which the Lessee rented from the Lessor pursuant to the tenancy agreement the parties signed on September 14, 2003 (respectively hereinafter: "the Returned Area" and "the First Tenancy Agreement"), on whichever date is the earlier of : (1) ten days from the date of the transfer of the business thereof and/or any part of the business thereof (including the move of any furniture or equipment whatsoever) into the rented premises; or (2) September 2, 2005. It is hereby agreed that at the Lessee's request of the Lessor, in writing, at least a month prior to this date, the Lessee may receive an extension of up to 10 days of this date, i.e., until October 2, 2005 at the latest (the date of evacuation as aforesaid shall be called hereinafter: "the Date of Evacuation of the Returned Area"). The Lessee hereby undertakes to evacuate the returned area, as aforesaid, in accordance with all provisions of the first tenancy agreement, as it is clean and freshly painted with Tambour Supercryl paint (in the same shade as it received the returned area or any other shade whereto the Lessor or the project manager agrees in writing).

For the avoidance of doubt, the parties hereby agree that as long as the Lessee fails to evacuate the returned area in accordance with the provisions of this agreement and the first tenancy agreement, the first tenancy agreement shall continue to apply to the Lessee for all intents and purposes. Likewise, the parties hereby clarify and agree that the failure to evacuate the returned area beyond 5

business days following the date of evacuation of the returned area, as defined above, shall constitute a fundamental breach of the first tenancy agreement in respect of the failure to evacuate on time, in respect whereof the Lessor may utilize any relief pursuant to the first tenancy agreement and pursuant to any law.

f. For the avoidance of doubt it is clarified that the Lessor may also, following the completion of the building, perform building works and other works in parts of the building, which are not the rented premises, including, but not solely, development works, provided that such works fail to preclude and/or damage the reasonable use of the Lessee of the rented premises for the tenancy objective and fail to infringe on the Lessee's rights pursuant to this agreement.

Likewise, the addition of stories and/or parts of stories and/or the enlargement of the areas permitted for use in the building and/or the alteration of the permitted designation of areas within the building shall not be deemed a beach of the Lessor's undertaking, as aforesaid, as long as this fails to preclude and/or harm the Lessee's reasonable use of the rented premises for the objective of the tenancy or fail to infringe the rights thereof, pursuant to this agreement.

The Lessor may perform alterations in the building plans and/or the rented premises, if it is required to do so by any competent authority, provided that the aforesaid alterations fail to preclude and/or damage the Lessee's reasonable use of the rented premises for the objective of the tenancy and/or fail to infringe the Lessee's rights pursuant to this agreement.

f. The project manager shall determine, at his discretion, as an expert and not as an arbitrator, whether the works and/or alterations and/or additions, as specified in sub-section 6 (f) above disturb the Lessee's reasonable use of the rented premises for the objective of the tenancy. In addition, the project manager shall determine, at his discretion, as an expert and not as an arbitrator, whether the initial adaptation works were performed in accordance with the plans in Appendices B1 and B2 to this agreement and whether divergences from the plans or specifications or alterations therein constitute substantial divergences or minor divergences and/or whether such may disrupt the Lessee's reasonable use of the rented premises. The parties agree that in the event that the project director's decision, as aforesaid, fails to be agreeable to either of the parties to this agreement, the parties shall jointly request the appointment of an arbitrator whereon they agree to decide such questions. The arbitrator shall be a professional in the field of engineering and/or construction. In the absence of agreement regarding the appointment of an arbitrator, shall be appointed by the chairman of the Contractors and Builders Association in Israel. The parties agree that in the event that either of the parties requests approaching an arbitrator, as aforesaid, the matter shall not constitute grounds for the non-performance and/or delay in performance of any of the provisions of the agreement, without the matter constituting the admission of any contention whatsoever and/or derogating from any contention and/or relief pursuant to any law and agreement.

# 7. <u>Parking</u>

A sketch of the building's parking spaces is attached hereto as <u>Appendix D</u> to this agreement (hereinafter: "the Sketch of Parking Spaces"). Eighteen ordinary parking spaces marked in red on the sketch of parking spaces shall be made available to the Lessee for the period of the tenancy for the sole use thereof, commencing at the beginning of the tenancy period, pursuant to this agreement.

The parties hereby agree that by way of giving written notice of 30 days in advance to the Lessor, the Lessee shall have the option to add and rent up to 12 additional parking spaces in the building to be allocated and marked by the Lessor (hereinafter: "the Additional Parking Spaces"), part of which shall be ordinary spaces and part shall be double spaces according to the relation and arrangement herein below: the first 8 additional parking spaces shall be double parking spaces) and the 4 remaining spaces to be rented to the Lessee thereafter shall be ordinary parking spaces. Rental of each of the additional parking spaces shall commence on the date according to the Lessee's provision of notice to the Lessor, as aforesaid, and shall extend until the expiration of the tenancy period.

Likewise, the parties hereby agree that, subject to the provision of 30 days' notice in advance and in writing to the Lessor, the Lessee shall have the right to reduce the number of additional parking spaces that it shall rent from the Lessor, as aforesaid, up to the rental of 18 ordinary parking spaces specified in the first sub-section of this section 7 herein, at the least. The type of additional parking spaces to be reduced, as aforesaid in this sub-section above, shall be in accordance with the type of additional parking spaces that the Lessee rented from the Lessor, in the reverse order to the order aforesaid, so that each additional parking space to be removed shall be the last additional parking space (ordinary or double) that the Lessee rented, in accordance with the contents of this section above.

In return for the use of the parking spaces, the Lessee shall pay the Lessor rent as specified in section 10 herein below.

In any event of the termination of the tenancy or the lawful revocation thereof, all as the case may be, the permission to use the parking spaces as aforesaid shall automatically be revoked as well. The provisions of this agreement concerning all that pertains to the rented premises shall apply to the parking spaces as well.

# 8. **Objective of the Tenancy**

a. Without derogating from the aforesaid, the objective of the tenancy is to conduct a business that manages and develops medical projects, in general, and medications, in particular, including a laboratory for research and development for the aforesaid purpose.

It is clarified that the Lessee has the responsibility to obtain all licenses required for the management of its business in the rented premises, if required, and the failure to obtain such shall not constitute grounds for the curtailment or the delay of the tenancy or reduction of the rent, even in the event that the business is closed as a result of the absence of a license as aforesaid.

b. In the event that the Lessee fails to obtain a permit to conduct its business and/or a business license for any reason whatsoever, the Lessee shall not have a claim nor shall a claim arise on any grounds and of any kind against the Lessor and by the signature of this agreement the Lessee waives a claim in advance, including but not solely in respect of the investments thereof in the rented premises.

Nothing in the aforesaid shall be deemed as permission by the Lessor for the Lessee to use the rented premises and/or to manage a business therein without a permit and/or by way of a divergence therefrom.

c. For the avoidance of doubt and without derogating from the aforesaid, the parties hereby agree that liability in respect of managing the Lessee's business not in accordance with a lawful permit shall apply solely to the Lessee and it undertakes to indemnify the Lessor in respect of any claim and/or obligation placed thereon for managing a business in the rented premises without a lawful permit and/or due to the failure to obtain the permits within 7 days of receiving the first demand of the Lessor, provided that in the event of a claim – the Lessor gave the Lessee written notice of the filing of the claim a reasonable amount of time in advance and enabled it to offer a defense against the claim, and in the event of an obligation – against the presentation of documentary proof and/or lawful tax invoices with respect to the performance of actual payment by the Lessor.

# 9. <u>Period of the Tenancy</u>

Subject to the fulfillment of all undertakings of the Lessee pursuant to the agreement, the Lessor hereby rents to the Lessee and the Lessee hereby rents from the Lessor the rented premises in an unprotected tenancy from the date of delivery of the rented premises until the date, December 15, 2008 (hereinafter: "the Period of the Tenancy").

Notwithstanding the aforesaid, the parties hereby agree and clarify that in any case where on the date of delivery the rented premises are not delivered to the Lessee as a result of an act and/or omission of the Lessee and/or anyone on behalf thereof and/or as a result of other reasons not under the Lessor's liability, save for force majeure, then the rented premises shall be deemed as having been delivered to the Lessee on the date of delivery and commencing on this date (the date of delivery), the Lessee shall be obligated with all its undertakings pursuant to this agreement, including payment of rent, maintenance fees, municipal rates and any other payment in relation to the entire rented premises.

# 9A. Right of First Refusal for Renting Additional Space

a. The Lessee is hereby granted the right of first refusal in connection with renting two areas on the 6<sup>th</sup> floor of the building, both outlined and marked in blue on the sketch attached hereto as Appendix A to this agreement, each of them in full (hereinafter: "the Right of Refusal" and "the Additional Areas"), solely during the first 18 months following the date of delivery of the rented premises as defined above (hereinafter: "the Period of the Right of First Refusal"), as follows:

The Lessor shall deliver notice to the Lessee of its intention to rent either of the additional areas (above and below: "the Additional Area") to a tenant who is interested therein (hereinafter: "the Potential Tenant") and the Lessee shall be given 7 days from the date of delivery of the Lessor's notice thereto to undertake in writing vis-à-vis the Lessor to rent the relevant additional area in its entirety, in accordance with the conditions offered by the potential tenant and subject to the remaining provisions of this agreement, *mutatis mutandi*. Insofar as the Lessee requests to measure the additional areas, the Lessor shall perform the measurement and the Lessee shall bear the expense of the measurement. If the Lessee undertakes, as aforesaid, to rent the pertinent additional space, as aforesaid, then all the provisions of section 9A (b) herein below shall apply in relation to the exercise of the right of first refusal and in accordance all the provisions of this agreement shall apply in relation to the rental of the additional area.

If the Lessee gives notice that it is not interested in renting the additional space or fails to deliver its undertaking in writing for the rental of the Additional Area within 7 days of the date the Lessor's notice was delivered thereto as aforesaid, the Lessor may rent the Additional Area to the potential tenant. The parties agree that in the event that an agreement fails to be signed between the potential tenant and the Lessor for the rental of the Additional Area as aforesaid and the Lessor is interested in renting the Additional Area to another potential tenant, then the Lessor shall be obligated to act again in accordance with the procedure described herein in this section above prior to the rental of the additional space.

- b. In the event that the Lessee exercises the right of first refusal for the rental of either of the Additional Areas, the provisions of this agreement shall apply in relation to the Additional Area that it rents as well, *mutatis mutandi*, and in accordance with the particulars specified herein below:
  - (1) The Lessee shall accept possession of the Additional Area, in its present state at the time of delivery thereof, "as is," subsequent to the Lessor providing final authorization for the plans the Lessee submits to the Lessor, in accordance with the contents of section 5 above and on the date of delivery as defined in section 6 above in connection with the rented premises, all this in connection with the pertinent Additional Area, *mutatis mutandi*, and subject to the Lessee's maintaining the schedules.

The Lessee shall perform at its sole liability and at its expense all the adaptation works in the Additional Area, and all subject to the provisions of this agreement, including section 14 of this agreement and subject to the contents stated herein below, including the Lessor's undertaking to participate in the costs of the performance of the initial permanent adaptation works in the Additional Area, at a cost per square meter and in the manner of participation in accordance with the provisions of this agreement, *mutatis mutandi*. Notwithstanding the aforesaid, the parties hereby agree explicitly that in the event that the Lessee exercises the right of first refusal to rent either of the Additional Areas, pursuant to this section 9 herein, in the last six months of the period of the right of first refusal, as defined above, the Lessee shall rent, as aforesaid, i.e., solely \$200 per square meter of the Additional Area, with the addition of VAT, and not the amount stated in section 5 (b) above.

For the avoidance of doubt, all provisions of this agreement in relation to the planning and performance of the initial adaptation works in the rented premises and in relation to the delivery of possession of the rented premises shall apply *mutatis mutandi* as well in relation to each of the Additional Areas, if and insofar as such are rented to the Lessee, as aforesaid in section 9A herein.

- (2) The period of tenancy of the Additional Areas, if and insofar as such are rented to the Lessee, as aforesaid, shall conclude on the date that the rental period of the rented premises expires.
- (3) If the Lessee exercises the right of refusal for rental of either of the Additional Areas, as aforesaid, the pertinent Additional Area shall be added to the area of the rented premises as defined herein in this agreement above, and all provisions of this agreement shall apply thereto, *mutatis mutandi*.

## 10. <u>Rent</u>

a. During the period of the tenancy, the Lessee undertakes to pay the Lessor in respect of the rented premises monthly rent as follows:

\$10.20 in respect of each square meter (gross) of the New Wing Area and the Old Wing Area

\$8 in respect of each square meter (gross) of the Machinery Area and the Gallery Area

\$46 U.S. for each parking unit (whether ordinary parking spaces or parking allocated to the Lessee within the context of double parking spaces, in which case it is clarified that the payment for double parking spaces shall stand at \$92)

(Hereinafter: "the Rent")

b. (1) With respect to all that pertains to the New Wing Area, notwithstanding the aforesaid in section 10 (a) above, the Lessee receives a grace period and shall not be obligated to pay rent solely for rental of the New Wing Area from the date of delivery, as aforesaid herein in this agreement above, until whichever is the earlier of: (a) the date of commencement of operating the business of the Lessee (including any part thereof) in an New Wing Area or in any part thereof, including moving any equipment and/or furniture whatsoever into the New Wing Area, or (b) September 2, 2005. However, it is clarified that the Lessee shall be obligated with all remaining payments and undertakings pursuant to this agreement, including municipal rates and management fees, commencing from the date of delivery of the New Wing Area.

(2) With respect to all that pertains to the Old Wing Area, notwithstanding the aforesaid in section 10 (a) above, the Lessee receives a grace period and shall not be obligated to pay rent solely for the rental of the Old Wing Area from the date of delivery, as aforesaid herein in this agreement above, until whichever is the earlier of: (a) the date of commencement of operating the business of the Lessee (including any part thereof) in the Old Wing Area or in any part thereof, including moving any equipment and/or furniture whatsoever into the area of the old wing, or (b) February 1, 2006. However, it is clarified that the Lessee shall be obligated with all remaining payments and undertakings pursuant to this agreement, including municipal rates and management fees, commencing on the date of delivery of the Old Wing Area.

c. Rent and all other payments stated in dollar amounts herein in this agreement shall be translated and paid in New Israeli shekels according to the known representative rate on the actual date of payment and, in any event, the value thereof in shekels shall not be less than the value thereof on the date fixed for the performance of each payment, pursuant to this agreement. Without derogating from the aforesaid herein in this section, in the event that between the date fixed for payment and the actual date of payment there is a devaluation of one or more percent in the value of the dollar, the Lessee shall pay the Lessor, forthwith upon the first demand of the Lessor, the difference in rent between the date fixed for payment and the date of actual payment.

## 11. **Payment of the Rent**

a. The Lessee shall pay the Lessor the rent, as aforesaid in section 10 above in advance for every three months of the tenancy period, on the first day of each 3-month period, as aforesaid.

The parties hereby agree that in order to facilitate payment and collection of the rent, the Lessee, up to and no later than the date of the commencement of the tenancy period each year, may deposit with the Lessor 4 checks, each of them in the amount of the entire rent for each of the quarters of the following rental year in a shekel amount required pursuant to the provisions of this agreement on the date of issuing the checks, as aforesaid, and the actual date of payment of each one of the checks shall be the first day of each quarter of the following tenancy year.

At the conclusion of each quarter of the rental period as well as on the date of termination of the tenancy period, the Lessee shall pay the Lessor the differences in the event that such were produced as a result of a rise in the dollar rate between the sum stated on the checks and the sum that the Lessee is to pay the Lessor in practice, according to the dollar rate on the actual date of payment of each of the checks, i.e., on the first day of the pertinent quarter.

- b. All payments that apply to the Lessee pursuant to this agreement, the Lessee shall pay them, as aforesaid, up to the time of 11:00 a.m. by way of a bank transfer and/or in any other manner that fails to be a standing order, according to the Lessor's instructions. If the date of payment falls on a day that is not a business day, the payments shall be paid on the first business day following thereafter.
- c. On the date of signature of this agreement by the Lessee, and as a condition to the signature thereof, the Lessee shall pay the Lessor rent for the first quarter of the rental period following forthwith each of the grace periods, as aforesaid in section 10 (b).
- d. Payment by way of checks, authorization of the performance of the bank transfer and/or any other means of payment shall not be deemed payment and solely the actual remittance of the checks and/or the actual transfer of the sums to the Lessor by the bank shall be deemed as payment of the rent. The parties hereby agree that non-remittance of checks not as a result of an act and/or omission of the Lessee shall not be deemed a breach of this agreement, subject to the Lessee's correction thereof and it shall ensure the full remittance of the checks and/or the performance of the payment in another manner within 4 days of the date of the demand of the Lessor and/or anyone on behalf thereof. Likewise, the parties hereby agree that in the event that the non-payment of the checks was caused by a strike at the bank, the aforesaid non-payment shall not be deemed a breach of this agreement as long as the strike continues at all banks in Israel wherein the Lessee holds a bank account.
- e. The Lessee shall pay the Lessor rent and shall make all other payments it is obligated to pay in accordance with this agreement for the entire period of the tenancy, even if for any reason not under the Lessor's liability the Lessee uses solely part of the rented premises and/or solely part of the time, whether of its own will or not of its own will.
- f. The Lessee hereby waives any contention of offset and the cause of action of offset, whether current and/or future, of any amount, whether limited or not, of the rent and/or the management fees and/or any other payment owing to the Lessor, pursuant to this agreement.

### 12. Other Payments

- a. In addition to the other payments specified herein in this agreement, the following payments shall apply to the Lessee during the tenancy period:
  - (1) All taxes, municipal rates, fees, charges, municipal and government, of any kind that apply and/or shall apply to the holder of the rented premises and/or imposed in respect of the very use of the rented premises, including, but not solely, general municipal rates, garbage removal expenses and other municipal taxes and/or such involved in the business the Lessee runs in the rented premises and/or the objective of the rental, including business tax, signage tax, fees and licenses for a business and management thereof, save for charges and taxes applying by the nature thereof to the owners of property such as: the charge for sewage and paving roads, betterment charge, etc.
  - (2) All fees and payments relating to the consumption of electricity in the rented premises.

The Lessee declares that it is aware that the Lessor is the owner of the sole rights vis-à-vis the Israel Electric Corporation Ltd. (hereinafter: "the Electric Corporation") with respect to all that is connected to receiving electricity in the building.

In light of the aforesaid, the Lessor hereby undertakes to supply the rented premises with electricity under the conditions and at a rate according to system load and consumption times for low voltage, customary from time to time, at the Israel Electric Corporation.

The Lessee hereby waives absolutely, finally and irrevocably the right thereof to enter into agreement with the Electric Corporation with respect to any matter and issue pertaining to the supply of electricity to the rented premises. It hereby declares and undertakes that its sole partner with respect to all that pertains to the supply of electricity to the rented premises shall be solely the Lessor (or, at the Lessor's request, the management company) and that it has no claims and shall have no claims and it hereby waives finally, absolutely and irrevocably any claims against the Electric Corporation concerning anything related to the supply of electricity to the rented premises.

The Lessee may not request directly of the Electric Corporation and/or any other entity, apart from the Lessor, that it shall supply electricity and it shall not contact the Electric Corporation with a request to install a separate electricity meter or to make payment directly to the Electric Corporation. The Lessee shall have no claim concerning any cause of action whatsoever against the Electric Corporation in respect of the failure to supply electricity or disruptions in the supply of electricity. Without derogating from the aforesaid, if the Lessee installs electronic equipment or any electricity whatsoever, it shall not be permitted to come forward with any protest or claim whatsoever as a result of the cessation of the supply of electricity and/or disruption in the supply thereof.

The Lessor may visit the rented premises at any reasonable time and, insofar as possible following prior coordination, to inspect any electrical device and equipment connected to the electricity grid, to test the safety thereof and the adaptation thereof to the safety standards and customary consumption habits, as such may be from time to time. If an electrical engineer on behalf of the Lessor believes that alterations must be made to the electricity system within the rented premises or that any electrical equipment whatsoever installed in the rented premises is likely to cause damage to the supply of electricity and/or that it comprises a safety drawback or hazard and/or it fails to meet accepted safety standards and/or the load it is likely to impose on the electricity system is likely to disrupt the operation thereof or cause excessive expenses, the engineer shall demand the repair and/or replacement and/or alteration of the system or equipment, as aforesaid, and the Lessee undertakes to take any means necessary, at its own expense, at the earliest possible time, provided that it installed the electrical device in the rented premises and/or it was installed at its request. The Lessee shall be liable for any damage caused to the Lessee and/or the Lessor and/or the rented premises and/or the equipment and building systems as a result of the operation of the improper electrical device that it installed at its request in the rented premises or that was damaged as a result of the unreasonable use of the rented premises by the Lessee.

The Lessor is aware and agrees that the Lessee may install a bellows in the Gallery Area and an additional bellows, chiller and generator in the Machinery Area, all at the liability and expense of the Lessee and subject to the provisions of section 14 herein below. It is clarified that subject to the agreement of the parties with respect to the conditions of maintenance and price thereof, the Lessor shall agree to maintain the bellows, the chiller and the generator, as aforesaid. Nonetheless, in any event, the Lessee shall bear liability for faults in any of the equipment, as aforesaid and any damage that is caused (insofar as such is caused) to the Lessee, the Lessor or any third party in connection thereto and the Lessor shall not bear any liability in connection therewith.

Without derogating from the aforesaid in any other place, the supply of electricity to the rented premises and/or other places in the building may be halted and/or limited in the following instances:

- Any disturbance in the electric current from the Electric Corporation reaching the building, for any reason
- In any event where there is risk or concern for risk to person or property
- In any other event where an electrical engineer on behalf of the Lessor instructs that the electricity supply must be halted.

Insofar as possible, the Lessor shall coordinate with the Lessee in advance such anticipated suspensions and/or disruptions in the electricity supply to the rented premises. The Lessor shall act swiftly and efficiently to renew the electricity supply fully or partially at the earliest possible time.

The Lessor may arrange for controls, inspections, handling and repairs of electrical devices and all equipment in connection with the electricity system, as it deems proper, from time to time and, for this purpose it may from time to time, subject to advance written notice, save for in emergencies or unanticipated instances, temporarily disconnect the electricity supply to the rented premises and/or the building, partially or fully. The Lessor shall act insofar as possible to curtail the time period of such electricity breaks, as aforesaid. The Lessee hereby waives any contention and claim in connection thereto.

In the event of a break in the supply of electricity to the rented premises, the Lessee shall be liable from every aspect and at any time to operate the Lessee's generator to supply electricity to the rented premises, if and insofar as the Lessee has a generator as aforesaid and insofar as the Lessee opts to do so. The parties hereby clarify and agree that the Lessor shall not be liable, at any time and for any reason, for the operation and/or non-operation of the generator of the Lessee, if and insofar as such generator shall be installed, as aforesaid.

The Lessee hereby undertakes to pay the Lessor (or at the request thereof to the management company) in respect of the consumption of electricity in the rented premises throughout the entire period of the tenancy in accordance with the reading of an electricity meter in the rented premises and the rate according to system load and consumption times for low voltage of the Electric Corporation, as they may be at the times of the charge, from time to time.

The Lessor is obligated to pay the Electric Corporation for the electricity to be supplied to the building without any connection to the Lessor's success in collecting the sums in respect of electricity consumption from the tenants. Accordingly, the Lessee hereby gives its consent that the Lessor (or the management company) may, subsequent to providing written warning of at least 72 hours in advance, disconnect the electricity supply to the rented premises, both in respect of the failure to pay for electricity consumption, as aforesaid, and in any event of a fundamental breach of this agreement by the Lessee, provided that solely for the purposes of this section it shall not be deemed a fundamental breach of the agreement but rather a breach with respect whereto written warning of 14 days was given to the Lessee and it failed to rectify the breach within this 14-day period. The Lessee hereby explicitly exempts the Lessor from any liability for any deficit and/or damage and/or loss likely to be caused thereto as a result of the interruption in the electricity supply in the circumstances specified herein above.

Notwithstanding the aforesaid, if, for any reason whatsoever, the electricity to the building shall not be supplied in bulk or the Lessor shall request that the rented premises or any part of the building shall be connected to the ordinary supply of electricity (not in bulk), whether permanently or temporarily, at the Lessor's request, the Lessor shall contact the Electric Company directly concerning all matters connected to the supply of electricity to the rented premises and the consumption thereof by the Lessee and the aforesaid herein in this section shall be revoked or altered, as the case may be, and all conditions and rules of the Electric Corporation regarding all that pertains to the connection and supply of electricity to the Lessee shall apply to the Lessee. The Lessee shall bear all expenses involved in connection with the aforesaid herein in this section. In the event that the Lessor requests that the Lessee be returned to the supply of electricity in bulk, the Lessee shall act as required.

Without derogating from the remaining provisions of the agreement with respect to the arrangement of alterations in the rented premises and as a special and fundamental provision of the agreement, the Lessee hereby undertakes to refrain from performing any works and/or alterations whatsoever in the electricity system in the rented premises and/or the building and/or any part thereof without obtaining the consent of the Lessor in writing and in advance and subject to the conditions of such consent.

In the event that as a result of a law, regulation, order or act of a government authority and/or other competent authority, in the opinion of the Lessor it becomes necessary to perform any alterations in the system of the electricity supply to the rented premises, the Lessor shall perform all such alterations, as aforesaid, and the Lessee shall have no contention whatsoever in respect of the performance of the alteration, as aforesaid. The Lessor shall coordinate the performance of the adaptation works, as aforesaid, with the Lessee, save for in urgent cases.

In addition, the Lessee shall pay the Lessor for the consumption of electricity for air-conditioning of the rented premises, pursuant to the relative consumption of water or electricity of the air-conditioning system in the building, in accordance with <u>Appendix E</u> of this agreement, while the Lessee's share shall be calculated according to the share of the rented premises in relation to the entire rented areas in the building. For the avoidance of doubt, the expenses in respect of electricity for air-conditioning shall come in addition to the rent and maintenance fees, pursuant to this agreement.

It is clarified that the Lessee has requested to supply the Old Wing Area with air-conditioning with a higher than ordinary level of cooling. In addition to the aforesaid in any other place, the Lessee shall pay the Lessor an additional payment in respect of the supply of air-conditioning with a stronger cooling power than ordinary, in accordance with the formula specified in Appendix E1.

The Lessor shall not bear liability and/or any obligation in connection with any damage, including direct damage and/or resulting damage and/or indirect damage the Lessee or any person, institution or corporation incurs as a result of a break in the supply of electricity and/or air-conditioning to the rented premises by the Lessor, as a result of the failure to pay on time as aforesaid, save in the event that such damage was caused as a result of a break in the electricity supply by the Lessor with malicious intent and not in accordance with the provisions of this agreement.

The Lessee hereby waives finally, absolutely and irrevocably any right to sue the Lessor and/or the management company in respect of breaks in the supply of electricity to the rented premises and/or the building and/or disruptions in such supply, provided that the Lessor failed to perform such disruptions with malicious intent and not in accordance with the provisions of this agreement and did its best to renew the regular supply thereof as soon as possible. The Lessee hereby exempts the Lessor explicitly from any liability for a deficit and/or damage and/or loss it is likely to incur as a result of the disruptions in the electricity supply to the rented premises, save if such were caused as a result of an act or omission with malicious intent of the Lessor and not in accordance with the provisions of this agreement. Notwithstanding the aforesaid in any other place, even if it is found that the Lessor is liable for the damages the Lessee or any third party incurs in any matter, including in connection with the supply or failure to supply electricity to the rented premises and/or other parts of the building, in any event the Lessor and/or the management company shall not bear liability for indirect damages and/or resultant damages and/or damages that are not monetary.

- (3) The cost of ongoing maintenance of the fire detection system within the rented premises (shall be implemented by the Lessor). The Lessor declares that to date of the signature of this agreement, such cost is estimated at NIS 10 for a detector per month.
- (4) Maintenance services shall be charged at the rate stated in section 16 herein below.
- (5) All payments and expenses in respect of the supply of gas, water and telephone in the rented premises and any other payment that shall apply in respect of the use of the rented premises and maintenance thereof, including maintenance of the systems therein, including air-conditioning systems within the rented premises.
- b. In the event that any of the sums that the Lessee is to pay the Lessor pursuant to section a above shall be based on an invoice that relates to the entire building, the Lessee shall pay the Lessor the appropriate relative share of the amount of the entire invoice, provided that for the purpose of calculating the relative share of the Lessee in the aforesaid payments, the proportion between the rented premises and the entire area of the building, whereto the invoice relates, shall be taken into account.
- c. The Lessee undertakes to ensure of its own accord and at its own expense that the rented premises are cleaned.

#### 13. Value Added Tax

The Lessee undertakes to pay the Lessor Value Added Tax in addition to and together with the payment of rent, including linkage differentials in respect thereof and/or interest for delay and, in addition to and together with any additional payment that it is obligated to pay the Lessor, pursuant to this agreement and/or that the Lessor paid in place of the Lessee and the Lessee is required to reimburse the Lessor, pursuant to the provisions of this agreement and the Lessor shall issue the Lessee a duly issued tax invoice. The date of settling payment of the VAT shall be the date of payment thereof by the Lessor to the VAT authorities, i.e., the 15<sup>th</sup> of the second month of each quarter of the tenancy period.

The aforesaid herein in this section is valid also in the event that another tax shall be imposed in addition to VAT or shall come in place thereof under conditions that the law shall apply to rent fees and shall impose or permit the transfer of the duty in respect thereof to the Lessee. The VAT shall be handled as is the rent, for all intents and purposes.

### 14. Alterations in the Rented Premises Subsequent to the Date of Delivery

- a. Following the date of delivery, the Lessee may perform solely in the rented premises (not including public areas, but including lavatories, kitchenettes and hallways), at its expense and liability, subsequent to attaining the permission of the Lessor, who shall refuse solely on reasonable grounds, works and alterations it requires to set up and/or move internal permanent or movable partitions, to install telephone systems, air-conditioning, plumbing, electricity and/or communications, to connect and install the machinery, computers and equipment thereof and any other additional work or alteration necessary in the opinion of the Lessee to conduct its business in the rented premises, save for alterations likely to damage the construction, walls, water and electricity systems thereof and/or alterations affecting the façade of the building, whether the external or internal façade or the reasonable use of the building by the users in other units, all under the following conditions:
  - (1) The Lessee shall transfer the plans for the aforesaid works for the Lessor's authorization and, insofar as the Lessor requires, also for the authorization of a safety consultant, the identity whereof shall be determined by the Lessor in advance and in writing. The Lessee shall bear the fees of the safety consultant, as aforesaid, and any cost and/or expense in connection therewith.
  - (2) The Lessor and safety consultant on behalf of the Lessor shall have the right to demand alterations to the plans, specification and works specifications and the Lessee undertakes to alter these in accordance with the demands of the Lessor and safety consultant at the expense of the Lessee and commence with the performance of the works solely subsequent to the Lessor and safety consultant having authorized such in writing.
  - (3) The provision of the Lessor's authorization for the performance of the works is conditional, in addition to the aforesaid, on the Lessee having delivered to the Lessor copies of the insurance policies, in accordance with the provisions of section 17 herein below.
  - (4) All works shall be performed by skilled professionals at a level accepted in similar high-tech buildings in the region of the rented premises and according to Israel standards and subject to the directives of the project manager.
  - (5) The Lessee shall perform the works in the rented premises in such manner and form that it fails to cause any disturbance to the activities in any other part of the building and/or to other tenants and the Lessee undertakes to strictly fulfill all instructions of the Lessor and take all means to prevent any disturbance, as aforesaid.

- (6) The Lessee shall bear liability for any damage caused during and as a result of the performance of the works in the rented premises to any person and any property, including herein in the building and/or the rented premises and/or to other tenants and/or other rented premises and/or the Lessor and agents thereof, whether the works were performed by the Lessee or by anyone on behalf thereof.
- (7) The Lessee agrees and authorizes that any sum that it expends to make alterations to adapt the rented premises for the purposes thereof, as aforesaid, shall not grant it vis-à-vis the Lessor any right to restitution or any payment in respect of the sums and/or the alterations it performed as aforesaid, not during the tenancy period nor during the evacuation of the rented premises or subsequent to the evacuation thereof.
- (8) The Lessee shall obtain at its expense all licenses, authorizations and permits required to perform the alterations from the competent institutions and authorities, insofar as such are required.
- b. Commencing on the date of signature of this agreement, Mr. Yuri Shushan and Mrs. Revital Cohen shall be responsible for safety on behalf of the Lessee in the rented premises and they shall be liable on behalf of the Lessee to obtain all authorizations and meet all standards required to meet the demands of the fire department, as they may be from time to time, in accordance with the contents solely of section 15 (h) including: (1) obtaining authorizations of all manufacturers of the materials and those performing the works, pursuant to section 14 (a) above, with respect to meeting standards, forthwith upon completion of the performance of the works and transmitting such to the Lessor on its first demand, (2) issuing authorizations to the Lessor forthwith upon the demand thereof with respect to meeting the standards of the fire department regarding the electricity works, fire detection and fire extinguishing systems, fire walls, areas and doors, performed by the Lessee and/or by anyone on behalf thereof in the rented premises and (3) ongoing management to ensure that escape routes in the rented premises to emergency exits shall be accessible at all times.

Those in charge of safety shall be available at all times at telephone numbers (054) 444-9991, (054) 645-0904 or (02) 548-9100. The Lessee may replace the entity responsible for safety by way of written notice to the Lessor.

The Lessee shall be liable for any damage the Lessor and/or any person and/or body and/or property shall incur as a result of the failure to fulfill the provisions and/or procedures of safety and security in the rented premises, in accordance with the provisions of this agreement and the directives of any authorities pertaining to the matter. The Lessee hereby undertakes to indemnify the Lessor within 7 days of receiving the first demand thereof in respect of any damage and/or expense caused to the Lessor as a result of any claim or demand referred vis-à-vis the Lessor and/or anyone on behalf thereof in respect of the Lessee's failure to meet the required safety standards and/or as a result of the failure to fulfill provisions and undertakings of safety specified herein in this agreement against the presentation of documentary proof and/or duly issued tax invoices with respect to the actual payment of the expenses.

In the event that the Lessee fails to completely fulfill the undertakings thereof pursuant to this section 14 (b) herein above, the Lessor may (but is not obligated to) perform the activities and undertakings applying to the Lessee or any part thereof, as aforesaid, and the Lessee shall repay the Lessor any expenses that it disbursed for this purpose within 7 days of receiving the first demand thereof and against the presentation of documents of proof and/or duly issued tax invoices with respect to the performance of the actual payment by the Lessor and all provided that the Lessor gave the Lessee advance written warning of 5 days prior to the performance of the activities, as aforesaid. Nothing in the contents of this section may derogate from the Lessee's duty to perform and fulfill all undertakings thereof pursuant to section 14 (b) as aforesaid and/or derogate from the liability of the Lessee, as specified in the section above, also in respect of any action and/or deed that the Lessor performs as a result of the Lessee's failure to fulfill the undertakings thereof as specified herein in this section.

# 15. Use of the Rented Premises

Without derogating from the validity of the remaining provisions of the agreement, the Lessee undertakes the following:

- a. To manage the work solely within the confines of the rented premises and to use the rented premises solely for the objective of the tenancy and not for any other purpose.
- b. To fail to place and/or hold any equipment, stock and any movables and/or other objects whatsoever in the courtyard and/or on the balconies of the rented premises and/or the building and/or in any other area outside the rented premises and to refrain from the use of any part of the building, aside from the rented premises, for any objective whatsoever, except for the use to access the rented premises.

Notwithstanding the aforesaid, the Lessee may place on the balconies of the rented premises garden furniture of the type to be authorized by the Lessor in advance and in writing.

It is hereby clarified that save for the kitchenette for the use of the Lessee and employees thereof, which is not to serve for the purposes of cooking, baking or frying and which shall be implemented in the rented premises subject to the Lessor's authorization of the plans of the Lessee in connection with the installation of a kitchenette, and pursuant to the provisions of this agreement, the Lessee may not install in the rented premises dining rooms, kitchens, kitchenettes, etc., unless it receives authorization for this in advance and in writing from the Lessor and, if it receives authorization as aforesaid, it may act solely in accordance with conditions to be determined, if determined, in the authorization, as aforesaid.

Notwithstanding the aforesaid herein in this section, if any movables whatsoever of the Lessee shall be found on the terraces and/or outside the rented premises and the Lessee fails to remove such following the first request of the Lessor, then the Lessor may but is not obligated to remove such movables from the building and/or the area at the Lessee's expense without there being any liability for the Lessor to pay for such. The Lessor shall not act as aforesaid, save if it gave 24 hours warning thereof to the Lessee in advance and in writing.

The failure to exercise the rights of the Lessor as above shall not constitute any consent on its part to holding the movables as aforesaid on the terraces and/or outside the rented premises, and it shall not grant the Lessee any additional right to continue to hold the movables there and it shall not preclude the Lessor from undertaking any procedure whereto it is entitled by law and/or pursuant to the conditions of this agreement.

c. To refrain from causing any nuisance, disturbance and unpleasantness to any other persons found in or visiting the area wherein the rented premises are located, to neighbors and/or the surroundings as well as to maintain the cleanliness of the rented premises and environs thereof.

The Lessee hereby undertakes to refrain from introducing to the sewage network and to ensure that it fails to cause the introduction thereto of unsuitable spills, pursuant to the provisions of the Ministry of Health on the subject.

A Lessee who produces a quantity of refuse and/or garbage in a regular and ongoing manner, which is unusual in the Lessor's opinion, the Lessor shall be entitled to impose on the Lessee the exceptional expenses of the removal of the refuse of the same Lessee from the building wherein the rented premises are located.

d. To fulfill all laws, regulations and bylaws applying and/or those that shall apply during the tenancy period to the rented premises, the use thereof and the business, works and activities to be performed therein by the Lessee and to be liable vis-à-vis the government and municipal institutions and authorities for the payment of all fines thereof, as a result of the failure to fulfill the provisions of this section herein.

- e. To use for the purpose of access to the rented premises solely the access routes marked and/or arranged in the building as they shall be from time to time, to park vehicles and transport vehicles in the places intended therefor and to refrain from the use of any motorized vehicles or other vehicle likely to damage the access routes and parking surfaces and to observe the instructions to be issued by the Lessor and/or anyone on behalf thereof from time to time in connection with the access arrangements and parking within the confines of the lot.
- f. To pay in full and on time all payments it owes to the Lessor and/or the competent authorities on the dates stated for the settlement thereof.
- g. To enable the Lessor and/or a representative thereof to visit the rented premises at any reasonable time and insofar as possible following advance coordination and inspect the state and use being made thereof in order to assess the degree of fulfillment of the provisions of this agreement and/or to take the actions and means determined herein in this agreement or in any law, which require entry to the rented premises, including herein the following:
  - (1) To perform within the confines of the rented premises the repairs necessary for the requirements of the building or any part thereof.
  - (2) To perform construction and/or demolition, which the Lessor is entitled to perform pursuant to this agreement. To the extent possible according to the sole discretion of the Lessor, the Lessee shall be given the possibility to perform such acts of its own accord within 7 days of the date of the Lessor's request and, in accordance with the provisions and authorization of the Lessor in advance and in writing, including with respect to the manner of performance of the activities and the identity of the entity performing the activities.
  - (3) To show the rented premises to potential buyers and/or tenants.

- (4) If some of the building's systems are located in the rented premises and access thereto is through the rented premises, the Lessee shall allow the Lessor access to the same systems at any time for the purpose of the inspection and repair thereof. In an emergency, insofar as there is no one present in the rented premises and/or the rented premises are locked and there is a need to enter the rented premises due to an emergency situation, the Lessor and/or anyone on behalf thereof shall telephone the Lessee's operations center, telephone no. (02) 625-7002 (the Shion Company). In the event that the aforesaid telephone number of the Lessee's center changes, the Lessee shall inform the Lessor of the new number forthwith and in writing. If the Lessor has telephoned the Lessee's center, it shall inform the person who answers the phone that he shall dispatch a representative of the Lessee hastily since there is an emergency situation and an urgent need to enter the rented premises. In the event there is no reply at the number, as aforesaid, for any reason and/or in the event that a representative of the Lessee fails to arrive within the time the Lessor or anyone on behalf thereof requires, from time to time, according to the circumstances of the matter, the Lessor and/or anyone on behalf thereof may break into the rented premises without delay. The Lessee agrees and declares that any damages and/or expenses it shall incur, directly and/or indirectly, in connection with the break-in, as aforesaid, shall be at the expense thereof and/or the sole liability thereof and it exempts the Lessor of any liability for any expense and/or damage it incurs, directly and/or indirectly, in connection with the break-in, even if it becomes apparent in retrospect that the Lessor could have avoided breaking in and/or could have broken in another manner and/or another place, all subject to the fact that the break-in, as aforesaid, shall be performed in cases where, in the circumstances of the matter, it was reasonable to assume that this constituted an emergency, which justified taking steps, as aforesaid, by the Lessor. For the avoidance of doubt, following the break-in, the Lessor shall not be obligated to place any security whatsoever at the rented premises subject to the fact that in the event it received a telephone response, as aforesaid, the Lessor made certain that a representative of the Lessee is aware of the situation at the rented premises.
- h. To fulfill the instructions of the Lessor and directives of the competent authorities connected to the arrangements and procedures of fire extinguishing and prevention of fires, the Home Front Command, safety and security, in connection solely with the rented premises and to purchase and maintain at its expense, pursuant to the abovementioned bodies, all precautionary and safety equipment necessary to apply and observe the aforementioned instructions (including firefighting equipment) and to connect it to the center on that floor, all in connection and in relation solely to the rented premises, save for public infrastructure and external walls of the rented premises, which fall under the liability of the Lessor and with respect whereto the provisions of this sub-section shall not apply to the Lessee, unless a provision and/or demand, as aforesaid, in connection therewith ensues from the type and/or manner of management of the Lessee's business in the rented premises.
- i. According to the demand of the Lessor, to demolish and/or alter any addition or alteration introduced by the Lessee to the rented premises and/or the building that were constructed not in accordance with the provisions of this agreement and to restore the state of the rented premises and building to the former state thereof, all at the Lessee's expense.

- j. The Lessee hereby undertakes to refrain from hanging and installing signs and/or other means of advertisement in the area and/or in any part of the building. The signage, location thereof, type thereof, size and form thereof shall be determined by the Lessor, at its sole discretion, and the Lessor shall install such at the expense of the Lessee.
- k. For the avoidance of doubt, it is hereby explicitly clarified that the Lessee may not install air-conditioners in the walls and/or windows of the rented premises.

## 16. Maintenance and Repairs

- a. The Lessee undertakes to use the rented premises throughout the period of the tenancy in a reasonable manner and to maintain the rented premises and all facilities therein or connected thereto in good condition, functional, clean and orderly.
- b. In return for payment of the aforesaid sums in sub-section d herein below, the Lessor hereby undertakes to supply the maintenance services specified in sub-section c herein below, all under the conditions specified there.
- c. Maintenance services provided by the Lessor shall be of the type, extent and under the conditions specified herein below:
  - (1) Maintenance of the structure, maintenance of the mechanical systems in the public areas, public plumbing, public sewage, public electricity, maintenance of elevators, gardening, maintenance of public signage, maintenance and cleaning of public areas, repair of problems and/or damages caused to systems of the rented premises as a result of reasonable and ordinary wear, save for the air-conditioning systems within the rented premises and the systems installed, added and/or altered in the rented premises by the Lessee and/or anyone on behalf thereof.
  - (2) Air-conditioning systems, including central cooling services, but not including treatment and maintenance of the air-conditioning appliances within the rented premises, on business days and at times that are customary. Heating shall be installed in the corner units.

The Lessor shall supply the Lessee, if such is required, with cooling services also during the winter season to an extent and under the conditions to be concluded between them.

For the avoidance of doubt, it is hereby explicitly clarified that subject to the undertaking of the Lessor to repair problems solely in the central air-conditioning system, if there are such, within a reasonable time from the date of receiving notice of the Lessee of the aforesaid impairment, nothing in the provisions of this agreement may imposed any liability whatsoever thereon for the disruptions likely to occur in the operation of the air-conditioning systems whether due to problems or maintenance activities or due to any other reason without exception, and the Lessee shall not be entitled to demand and/or receive from the Lessor any compensation and/or damage fees and/or payment in respect thereof for any reason whatsoever.

The Lessee may not touch the air-conditioning systems in the rented premises and/or deal with them and/or maintain them and/or repair them and/or perform any action and/or enable others to do so, save for licensed contractors to whom the Lessor agrees in advance and in writing to their handling of the air-conditioning system in the rented premises and to do anything of the aforesaid with the equipment. If the Lessee breaches any of the provisions of this section and as a result thereof damage is caused to the air-conditioning systems, the Lessee shall bear the full expenses of the repair of the damage in practice, according to invoices to be presented to the Lessee together with interest for delay. For the avoidance of doubt, the Lessee shall bear all costs of the handling and maintenance of the air-conditioning systems within the rented premises.

- (3) Environmental protection to an extent to be determined from time to time by the Lessor according to its sole and exclusive discretion.
- (4) Insurance The relative suitable share of the expenses and insurance fees that the Lessor shall pay for insurance of the building and systems therein against loss or damage as a result of the risks of fire, explosion, earthquake, storm and gale, flood, water damage, strikes, riots and malicious damage, as well as any additional risk necessary in the Lessor's opinion. This insurance shall not include the contents of the rented premises s well as repairs, alterations and additions to the rented premises made by and/or for the Lessee.

The parties hereby agree explicitly that nothing in the arrangement of insurance, as aforesaid herein in this section, may derogate from the Lessee's liability, whether pursuant to this agreement or according to law, and nothing therein may impose any liability whatsoever on the Lessor with respect to loss and/or damage to the building.

#### (Herein below: "Maintenance Services")

d. In return for maintenance services the Lessee shall pay the Lessor, in addition to the rent specified in section 10 above and in addition to the payments specified in section 12 above, the sum of \$2.50 a month for each square meter of the rented premises (gross), save in respect of the Machinery Area and the Gallery Area (hereinafter: "the Maintenance Fees").

Maintenance fees shall be translated into shekels on the date of signature of this agreement and shall constitute the base for the payment of maintenance fees ("the principle"), and shall be paid to the Lessor while linked to the Index. For the avoidance of doubt, it is clarified that the linkage differentials shall be calculated in accordance with the known index on the date of any payment in practice of maintenance fees, as opposed to the basic index.

The Lessee shall pay the Lessor maintenance fees in advance for every 3 months of the tenancy period, as specified in section 11 above.

- e. Together with the payment of the maintenance fees, the Lessee shall pay the Lessor the VAT that applies to such payments against a duly issued tax invoice. The date of settling the VAT shall be the date of payment thereof to the VAT authorities pursuant to law, which is to say the 15<sup>th</sup> day of the second month of each quarter of the tenancy period.
- f. For the avoidance of doubt, the parties agree that the Lessor as aforesaid shall not be deemed "the guardian" of the rented premises and/or the contents thereof, regarding the provisions of the Watchmen Law, 5727-1967.
- g. The Lessee undertakes to inform the Lessor, as the case may be, forthwith with no delay, of any loss, impairment, or damage caused to the rented premises or to any part thereof.
- h. Without derogating from the aforesaid, the Lessee undertakes to repair at its own expense any fault or impairment wherefore the Lessee is liable pursuant to section 17A herein below at the latest within seven (7) days of the date of the occurrence thereof.
- i. In the event the Lessee fails to fulfill in full an undertaking pursuant to sub-sections a to h above, the Lessor of its own accord may perform (but is not obligated to do so) the maintenance and repairs that apply to the Lessee, subsequent to having given 7 days' warning in advance and in writing to the Lessee. The Lessee shall reimburse the Lessor for all expenses that it expended for this purpose within 7 days of receiving its first demand and against the presentation of documentary proof with respect to payment of the actual expenses. Nothing in the aforesaid herein in this section may derogate from the Lessee's duty to perform the repairs of the rented premises.

## 17. Insurance and Liability

A. In the relations between the parties and without derogating from the liability of the Lessee pursuant to any law, the Lessee shall be solely liable for any damage caused to any person and/or body and/or property during and as a result of the performance of the works in the rented premises by the Lessee and/or anyone on behalf thereof, save for damages in respect of the performance of the initial adaptation works to be performed by the Lessor, pursuant to the provisions of this agreement and, as well, the Lessee shall be liable for any damage caused to any person, body or property in connection with the possession and/or use thereof and/or anyone on behalf thereof, including the guests thereof in the rented premises. The Lessee undertakes to indemnify the Lessor in respect of any damage proved or monetary expense caused thereto, as a result of any claim or demand to be addressed vis-à-vis the Lessor, in connection with the incidents within the confines of the Lesse's liability.

The parties hereby agree that the Lessee shall indemnify the Lessor, as aforesaid herein in this section above, on condition that the Lessor notified the Lessee forthwith upon receiving the claim or demand, enabled the Lessee to participate in the defense and did not reach a settlement without the authorization of the Lessee. It is clarified that the Lessee shall bear any expenses, including lawyers' fees that the Lessor bears in connection with all the aforesaid, against the presentation of suitable invoices to the Lessee. In any event, the Lessee shall be liable to restore the rented premises to the former state thereof as on the date of delivery, including the initial adaptation works, as defined above, and subject to reasonable wear.

- B. (1) Prior to the date of delivery as defined in section 6 (d) above, and without derogating from the generality of the aforesaid in section A above and from the Lessee's undertakings pursuant to this agreement and pursuant to the provisions of any law and in addition thereto, the Lessee undertakes to purchase at its expense and maintain in effect throughout the entire tenancy period the insurance policies specified herein below with an extent of coverage as defined alongside them, as follows:
  - a. Employers' Liability Insurance Insurance of the Lessee's liability vis-à-vis the employees thereof in respect of any personal injury to any employee during and as a result of the employment thereof, with a customary liability limit at the time of the arrangement of the insurance.
  - b. Third Party Liability Insurance Insurance of the Lessee's liability vis-à-vis the Lessor and any third party whatsoever in an amount that shall not be less than a shekel sum equivalent to \$1,000,000. The policy shall include a "cross liability" section. The policy shall be extended to indemnify the Lessor in respect of the liability thereof for acts and/or omissions of the Lessee.

c. Property Insurance – Insurance of the contents of the rented premises including improvements and investments made therein of any kind and type whatsoever, to the full value thereof against all risks customary including fire, explosion, earthquake, storms, gales, floods, water damage, airplanes, collisions, strikes, riots, malicious damages, burglary and broken glass.

The parties hereby agree that the Lessee may refrain from arranging the insurance against broken glass as aforesaid in sub-section c herein provided that the exemption in section 17 (b)(2)(1) herein below shall apply as if broken glass insurance had been arranged.

- d. Consequential Damage Insurance Consequential damage insurance for a period no less than 12 months as a result of loss or damage to the property of the Lessee, the rented remises and the building from risks as specified in section 17B (1)(c) above. The parties hereby agree that the Lessee may refrain from the arrangement of the insurance as aforesaid herein in this sub-section (d) provided that the exemption in section 17 (b)(2)(1) herein below shall apply, as if such insurance had been arranged.
- e. In the event and insofar as the Lessee shall perform any works whatsoever in the rented premises, subsequent to the completion of all the initial adaptation works, as aforesaid in section 5 herein in this agreement the insurance of the works performed by the Lessee and/or on behalf thereof in the rented premises as well as "third party liability insurance" at the time of the performance of the works with a liability limit that shall be no less than the sum of \$500,000 and employers' liability insurance with a liability limit customary at the time of the arrangement of the insurance. Third party liability insurance shall be extended to include a cross-liability section as well as indemnity of the Lessor in respect of the liability thereof as the owner and/or manager of the rented premises.
- f. (1) Without derogating from the Lessee's liability pursuant to this agreement or according to any law, the Lessee declares that it shall arrange and fulfill, at its expense, whether of its own accord or by way of contractors on behalf thereof, commencing on the date of the beginning of the performance period of the adaptation works in the rented premises (hereinafter in this section: "the Works"), with a licensed reputable insurance company, a Works Insurance policy as specified herein below (hereinafter: "Works Insurance"), throughout the entire period of the works, in its name, in the contractor's name, the sub-contractors, in the Lessor's name, the management company and the name of those coming by virtue thereof, against loss, damage or liability connected to or ensuing from the performance of the works. Works insurance shall include the following insurance chapters specified herein below:

Chapter (1) – Property Damage

All Risks Insurance insures against the physical and unanticipated loss or damage that shall be caused to the works during the period of insurance. The chapter comprises explicit expansion with respect to coverage of proximate property and property being worked on with a liability limit in the amount of at least \$50,000. The insurance shall include a section with respect to the waiver of the right of subrogation in favor of the Lessor, the management company and anyone acting on behalf thereof as well as vis-à-vis other rights holders in the building wherein the rented premises are located (who have a similar waiver in favor of the Lessee in the insurance of the property thereof), provided that the waiver, as aforesaid, shall not apply in favor of a person who caused damage maliciously.

#### Chapter (2) – Third Party Liability

Liability insurance vis-à-vis third parties in respect of bodily injury or damage to property caused during the period of the works, with a liability limit of \$1,000,000 per incident for the insurance period.

Coverage shall include explicitly also a section on cross-liability. The chapter as aforesaid shall not include any limit on the matter of the following topics:

- a. Subrogation claims of the National Insurance Institute in respect of employees of contractors and sub-contractors employed on the site of the Works.
- b. Personal injury ensuing from the use of mechanical engineering equipment, which is a motorized vehicle, and there is no duty to insure it with compulsory insurance.
- c. Liability for damage caused as a result of earthquakes and the weakening of an abutment with a liability limit in the amount of \$250,000 per incident.

Chapter (3) – Employers Liability

Liability insurance vis-à-vis employees performing the works in respect of personal injury or illness caused to any one of them within the confines of the performance of the works during the period of performance, while performing and as a result of the performance of the works, with a liability limit of \$5,000,000 for the Plaintiff per incident and period of insurance. The insurance shall not include any limit with respect to contractors, sub-contractors and employees thereof, works performed at heights and in depth, lures and poisons, as well as with respect to the employment of youth.

Extent of insurance coverage in contractors' works insurance shall be no less than the conditions known as "*Bit* 2005" conditions or a policy similar thereto at the time the insurance is arranged.

(2) Works insurance shall include an explicit condition to the effect that the insurer may not revoke it and/or restrict the extent thereof unless the insurer delivered notice to the Lessor by way of registered mail of its intent to do so at least 30 days in advance.

(3) For the avoidance of doubt, the Lessee and/or anyone on behalf thereof shall bear the sums of the deductible stated in the insurance policies. These sums may be set off by the Lessor from any amount owing to the Lessee pursuant to this agreement.

(4) The policies shall include a provision to the effect that solely the Lessee and/or anyone on behalf thereof alone shall be liable for the payment of the premium.

(5) The policies shall include a provision to the effect that they constitute primary policies for each policy that was separately taken out by an individual of the individuals of the insured party.

(6) The Lessee undertakes to present to the Lessor, no later than the date of commencement of the performance of the works authorization of the arrangement of insurance by the insurer thereof and/or the insurer of the contractor on behalf of the Lessee of the performance of works insurance, in accordance with the authorization of the arrangement of insurance attached hereto to this agreement as **Appendix F1**, and constituting an integral part thereof (hereinafter: "Authorization of the Arrangement of Insurance"). The parties hereby agree explicitly that the arrangement of the insurances, as aforesaid, the presentation thereof and/or the amendment thereof fail to constitute authorization with respect to the suitability thereof and shall not impose any liability whatsoever on the Lessor and/or the management company and shall not restrict the liability of the Lessee pursuant to this agreement or pursuant to any law.

(7) The Lessee, in its name and in the name of the contractor/s on behalf thereof, hereby exempts the Lessor, the management company and those on behalf thereof as well as other rights holders in the building wherein the rented premises are located (who have agreements that grant them rights in the building wherein the rented premises are located, which include a similar exemption in favor of the Lessee) from any liability for any loss or damage whatsoever to property of the Lessee and/or anyone on behalf thereof, provided that the exemption, as aforesaid, shall not apply in favor of an individual who caused damage maliciously.

- (2) The following provisions shall apply to policies, as aforesaid in section 17B(1) above:
  - a. The Lessee shall perform the aforesaid insurances with a recognized and duly licensed insurance company, shall update the sums of the insurance, shall strictly fulfill all provisions of the policies and shall pay the premiums on time.
  - b. The Lessee shall ensure that the insurer waives the right of subrogation against the Lessor, other tenants and other possessors of property, the managers and employees thereof and anyone on behalf thereof, while all that pertains to the other tenants and possessors, as aforesaid herein in this sub-section b, shall be subject to the fulfillment of a similar section in the agreements signed therewith. This sub-section shall not apply in favor of anyone who has caused damage maliciously.
  - c. At the Lessor's request, the Lessee shall present to the Lessor all insurance policies issued thereto in accordance with this section 17 or the insurance authorization for the rented premises, attached hereto as Appendix F to this agreement, signed by the insurer. In addition, the Lessee shall present to the Lessor and at the request thereof any amendment or revision to the policy and at the reasonable request of the Lessor, the Lessee shall be obligated to add and/or update and/or amend the insurance policies to the satisfaction of the Lessor so that they fulfill the criteria set forth herein in this section 17.
  - d. The Lessee undertakes to use the funds received from the insurance company in accordance with the policies solely to rectify forthwith the damages and/or policies. Nothing in the aforesaid may limit and/or derogate from the Lessor's right to exercise the rights thereof pursuant to the policies. The policy shall include a provision that the Lessor and the insurance company undertake to act pursuant to this section.
  - e. The Lessee's insurances shall be defined as primary insurance and shall include an explicit condition to the effect that they take precedence over any other insurance the Lessor has arranged.

This insurance entitles the Lessor to full indemnity owing pursuant to the conditions thereof without the Lessor's insurers demanding participation in coverage of the damage or liability connected to the tenancy agreement. Likewise, the policies shall include a provision to the effect that they shall not be restricted or revoked unless written notice by way of registered mail shall be delivered to the Lessor 30 days in advance.

f. The Lessee declares that it shall have no contention or demand or claim against the Lessor, the services company or other tenants in the building in respect of any damage whereto it is entitled to indemnity in respect thereof, according to the insurances that it undertook to arrange pursuant to this section or was entitled to had it not been for the deductible for damages stated in the same insurances, and it hereby exempts the Lessor and other tenants and other possessors in the building from any liability for damage as aforesaid.

Nothing in the arrangement of the aforesaid insurances by the Lessee may restrict or derogate in any manner whatsoever from the undertakings of the Lessee in accordance with this agreement or release it from the duty to compensate the Lessor and/or any other person whatsoever in respect of any damage caused directly or indirectly in connection with the property wherefore it is liable in respect thereof and/or as a result of the activity thereof and/or from the Lessee's use of the rented premises and/or as a result of the non-fulfillment of the provisions of this agreement by the Lessee and/or as a result of the performance of works in the rented premises by the Lessee. Payment of any insurance benefits whatsoever to the Lessor shall serve solely to be deducted from the amount of indemnity and/or compensation whereto the Lessor is entitled, as the case may be, in respect of the damage or loss.

The contents of this section shall add to and not derogate from any other provision herein in this agreement with respect to the exemption from liability vis-à-vis the Lessor and with respect to the imposition of liability on the Lessee.

- g. The Lessee undertakes to fulfill the conditions of the policy, to pay the insurance fees in full and on time, to ensure and make certain that the insurance policies for the rented premises shall be renewed from time to time, as required and shall remain valid throughout the entire period of the tenancy.
- h. If the Lessee fails to fulfill the undertaking thereof according to this section 17 herein in its entirety, the Lessor shall be entitled, but not obligated, to arrange the insurances or part thereof in place of the Lessee and at the expense thereof and to pay in place of the Lessee any amount, without derogating from the Lessor's right to any other relief. In such instance, the Lessor shall be entitled to the refund of the expenses thereof in this context together with interest for delay as specified in section 2 above.
- i. Without derogating from the generality of the aforesaid in section a above, the Lessee shall be liable for any claim wherefore the Lessor is likely to be obligated as a result of the Lessor's breach or failure to fulfill the provisions of any law or license or competent authority or as a result of the breach of an undertaking of the Lessee pursuant to this agreement, and the Lessee shall indemnify the Lessor in respect of any expense or damage whatsoever, if there are such, in connection therewith.

The parties hereby clarify and agree that the Lessee is solely liable and shall indemnify and compensate the Lessor forthwith upon its first demand in respect of any damage and/or expense the Lessor incurs, directly or indirectly, including as a result of a claim or complaint from any third party whatsoever in connection with the use and/or handling by the Lessee of chemical and/or biochemical and/or other materials including but not solely the storage thereof, the spill thereof, the drainage thereof including the leaking thereof, for any reason whatsoever, emission of gases of any kind and for any reason from the rented premises and/or from any apparatus and/or system in the rented premises, and including the animals and/or animal house held in the rented premises, if such is held. Indemnity by the Lessee of the Lessor as aforesaid herein in this sub-section shall be against the presentation of documentary proof and/or suitable invoices to the Lessee.

Notwithstanding the aforesaid in any other place, the Lessor shall not be liable in any case for any damage, expense, loss or impairment caused, directly or indirectly, to any person and/or body in connection with the equipment and/or materials and/or animals and/or animal house whereof the Lessee makes use in the rented premises, including all byproducts thereof, as well as, but not solely, the transport thereof, storage thereof, evacuation thereof or emptying thereof. And the Lessee hereby declares that it agrees to be solely liable and indemnify the Lessor forthwith upon its first demand in respect of any expense or damage in connection therewith.

d. If possible, all the insurances shall indicate therein that following each payment of compensation by the insurer, the limits of liability shall automatically be restored to their former state. The Lessee shall be liable to pay the additional premium resulting therefrom.

## 18. Transfer and Endorsement of Rights

a. The Lessee shall not be entitled to transfer the rights in the rented premises and rights pursuant to the agreement or to permit any use whatsoever of the rented premises or any part thereof to anyone else, whether for proceeds or not for proceeds, directly or indirectly, without obtaining the permission of the Lessor to do so, in advance and in writing. The Lessor shall refuse to give the consent thereof solely on reasonable grounds.

- b. The Lessor may sell and transfer to another the rights thereof in the lot and/or the building or any of the units thereof, including the rented premises and/or the rights pursuant to the agreement or to encumber them or mortgage them without the need for the prior consent of the Lessee, provided that the Lessee's rights pursuant to the provisions of the agreement and/or according to any law shall not be infringed. The Lessor shall inform the Lessee insofar as it shall sell the rights thereof in the rented premises to another.
- c. Without derogating from the aforesaid, the Lessor may transfer, assign, endorse and mortgage in favor of another all the rights thereof to the rent, subject of the agreement, and the Lessee shall act pursuant to and in accordance with the written provisions with which the Lessor provides him on this matter, provided that the rights of the Lessee according to the provisions of the agreement and/or according to any law shall not be infringed.
- d. The Lessee undertakes to inform the Lessor of any change in ownership of the Lessee, within 7 days of the occurrence of such change.
- e. The parties agree that the Lessee may transfer part of the rights thereof in the rented premises, pursuant to this agreement, to a sub-tenant, subject to the cumulative fulfillment of the conditions following herein below: (1) the sub-tenant is a factory in the high-tech industry; (2) the Lessee shall obtain the consent of the Lessor to the identity of the sub-tenant, in advance and in writing, and the parties agree that the Lessor shall only refuse the preference of the Lessee on reasonable grounds; and (3) the Lessee shall remain solely liable for the fulfillment of all conditions and undertakings pursuant to this agreement vis-à-vis the Lessor, including but not solely all payments (of any kind), the objective of the rented premises, the use of the rented premises, the maintenance and evacuation of the rented premises, with respect to the entirety of the rented premises.

## 19. Fundamental Sections and Advance Agreed Compensation

- a. The parties hereby agree that the provisions of sections 6(a), 6(e1), 8(a), 9, 10, 11, 12(a), 13, 14, 15(a)(b)(h), 16(c)(d)(e), 17, 18(a), 21 and 22 are principal and fundamental sections of this agreement as the term is defined pursuant to the Contracts (Reliefs Due to Breach of Contract) Law 5731-1970. The breach of these sections or any one of them shall be deemed a fundamental breach as this term is defined pursuant to the Contracts (Reliefs Due to Breach of Contract) Law 5731-1970.
- b. The breach of the provisions of sections 9, 10, 11, 12(a), 14, 16(c)(d)(e), 17 and 21 of this agreement that failed to be rectified even subsequent to the provision of a warning of 7 days in writing to the Lessee shall grant the Lessor, in addition to all reliefs and remedies granted thereto, the right to agreed compensation estimated in advance in the amount of the rent and maintenance fees in respect of the rented premises for 4 months of rent, with the addition of VAT, as it may be from time to time (hereinafter: "the Agreed Compensation"). The agreed compensation shall be linked to an index from the basic index to an index to be known at the time of actual payment. The parties hereby declare that the amount of agreed compensation is effective and reasonable and has been determined by them in accordance with damages they anticipate in the event of a fundamental breach of the agreement.

- c. Without derogating from the undertakings of the Lessee pursuant to this agreement, the parties hereby agree that a delay by the Lessee in the payment of rent and/or any other payment imposed thereon, pursuant to this agreement, that exceeds 3 business days shall bear interest for delay, as defined herein in this agreement, which shall apply commencing on the first day of the delay in payment, all in addition to and without derogating from any other reliefs and remedies granted to the Lessor pursuant to this agreement and/or pursuant to any law.
- d. For the avoidance of doubt, the parties agree that a delay in payment of the rent, management fees and/or any other payment, which the Lessee is obligated to pay to the Lessor, pursuant to the provisions of this agreement that fails to exceed 3 business days shall not be deemed a breach of this agreement and shall not entitle the Lessor to any relief of any kind and type whatsoever.

### 20. <u>Revocation of the Tenancy and the Agreement</u>

The Lessee hereby agrees and undertakes that notwithstanding the provisions of this agreement with respect to the period of the tenancy, the Lessor may – but is not obligated to – revoke this agreement and evacuate the Lessee from the rented premises by a one-sided notice of 14 days in advance and in writing, provided that the Lessee is given an opportunity of 14 days to rectify the breach in each of the following cases specified herein below:

- a. If the Lessee breached and/or failed to fulfill on time one of the conditions and/or undertakings, pursuant to the fundamental sections.
- b. If a receiver and/or a liquidator (including a provisional one) is appointed for the Lessee and/or the property thereof, all or in part, and/or the business thereof, and the appointment is not revoked within 45 days and/or if the Lessee is declared bankrupt, all as the case may be.

## 21. Evacuation of the Rented Premises

- a. The Lessee hereby undertakes to evacuate the rented premises on termination of the tenancy period or on the lawful revocation of this agreement, all according to whichever is the earlier and according to the matter and to return the rented premises to the exclusive possession of the Lessor in the same state it was in as on the date of delivery, including the initial adaptation works, as it is clean and freshly painted with Tambour Supercryl paint (in the same shade as when it received the rented premises) and subject to reasonable and accepted wear.
- b. In addition and without derogating from the reliefs and remedies duly granted to the Lessor pursuant to the provisions of this agreement and/or the provisions of law, the Lessee hereby undertakes that if it fails to evacuate the rented premises as aforesaid in section a above, the Lessee shall pay the Lessor for each day of delay agreed usage fees, agreed and estimated in advance, in the amount of double (twice) the rent owing to the Lessor in respect of each day. This sum shall be linked to an index of the known index on the date whereon the Lessee was required to vacate the rented premises, pursuant to section a above, and until the index that shall be known on the date of actual payment.
- On the evacuation of the rented premises, the Lessee may take with it all movable equipment it introduced into the rented premises at its c. expense, which may be dismantled, including the equipment specified in <u>Appendix C</u>, which shall be evaluated and attached to this agreement with the advance agreement of the parties in writing, if and insofar as it shall be attached, and unless it is agreed otherwise, the permanent systems the Lessee introduced to the rented premises at its expense, which may be dismantled (together hereinafter: "the Equipment"), provided that the Lessee shall repair at its expense all that requires repair as a result of the aforesaid dismantling activities in order to restore the rented premises to the former state at the time of the delivery, as aforesaid in section a above. The repairs shall be performed prior to the termination of the tenancy period or the revocation thereof, pursuant to this agreement, and in accordance with the directives of an engineer on behalf of the Lessor and, in any event, without damaging the structure thereof and/or systems therein and/or the ongoing activities of the tenants of the building. If the Lessee fails to dismantle the equipment or any part thereof as aforesaid, the Lessor shall have the right and option to dismantle them and remove them or, alternatively, to take possession thereof without any duty of paying indemnity and/or compensation and/or refund and/or making any payment whatsoever applying thereto. If the Lessor demanded the evacuation of the equipment within 7 days of the termination of the tenancy period or the revocation thereof and the Lessee fails to evacuate the premises, then in order to pay proper usage fees as determined in sub-section b above, the Lessee shall be deemed as one who has failed to vacate the rented premises as long as the Lessee fails to dismantle and remove the equipment from the rented premises and fails to adapt the rented premises to the former state thereof as on the date of delivery.

## 22. <u>Securities</u>

To ensure the fulfillment of the Lessee's undertakings pursuant to this agreement, the Lessee shall deposit with the Lessor at the time of the signature of this agreement and as a condition for receiving possession of the rented premises the following securities:

- a. An automatic unconditional bank guarantee, which may be paid off according to first demand and without giving reasons in a shekel amount equivalent to \_\_\_\_\_\_\_U.S. dollars (the value of the rent and management fees with the addition of VAT in respect of a period of 6 (six) months of rent) (hereinafter: "the Guarantee" or "the Security") with the text as specified in <u>Appendix G</u> and subject to the conditions specified herein above and below. The guarantee shall be unconditional and not given to endorsement and may be forfeited in full or by installments at any time. The guarantee shall be linked to the representative rate of the U.S. dollar, as specified in the text of the guarantee attached hereto as Appendix G. The validity of the guarantee shall be commencing from the date of the signature of this agreement, throughout the entire period of the tenancy with the addition of 3 more months and the validity thereof shall be renewed periodically, a month before the date whereon the validity thereof is intended to expire until the conclusion of the additional tenancy period, with the addition of 3 months following the termination of the additional tenancy period. The guarantee shall be duly stamped. All expenses involved in issuing the guarantee shall apply solely to the Lessee. In the event that the guarantee is duly forfeited pursuant to this agreement, the Lessee undertakes to deposit forthwith, following the forfeiture as aforesaid, an additional guarantee with the text and the conditions as stated above.
- b. Without derogating from the remaining provisions of this agreement, the Lessor may utilize the security, all or in part, as it opts to do, as follows:
  - (1) In the event that the rented premises fail to be evacuated at the required time, the Lessor may utilize the security in full or in part and in such manner that the funds to be paid shall be deemed, *inter alia*, as agreed compensation, estimated in advance, as determined herein in this agreement.
  - (2) In the event of the failure to make a payment that applies pursuant to this agreement to the Lessee, the Lessor shall be entitled to utilize the security in the amount of the sum of the payment required and together with linkage differentials, fines, interest for delay and all other expenses of the Lessor.

In the event that the failure to make a payment constitutes a fundamental breach of the agreement, the Lessor may utilize the security in the amount of the sum required or in the amount of agreed compensation pursuant to this agreement, according to whichever is the higher between them.

- (3) In the event of damage to or loss of the rented premises and/or the contents thereof that apply pursuant to this agreement to the Lessee, the Lessor shall be entitled to utilize the security in the amount of the sum required for the repair thereof, together with 15% handling fees. "Repair" shall have the meaning: including replacement.
- (4) In order to cover the damages and expenses thereof, in the event of a fundamental breach of the agreement.
- (5) In order to cover the damages and expenses thereof in the event of a breach, which is not a fundamental breach, if such fails to be rectified within 7 days of the date whereon the Lessor gave written warning thereof.
- c. Notwithstanding the aforesaid in this section 22, it is hereby clarified that the Lessor may not utilize the guarantee and/or any other security pursuant to this agreement unless subsequent to the delivery of notice thereof of 7 days in advance and in writing to the Lessee, during which time the Lessee failed to rectify the breach contended by the Lessor.
- d. The provision of a security according to this section fails to constitute a waiver on the part of the Lessor of the right thereof to other reliefs against the Lessee, whether the reliefs are explicitly stated in the body of the agreement or whether such are reliefs available to the Lessor by virtue of any law.
- e. The guarantee shall be returned to the Lessee up to three months following termination of the tenancy period or following the presentation of all documentary proof with respect to the performance of all payments pursuant to this agreement by the Lessee whichever is the earlier of the two dates aforesaid.

#### 23. Proprietor's Custom – Lessor's Seizure of the Rented Premises

Without derogating from the validity of the aforesaid herein in this agreement and in addition to all reliefs and remedies granted to the Lessor pursuant to this agreement and/or according to any law, the parties hereby agree as follows:

- a. On termination of the tenancy period and/or in any case of the expiration or revocation of this agreement, all according to whichever is the earlier, the Lessor may act with respect to the rented premises or in any part thereof as is customary for proprietors.
- b. If the Lessee fails to evacuate the rented premises on termination of the tenancy period and/or on the expiration thereof and/or on the revocation of this agreement, all according to whichever is the earlier, the Lessee shall be deemed as a trespasser of the Lessor's property in the rented premises and in any part thereof, commencing on the date whereon the Lessee was required to vacate the rented premises, as aforesaid, until the actual evacuation thereof. In such event, as aforesaid, the Lessor, subsequent to giving advance written warning of two business days, may and is entitled to preclude the Lessee or anyone of the units thereof and/or any person on behalf thereof from entering the rented premises and making use of the rented premises or any part thereof. For this purpose, the Lessor is entitled to and may, *inter alia*, use reasonable force, replace the locks of the rented premises, disconnect and/or instruct that the electricity, water, telephone, gas and air-conditioning be disconnected and preclude the Lessee's access and entrance, including to the building, and all subject to any law.

## 24. Cancelled

### 25. Miscellaneous

- a. The titles in this agreement were added solely for the convenience of reading and use and fail to instruct with respect to the contents and construal of the agreement.
- b. The appendices attached hereto to this agreement constitute an integral part thereof.
- c. If a party to the agreement, subsequent to providing written early warning of 7 days to the other party, pays any amount whatsoever, the duty of payment whereof applies to the other party effective by the provisions of any law or valid by the provisions of this agreement, the party that is obligated for the payment shall reimburse the paying party with the amount it paid together with interest for delay from the date of payment by the paying party until the date of the actual reimbursement by the party owing the sum, against the presentation of documentary proof and/or duly issued tax invoices with respect to the performance of the payment in practice by the paying party.

- d. The parties choose the city Tel Aviv-Jaffa as the place of exclusive jurisdiction for the purposes of the provisions of this agreement.
- e. Any alteration or amendment to or waiver in the agreement or in any condition of the conditions thereof shall be made in writing and signed by the parties.
- f. The Lessor's consent to any divergence from the conditions of the agreement shall not serve as a precedent and/or shall not constitute any waiver and no analogy shall be learned therefrom to any other instance.
- g. The Lessee hereby declares that it has been explicitly informed that Adv. Dana Dotan and/or Adv. Yael Langer and/or Adv. Amit Wengerovitz and/or Adv. Sharon Rosenzweig and/or Adv. Hagit Rothstein represent solely the Lessor in the agreement and the transaction, subject of this agreement and the Lessee may be represented by another attorney.
- h. The costs of the stamps for this agreement shall be paid by the party requesting that the agreement have stamps.
- i. The addresses of the parties for the objectives of the agreement are as aforesaid in the Preamble and any notices that are to be delivered according to the agreement or in connection thereto shall be in writing and shall be delivered by hand or by way of registered mail, according to these addresses. Notwithstanding the aforesaid, following the signature of this agreement the Lessee's address shall be the address of the rented premises. If a notice is sent by registered mail, it shall be deemed to have reached the knowledge and domain of the party being addressed within 72 hours of the time it was dispatched thereto.
- j. This agreement exhausts and faithfully reflects all that has been agreed by the parties. No representation and/or undertaking that have not found expression herein in this agreement shall have any validity. Any representation and/or agreement and/or undertaking that preceded this agreement are hereby null and void.
- k. Notwithstanding all the aforesaid in any other place herein in this agreement, in any event, the Lessor and/or the management company shall not be liable, pursuant to this agreement, for indirect damages and/or resultant damages, save for damages, as aforesaid, that were caused maliciously by the Lessor directly.

(-)

# Kapps-Pharma Ltd.

# /s/ YURI SHOSHAN

Lessee STAMP: Bioline Innovations Jerusalem Limited Partnership By Its General Partner Bioline Innovations Jerusalem Ltd.

I, the undersigned, Joeri Kreisberg, attorney for the Lessee, Bioline Innovations Jerusalem Limited Partnership, hereby authorize that Morris Laster, Aharon *Illegible* and Rami *Illegible* have signed this agreement in the name of the Lessee and they are approved signatories to sign this agreement and the signatures thereof on the agreement obligate the Lessee for all intents and purposes.

(-)

Attorney

STAMP: Joeri Kreisberg, Adv. License No. 19903

# List of Appendices

1.	Appendix A:	Sketch of the rented premises and additional areas
2.	Appendix B:	Schedules
3.	Appendix B1:	Initial adaptation specification works
3.	Appendix C:	Equipment that the Lessee may take with it on termination Of the tenancy period
4.	Appendix D:	Sketch of the parking spaces
5.	Appendix E:	Formula for the calculation of air-conditioning electricity consumption in the rented premises
6.	Appendix E1:	Formula for the calculation of expenses in respect of particularly high-powered air-conditioning for the Old Wing Area
6.	Appendix F:	Authorization of insurance for the rented premises
7.	Appendix F1:	Authorization of insurance of the works
8.	Appendix G:	Text of the bank guarantee

## <u>Amendment and Update of the Unprotected Lease Agreement Between</u> Kapps-Pharma Ltd. <u>(the "Lessor") and Bioline Innovations Jerusalem,</u> <u>Limited Partnership (the "Lessee")</u>

#### This agreement was made and executed on December 14, 2009

- Whereas The Lessee leases, from the Lessor, various areas in a building in the industrial area in Har Hotzvim in Jerusalem (hereinafter: "the Building"), as specified in section 1a below, and 22 regular parking spaces and 6 double parking spaces in the building's parking lot, marked in the parking space blueprint which is attached as <u>Appendix A</u> to this agreement (hereinafter "the Leased Premises"), in accordance with the provisions and terms of the lease agreement signed by the parties on July 10, 2005, (hereinafter: "the Main Agreement"), the amendment agreement dated October 23, 2007 (hereinafter: "the Amendment and Supplemental Agreement") and the parties' verbal agreement regarding the Lessee's leasing of the storeroom area, as defined below;
- Whereas The Lessee notified the Lessor on June 30, 2008 of its decision to exercise the first extension period, as described in section 3 of the amendment and supplemental agreement, with regard to all of the areas in the leased premises, and there has been an agreement on additional updates regarding the leasing of the leased premises, including terms relating to the leasing of the storeroom area as defined below, all subject to the provisions and terms of this agreement;

The parties therefore agree, provide and declare as follows:

1. The preamble to this agreement constitutes an integral part thereof.

- 2. It is hereby agreed that the total area of the leased premises, as defined above, is 1,781.50 square meters (gross) in total, along with the parking spaces as described above, and that the said area is divided as follows:
  - (a) 751 square meters (gross) on the 6th floor of the building's new wing, as outlined in color and marked with the letter A and with the words "the Company's Offices," on the blueprint attached as <u>Appendix B</u> to this agreement, and which the Lessee leases from the Lessor pursuant to the main agreement (hereinafter: "the New Wing Area");
  - (b) 623 square meters (gross) on the 6th floor of the building's old wing, as outlined in color and marked with the letter B and with the words "the Company's Laboratories," on the blueprint attached as <u>Appendix B</u> to this agreement, and which the Lessee leases from the Lessor pursuant to the main agreement (hereinafter: "the Old Wing Area");
  - (c) 31 square meters (gross) on the 6th floor of the building's Old Wing, as outlined in color and marked with the letter C and with the words "Machinery Area" in the blueprint attached as <u>Appendix B</u> to this agreement, and which the Lessee leases from the Lessor pursuant to the main agreement (hereinafter: "the Machinery Area");
  - (d) 14 square meters (gross) of a gallery area on the 6th floor of the building's New Wing, which, pursuant to the main agreement, are designated for the placement of machinery, as outlined in color and marked with the letter "D" and with the word "Gallery" on the blueprint attached as <u>Appendix B</u> to this agreement, and which the Lessee leases from the Lessor pursuant to the main agreement (hereinafter: "the Gallery Area");
  - (e) 225 square meters (gross) on the 6th floor of the building's New Wing, as outlined in color and marked with the letter "E" on the blueprint attached as <u>Appendix B</u> to this agreement, and which the Lessee leases from the Lessor pursuant to the amendment and supplemental agreement (hereinafter: "the Additional Area");

- (f) 70 square meters (gross) on the 6th floor of the building's New Wing, as outlined in color and marked with the letter "F" on the blueprint attached as <u>Appendix B</u> to this agreement (hereinafter: "the Optional Area"), and which the Lessee leases from the Lessor pursuant to section 4(a) of the amendment and supplemental agreement, and subject to the following provisions of this agreement relating to the size of the optional area;
- (g) 67.5 square meters (gross) on the 6th floor of the building's New Wing, which are designated for storage only, as outlined in color and marked with the letter "G" and with the word "Storeroom" on the blueprint attached as <u>Appendix B</u> to this agreement (hereinafter: "the Storeroom Area"), and which the Lessee leases from the Lessor pursuant to the parties' verbal agreement and subject to all the provisions and terms of this agreement; it is hereby noted that subject to the provisions and terms of section 4 below, the Lessee will in actuality pay for an area of only 40 square meters (gross) with regard to the storeroom area, despite the fact that in actuality the Lessee will use all of the storeroom area as described above in this section 2(g);
- 3. It is hereby noted that the Lessee has, since November 11, 2007, exercised its right of first refusal regarding the leasing of the Optional Area in the building a right granted to the Lessee in section 4 of the amendment and supplemental agreement and that on November 11, 2007, possession of the Optional Area was transferred to the Lessee. It is noted that pursuant to the amendment and supplemental agreement, the size of the Optional Area is 75 square meters (gross), and that nevertheless, the parties hereby agree that the area of the Optional Area is in actuality 70 square meters (gross) and that it is therefore hereby agreed that beginning on December 1, 2008, and from this date forward only, the area of the Optional Area will be updated so that it is 70 square meters (gross) (and not as stated in the amendment and supplemental agreement), and that this agreed area (70 square meters (gross)) is final and may not be disputed.

(a) It is hereby agreed that the Lessee is leasing the storeroom area from the Lessor and 2 of the double parking spaces included in the leased premises as defined above in the preamble to this agreement (hereinafter, together: "the Storeroom and the Additional Double Parking Spaces"), beginning on April 1, 2008, and that beginning on the said date, the storeroom and the additional parking spaces will be automatically added to the definition of the leased premises pursuant to the main agreement and pursuant to the amendment and supplemental agreement (hereinafter, together: "the Agreements"), [and that they] constitute an integral part of the leased premises and that they are leased to the Lessee for the entire duration of the lease as stated in the agreements and in this agreement, for all intents and purposes.

4.

(b) The storeroom area was delivered to the Lessee on the delivery date described above in this section 4, on an "as is" basis with regard to the said date – i.e., in shell condition and including only storeroom lighting. The Lessee may, at its expense only and subject to the provisions and terms of the agreements with regard to the execution of work and/or modifications (including section 14 of the main agreement), carry out any additional work in the storeroom area, as it requires in order to adapt the storeroom to its needs. To remove all doubt, it is noted that notwithstanding any other provision, the Lessor has not in any event paid and/or participated and will not pay and/or participate in any cost whatsoever in connection with any adaptation work whatsoever in the storeroom.

- (c) The Lessee is leasing the storeroom as an area that will be used for storage purposes only.
- (d) It is agreed that the Lessee will, with regard to the leasing of the storeroom area as described above, and for the lease purpose described in section 4(c) above, pay together with and in addition to any payment imposed on the Lessee with respect to the leasing of the leased premises pursuant to the provisions of the agreements rental payments and maintenance fees (hereinafter, also: "Maintenance Fees") in a total amount of \$US 5 per square meter (gross) of the storeroom area, with the addition of all payments that the Lessee is required to pay pursuant to the agreements for leasing the leased premises pursuant to the agreements and of this agreement, including municipal real property tax. It is also agreed that subject to the leasing of the storeroom area in accordance with all of the provisions and terms of this agreement, the Lessee will pay only the rental payments and maintenance fees for an area of only 40 square meters (gross).
- (e) In addition, it is hereby expressly agreed that if the Lessee makes any use of the storeroom area or of any part thereof which is other than as described in section 4(c) above, the Lessee beginning at the time that the use is so changed will pay to the Lessor, with respect to the leasing of the entire storeroom area (i.e., for 67.50 square meters (gross)), rental payments and maintenance fees in the amount of the rental payments and maintenance fees that apply to the leasing of the New Wing Area in accordance with the agreements (instead of the rental payments and maintenance fees described in section 4(d) above).
- (f) It is also agreed that with respect to the leasing of the two additional double parking spaces (as described in section 4(a) above), the Lessee will pay to the Lessor any rental payments, management fees and all other payments imposed on the Lessee with regard to the leasing of parking spaces pursuant to the agreements– in full and in a timely manner.

- (g) At the time of the signing of this agreement, the Lessee will pay to the Lessor the rental payments and maintenance fees for the leasing of the storeroom and the additional double parking spaces, as described above, for the lease period from April 1 2008 through December 31, 2008. It is also agreed that beginning on January 1, 2009, payment of the rental payments and maintenance fees for the storeroom and the additional double parking spaces will be added to payment of the rental payments for the other areas and parking spaces in the leased premises, on the first day of each calendar quarter, as provided in the agreements.
- (h) It is noted that the Lessee is required to purchase and expand the insurance policies that are required pursuant to the agreements, such that they will apply to all of the area of the leased premises, including the storeroom and the additional double parking spaces.
- 5. In order to remove doubt, it is hereby noted that the Lessee has exercised in full any right of [first] refusal and/or option to rent Additional Areas and/or parking spaces which were granted to it pursuant to the agreements, and that the Lessee has no additional right of first refusal or option for the rental of any Additional Areas whatsoever and/or of any additional parking spaces whatsoever in the building.
- 6. The parties hereby agree regarding the Lessee's having exercised the first extension period, as provided in the amendment and supplemental agreement, such that the leasing of the entire leased premises will be extended for a period commencing on December 16, 2008 and concluding on December 15, 2010 (hereinafter: "the First Extension Period.")

During the first extension period, the Lessee will pay to the Lessor the rental payments in accordance with all provisions of the agreements and of this agreement (hereinafter, together: "the Lease Agreement") and any other payments imposed on the Lessee pursuant to the lease agreement in connection with the leasing of the leased premises, including maintenance fees, municipal property taxes and electricity.

7. Additionally, at the time of the signing of this agreement, the Lessee will give the Lessor a written confirmation from the bank regarding the extension of the collateral (the bank guarantees) which had been delivered to the Lessor with regard to the leasing of the leased premises, such extension to be through March 15, 2011, and by one month prior to the commencement of the first extension period, the Lessee will give the Lessor a written confirmation from the Lessee's insurance company regarding the expansion, renewal and extension of the various insurance policies that the Lessee undertook to arrange as provided in section 17 of the main agreement, for the first extension period and with regard to the entire leased premises.

It is also hereby noted that beginning on January 1, 2009, the invoice that the Lessor will issue to the Lessee with regard to the payment of the rental payments will consolidate the account for the 1,669 square meters (gross) of the leased premises' area – i.e., the account for the leased premises' area excluding the Machinery Area, the Storeroom Area, and the Gallery Area in the leased premises.

8. The other provisions of the agreements remain unchanged. The parties expressly agree that during the current lease period and the first extension period, the agreements and all of their provisions will continue to apply to the parties and to the leasing of the leased premises, with the necessary changes, and subject to all the terms and provisions of this agreement.

(-)

Kapps-Pharma Ltd.. Partnership

# /s/ YURI SHOSHAN /s/ MORRIS LASTER

Bioline Innovations Jerusalem, Limited

By its general partner, Bioline Innovations Jerusalem Ltd.

I the undersigned Tal Lecker, attorney for the Lessee Bioline Innovations Jerusalem, Limited Partnership, hereby confirm that Mr. Yuri Shoshan and Mr. Aharon Schwartz and Mr. Morris Laster have signed this agreement in the name of the Lessee and that they are authorized to sign the agreement and that their signature of the agreement binds the Lessee for all matters and purposes.

## /s/ TAL LECKER

Attorney

Tal Lecker Yigal Arnon & Co. Rivlin Street 22, Jerusalem License No. 39931

Bioline Innovations Jerusalem Limited Partnership By its general partner, Bioline Innovations Jerusalem Ltd.

## AMENDMENT TO EMPLOYMENT AGREEMENT

This Amendment to Employment Agreement (the "**Amendment**"), dated as of January 2, 2010 is made between **BioLineRx Ltd.**, which has a place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel ("**BioLine**") and **Dr. Kinneret Savitsky** with an address at 44 Metudela Street, Tel Aviv 69867 (the "**Employee**").

WHEREAS, the Employee and BioLine Innovations Jerusalem, L.P., a limited partnership controlled by BioLine ("**BIJ**") have entered into a certain Engagement Offer dated October 13, 2004 (collectively the "**Employment Agreement**"), which Employment Agreement replaced the previous Engagement Offer entered into between BioLine and the Employee, dated May 6, 2004; WHEREAS, the Employee has been appointed by the Board of Directors of BioLine as Chief Executive Officer of BioLine, effective as of January 2, 2010; and

WHEREAS, as a result of the nomination the parties wish to amend certain provisions in the Employment Agreement.

NOW THEREFORE, the parties hereby agree as follows:

- 1. The Employee shall be promoted to the position of Chief Executive Officer of BioLine commencing on January 2, 2010. Consequently, the Employment Agreement shall be amended such that the Employee shall be employed by BioLine, instead of by the General Partner of BIJ, and any reference in the Employment Agreement to the term "Management Company" shall be replaced with the term "BioLine". Except as explicitly set forth below, the change in the entity employing Employee shall not in any way derogate from Employee's rights in connection with Employee's employment by BIJ until January 2, 2010 and any such rights shall continue to accumulate with Employee's employment by BioLine.
- 2. The preamble to the Employment Agreement shall be deleted in its entirety and replaced with the following language: "This letter agreement (this "Agreement") sets forth the terms and conditions concerning your employment by BioLineRx Ltd. ("BioLine"). Should you accept the terms and conditions of this Agreement it shall constitute a binding agreement by and between BioLine and yourself."
- 3. Section 9 of the Employment Agreement shall be deleted in its entirety and replaced with the following language: "BioLine shall pay or cause to be paid to the Employee during the term of this Agreement a gross salary in the amount of seventy thousand New Israeli Shekels (NIS 70,000 per month (the "Salary"). The Salary will be paid no later then the 9<sup>th</sup> day of each calendar month after the month for which the Salary is paid, after deduction of any and all taxes and charges applicable to Employee, as may be in effect or which may hereafter be enacted or required by law. Employee shall notify BioLine of any change which may affect Employee's tax liability."
- 4. Section 12 of the Employment Agreement shall be deleted in its entirety and replaced with the following language: "<u>Vacation</u>. During the term of the employment, Employee shall be entitled to vacation in the number of twenty (20) working days per year, as adjusted in accordance with applicable law. A "working day" shall mean Sunday to Thursday inclusive, and the use of said vacation days will be coordinated with BioLine. Employee shall be entitled to accumulation and redemption of vacation days in accordance with BioLine's employees' handbook, which may be amended from time to time in BioLine's sole discretion."

- 5. Section 14 of the Employment Agreement shall be deleted in its entirety and replaced with the following language "In addition to any previous grant of options to Employee, and subject to the approval of the BioLine Board of Directors, Employee shall be granted five hundred thousand (500,000) options to purchase Ordinary Shares par value NIS 0.01 each of BioLine, to be granted pursuant to, and in accordance with, the terms and conditions of the share option plan adopted by BioLine."
- Section 15 of the Employment Agreement shall be deleted in its entirety and replaced with the following language: "Automobile. For purposes of 6. performance of Employee's duties and tasks, and during the Employment Period, BioLine shall make available to Employee a company vehicle, leased or owned by BioLine of a type to be elected by BioLine, in accordance with its policies which may be amended from time to time (the "Company Car"). Employee shall use the Company Car in accordance with BioLine's car policy then in effect, as well as the requirements of the leasing company and the insurance company. BioLine shall bear the cost of maintenance and repairs, and any insurance deductibles for the Company Car, in accordance with its policies and the Car Agreement which will be signed between Employee and BioLine. Employee shall be liable for paying for fuel, as well as any parking and/or traffic fines received in connection herewith, and for any damages and expenses in case of negligent use of the Company Car and/or use of the Company Car not in accordance with BioLine's applicable policies. All taxes arising out of the use of the Company Car shall be borne by Employee, and Employee acknowledges that such taxes will be withheld from Employee's salary as required by law. Employee further acknowledges that the tax treatment of the benefit through use of the Company Car is subject to change, and any economic impact resulting from such changes will be in Employee's sole responsibility. For the avoidance of doubt, Employee agrees and confirms that the cost of the leasing and/or the cost of the use of the Company Car shall not constitute a component of Employee's Salary, including with regard to social benefits and/or any other right to which Employee is entitled by virtue of this Agreement or under law. The Employee shall be required to follow rules and regulations as to the usage of the Company Car as described in the "Company Car Lease Agreement" or "Car Addendum" provided to the Employee prior to receipt of the Company Car. The Company Car will remain in BioLine's ownership, and will be returned to BioLine immediately upon termination of Employee's employment with BioLine for any reason, as of the date of termination. The Employee shall not be entitled to use a Company Car during unpaid leaves or absences, unless specifically approved by BioLine in writing."
- 7. Except as explicitly set forth in this Amendment, the terms of the Employment Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their duly authorized representatives as of the date first written above.

## BioLineRx Ltd.

By:	/s/ Philip Serlin	
Name:	PHILIP SERLIN	_
Title:	Chief Financial Officer	

## **Dr. Kinneret Savitsky**

By:	/s/ Kinneret Savitsky	
Name:	KINNERET SAVITSKY	



19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel

January 27, 2005

Dr. Leah Klapper 11 Shapira Street Apartment #38 Ramat-Gan, 52506

Dear Dr. Klapper,

## Re: <u>Engagement Offer</u>

Further to our discussions, we are pleased to offer you employment with us under the following terms and conditions.

By signing this letter you indicate your acceptance of the offer, thus turning this letter into a binding employment contract between you and us (this "**Agreement**"). For purposes of convenience, BioLine Innovations Jerusalem, L.P. will be called in this letter "BIJ" or "we" and you will be called the "Employee" or "you".

## General

1. <u>Position</u>. You shall serve in the position described in <u>Exhibit A</u>. In such position you shall report regularly to, and be subject to the direction and control of, BIJ's General Manager. You shall perform your duties diligently, conscientiously and in furtherance of BIJ's best interests. You agree and undertake to inform BIJ, immediately after you become aware of it, of any matter that may in any way raise a conflict of interest between yourself and BIJ. You shall not receive during your employment by BIJ any payment, compensation or benefit from any third party in connection, directly or indirectly, with the execution of your position in BIJ.

2. <u>Full Time Employment</u>. You will be employed on a full time basis. You shall devote your entire business time and attention to the business of BIJ and you shall not undertake or accept any other paid or unpaid employment or occupation or engage in any other business activity except with the prior written consent of BIJ, which shall not be unreasonably withheld. You confirm and declare that your position is one that requires a special measure of personal trust and loyalty. Accordingly, the provisions of the Hours of Work and Rest Law-1951 shall not apply to you and you shall not be entitled to any compensation for working more than the maximum number of hours per week set forth in said law or any other applicable.

3. <u>Location</u>. You shall perform your duties hereunder at BIJ's facilities in Jerusalem, Israel, but you understand and agree that your position may involve domestic and international travel.

4. <u>Employee's Representations and Warranties</u>. You represent and warrant that the execution and delivery of this Agreement and the fulfillment of all its terms: (i) will not constitute a default under or conflict with any agreement or other instrument to which you are a party to or by which you are bound; and (ii) do not require the consent of any person or entity. Further, with respect to any past engagement you may have had with third parties and with respect to any allowed engagement you may have with any third party "**Other Employers**"), you represent, warrant and undertake that: (a) your engagement with BIJ is and/or will not be in breach of your undertakings towards Other Employers, and (b) you will not disclose to BIJ, or use, in provision of any services to BIJ, any proprietary or confidential information belonging to any Other Employers.

## Term of Employment

5. <u>Term.</u> Your employment by BIJ shall be deemed to have commenced on the date set forth in <u>Exhibit A</u> (the "Commencement Date") and shall continue until it is terminated pursuant to the terms set forth herein.

6. <u>Termination at Will</u>. Either party may terminate the employment relationship hereunder at any time by giving the other party a prior written notice as set forth in **Exhibit A** (the "**Notice Period**").

7. <u>Termination for Cause</u>. In the event of a termination for Cause (as defined below), BIJ may immediately terminate the employment relationship effective as of the time of written notice of the same. "**Cause**" means (a) a serious breach of trust including but not limited to theft, embezzlement, self-dealing, prohibited disclosure to unauthorized persons or entities of confidential or proprietary information of or relating to BIJ and the engaging by yourself in any prohibited business competitive to the business of BIJ; or (b) any willful failure to perform or failure to perform competently any of your fundamental functions or duties hereunder, which was not cured within thirty (30) days after receipt by you of written notice thereof, or (c) other cause justifying termination or dismissal without severance payment under applicable law.

8. <u>Notice Period; End of Relations</u>. During the Notice Period, the employment relationship hereunder shall remain in full force and effect and there shall be no change in your position with BIJ, in your Salary and all other benefits to which you are entitled, or in any other obligations of either party hereunder, and you shall cooperate with BIJ and assist BIJ with the integration into BIJ of the person who will assume your responsibilities. However, BIJ, at its own discretion, may terminate this Agreement and the employment relationship at any time immediately upon a written notice and pay you a one time amount equal to the Salary and the benefits referred to in Section 11 that would have been paid to you during the Notice Period in lieu of the prior notice.

## **Covenants**

9. <u>Proprietary Information; Confidentiality and Non-Competition</u>. By executing this Agreement you confirm and agree to the provisions of BIJ's Proprietary Information, Confidentiality and Non-Competition Agreement attached in <u>Exhibit B</u> hereto.

## Salary; Insurance; Advanced Study Fund

10. <u>Salary</u>. BIJ shall pay to you as compensation for the employment services, an aggregate monthly compensation in the amount set forth in <u>Exhibit</u> <u>A</u> (the "Salary"). Except as specifically set forth herein, the Salary includes any and all payments to which you are entitled from BIJ hereunder and under any applicable law, regulation or agreement. The Salary includes any and all reimbursement of daily travel costs to which you are entitled under applicable law, and any and all other payments to which you are entitled from BIJ hereunder and under terms of employment shall be reviewed by BIJ's management at least once a year, and may be updated at the discretion of BIJ's management. The Salary is to be paid to you no later then the 5<sup>th</sup> day of each calendar month after the month for which the Salary is paid after deduction of applicable taxes and the like payments.

11. <u>Insurance and Social Benefits</u>. BIJ will insure you under an "Manager's Insurance Scheme" to be selected by BIJ in coordination with you; or if so requested by you under your existing "Manager's Insurance Scheme" (the "**Insurance Scheme**") as follows: (i) BIJ will pay an amount equal to 5% of the Salary towards a fund for life insurance and pension, and shall deduct 5% from the Salary and pay such amount towards the Insurance Scheme for your benefit; (ii) BIJ will pay an amount of up to 2.5% of the Salary towards a fund for the event of loss of working ability (Ovdan Kosher Avoda); and (iii) BIJ will pay an amount equal to 8 1/3% of the Salary towards a fund for severance compensation.

BIJ together with you will maintain an advanced study fund (Keren Hishtalmut Fund) such that you and BIJ shall contribute to such fund an amount equal to 2.5% and 7.5%, respectively, up to the relevant tax exempt ceiling. Your aforementioned contribution is to be transferred to such fund by BIJ from each monthly Salary payment.

All amounts paid by BIJ in accordance with this Section will be transferred to you, and all title and rights in the Insurance Scheme shall be assigned to you, upon the termination of your employment in any circumstances other than in case of termination of your employment for Cause, and the same shall constitute the full and only compensation to be paid by BIJ to you in such circumstances.

The agreement set forth in this provision is in accordance with Section 14 of the Severance Compensation Law, 1963, and in accordance with the general approval of the Labor Minister, promulgated under said Section 14, regarding employer's payment to pension fund and insurance fund in lieu of severance pay pursuant to Section 14 of the Severance Compensation Law, 1963; a copy of which is attached hereby as **Exhibit C**, which Schedule shall be signed by both parties to this Agreement.

### **Additional Benefits**

12. <u>Expenses</u>. BIJ will reimburse you for pre approved by your superior, business expenses borne by you, in accordance with BIJ's policies as determined by BIJ from time to time. As a condition to reimbursement, you shall be required to provide BIJ with all invoices, receipts and other evidence of expenditure as may be reasonably required by BIJ from time to time.

13. <u>Vacation</u>. You shall be entitled to that number of vacation days per year as set forth in **Exhibit A**, and the use of said vacation days will be coordinated with BIJ. In the event that the demands of your activities preclude or limit your ability to actually use such vacation days in any year, you shall be entitled to the balance of the unused vacation only in the next succeeding year or, if unable to take the balance in that next succeeding year, to receive an amount equal to the rate of Salary then applicable to the vacation time not taken during such year.

14. <u>Sick Leave; Recreation Pay</u>. You shall be entitled to full paid sick leave and Recreation Pay (Dmei Havra'a) pursuant to applicable law and according to BIJ's policy.

15. <u>Options</u>. You shall be granted options to purchase Ordinary Shares par value NIS 0.01 each of BioLineRx Ltd., a limited partner of BIJLP ("**BioLineRx**"), in the amount set forth in **Exhibit A**, to be granted pursuant to, and in accordance with, the terms and conditions of the share option plan adopted by the Company (the "**Options**").

16. <u>Automobile</u>. For purposes of performance of your duties and tasks, BIJ shall make available to you a leased automatic automobile, of a type to be elected by BIJ, in accordance with its policies (e.g., Mazda 3, Toyota Corolla) (the "**Leased Car**"). BIJ shall bear and pay for the cost of fuel, maintenance and repairs, and any insurance deductibles for the Leased Car, in accordance with its policies. You shall be liable for paying any parking and/or traffic fines received in connection herewith, and for indemnification of BIJ in case of negligent use of the Leased Car and/or use of the Leased Car not in accordance with BIJ's applicable policies. For the avoidance of doubt, you agree and confirm that the cost of the leasing and/or the cost of the use of the Leased Car shall not constitute a component of your Salary, including with regard to social benefits and/or any other right to which you are entitled by virtue of this Agreement or under law. The Leased Car will remain in BIJ's ownership, and will be returned to BIJ by you at the end of the Notice Period upon termination of your employment with BIJ for any reason, if and as of the date on which your services are no longer required by BIJ.

## **Miscellaneous**

17. The laws of the State of Israel shall apply to this Agreement and the sole and exclusive place of jurisdiction in any matter arising out of or in connection with this Agreement shall be the Tel-Aviv Regional Labor Court; the provisions of this Agreement are in lieu of the provisions of any collective bargaining agreement, and therefore, no collective bargaining agreement shall apply with respect to the relationship between the parties hereto (subject to the applicable provisions of law); no failure, delay of forbearance of either party in exercising any power or right hereunder shall in any way restrict or diminish such party's rights and powers under this Agreement, or operate as a waiver of any breach or nonperformance by either party of any terms of conditions hereof; in the event it shall be determined under any applicable law that a certain provision set forth in this Agreement is invalid or unenforceable, such determination shall not affect the remaining provisions of this Agreement unless the business purpose of this Agreement is substantially frustrated thereby; this Agreement constitutes the entire understanding and agreement between the parties hereto, supersedes any and all prior discussions, agreements and correspondence with regard to the subject matter hereof, and may not be amended, modified or supplemented in any respect, except by a subsequent writing executed by both parties hereto; you acknowledge and confirm that all terms of your employment are personal and confidential, and undertake to keep such term in confidence and refrain from disclosing such terms to any third party.

Please indicate your acceptance to the terms of this letter by signing and dating them and returning a counterpart hereof to us. BIJ's signature on this letter will bind BIJ only if coupled with your signature.

Sincerely yours,

BioLine Innovations Jerusalem, L.P. By its General Partner, BioLine Innovations Jerusalem Ltd.

By:/s/ Yuri Shoshan

Title: Yuri Shoshan, Director

I, the undersigned, Leah Klapper hereby agree to all terms of this letter, and in witness hereof have signed this letter on this date of 17/2, 2005.

Signature: <u>/s/ Leah Klapper</u>

# Exhibit A To Personal Employment Agreement by and between BioLine Innovations Jerusalem, L.P. and the Employee whose name is set forth herein

1.	Name of Employee:	Leah Klapper
2.	ID No. of Employee:	069474898
3. Address of Employee:		11 Shapira Street, Apartment #38, Ramat-Gan, 52506
4. Position in BIJ:		Vice President of Pre-Clinical Development
5.	Commencement Date:	January 1, 2005
6.	Notice Period:	30 days
7.	Salary:	NIS 25,000 (Gross)
8.	Options	50,000 options. For the avoidance of doubt, the aforementioned number of options has already been promised to you by BioLineRx directly pursuant to a past employment agreement with BioLineRx, and this <b>DOES NOT</b> constitute an additional promise of options.
9.	Vacation Days Per Year:	21 days

## Exhibit B To Personal Employment Agreement by and between BioLine Innovations Jerusalem, L.P. and the Employee whose name is set forth herein

Name of Employee: Leah Klapper

ID No. of Employee: 069474898

## 1. General

All the capitalized terms herein shall have the meanings ascribed to them in the Letter of Agreement to which this Exhibit is attached (the "**Agreement**"). For purposes of any undertaking of the Employee toward BIJ, the term BIJ shall specifically include BioLineRX Ltd., BioLine Innovations Jerusalem Ltd. and any and all subsidiaries and affiliates of BIJ.

The Employee's obligations and representations and BIJ's rights under this Exhibit shall apply as of the Commencement Date of the employment relationship between BIJ and the Employee, and as of the first time the Employee became engaged with BIJ, regardless of the date of execution of the Agreement.

## 2. Confidentiality; Proprietary Information

2.1 **"Proprietary Information"** means confidential and proprietary information concerning the business and financial activities of BIJ, including patents, patent applications, trademarks, copyrights and other intellectual property, and information relating to the same, technologies and products (actual or planned), know how, inventions, research and development activities, trade secrets and industrial secrets, and also confidential commercial information such as investments, investors, employees, customers, suppliers, marketing plans, etc., all the above - whether documentary, written, oral or computer generated. Proprietary Information shall also include information of the same nature which BIJ may obtain or receive from third parties.

2.2. Proprietary Information shall be deemed to include any and all proprietary information disclosed by or on behalf of BIJ and irrespective of form but excluding information that (i) was known to Employee prior to Employee's association with BIJ and can be so proven; (ii) is or shall become part of the public knowledge except as a result of the breach of the Agreement or this Exhibit by the Employee; (iii) reflects general skills and experience gained during Employee's engagement by BIJ; or (iv) reflects information and data generally known in the industries or trades in which BIJ operates.

2.3. Employee recognizes that BIJ received and will receive confidential or proprietary information from third parties (specifically including the entities referred to in Section 1 above), subject to a duty on BIJ's part to maintain the confidentiality of such information and to use it only for certain limited purposes. In connection with such duties, such information shall be deemed Proprietary Information hereunder, *mutatis mutandis*.

2.4 Employee agrees that all Proprietary Information, and patents, trademarks, copyrights and other intellectual property and ownership rights in connection therewith shall be the sole property of BIJ and its assigns. At all times, both during Employee's engagement by BIJ and after Employee's termination, Employee will keep in confidence and trust all Proprietary Information, and the Employee will not use or disclose any Proprietary Information or anything relating to it without the written consent of BIJ, except as may be necessary in the ordinary course of performing Employee's duties under the Agreement. 2.5. Upon termination of Employee's employment with BIJ, Employee will promptly deliver to BIJ all documents and materials of any nature pertaining to Employee's work with BIJ, and will not take with Employee any documents or materials or copies thereof containing any Proprietary Information.

2.6. Employee's undertakings set forth in this Section 2 shall remain in full force and effect after termination of this Agreement or any renewal thereof.

## 3. Disclosure and Assignment of Inventions

3.1. **"Inventions**" means any and all inventions, improvements, designs, concepts, techniques, methods, systems, processes, know how, computer software programs, databases, mask works and trade secrets, whether or not patentable, copyrightable or protectible as trade secrets; **"BIJ Inventions**" means any Inventions that are made or conceived or first reduced to practice or created by Employee, whether alone or jointly with others, during the period of Employee's employment with BIJ, and which: (i) are developed using equipment, supplies, facilities or Proprietary Information of BIJ, (ii) result from work performed by Employee for BIJ, or (iii) related to the field of business of BIJ, or to specific fields of research and development undertake by BIJ.

3.2. Employee undertakes and covenants that Employee will promptly disclose in confidence to BIJ all Inventions deemed as BIJ Inventions.

3.3. Employee hereby irrevocably transfers and assigns to BIJ all worldwide patents, patent applications, copyrights, mask works, trade secrets and other intellectual property rights in any BIJ Invention, and any and all moral rights that Employee may have in or with respect to any BIJ Invention.

3.4. Employee agrees to assist BIJ, at BIJ's expense, in every proper way to obtain for BIJ and enforce patents, copyrights, mask work rights, and other legal protections for BIJ Inventions in any and all countries. Employee will execute any documents that BIJ may reasonably request for use in obtaining or enforcing such patents, copyrights, mask work rights, trade secrets and other legal protections. Such obligation shall continue beyond the termination of Employee's employment with BIJ. Employee hereby irrevocably designates and appoints BIJ and its authorized officers and agents as Employee's agent and attorney in fact, coupled with an interest to act for and on Employee's behalf and in Employee's stead to execute and file any document needed to apply for or prosecute any patent, copyright, trademark, trade secret, any applications regarding same or any other right or protection relating to any Proprietary Information (including BIJ Inventions), and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights, trademarks, trade secrets or any other right or protection relating to any Proprietary Information (including BIJ Inventions), with the same legal force and effect as if executed by Employee himself.

## 4. <u>Non-Competition</u>

4.1. In consideration of Employee's terms of employment, which include special compensation for Employee's undertakings under this Section 4, and in order to enable BIJ to effectively protect its Proprietary Information, Employee agrees and undertakes that she will not, so long as she is employed by BIJ and for a period of 12 months following termination of his employment for whatever reason, directly or indirectly, be engaged in, or employed by, any business or venture that is engaged in any activities competing with BIJ and its business activities in which Employee was involved, or by providing products or services substantially similar to products or services offered by BIJ; provided, however, that Employee may own securities of any corporation which is engaged in such business and is publicly owned and traded but in an amount not to exceed at any one time one percent (1%) of any class of stock or securities of such corporation, and so long as Employee has no active role in such corporation as director, employee, consultant or otherwise.

4.2. Employee agrees and undertakes that during the period of Employee's employment and for a period of twelve (12) months following termination of his employment for whatever reason, Employee will not, directly or indirectly, including personally or in any business in which Employee may be an officer, director or shareholder, solicit for employment any person who is employed by BIJ, or retained by BIJ as a consultant, advisor or the like service provider (collectively, "**Consultant**"), if such Consultant is prevented thereby from continuing to render its services to BIJ, on the date of such termination or during the preceding twelve (12) months.

## 5. Reasonableness of Protective Covenants

Insofar as the protective covenants set forth in this Agreement are concerned, Employee specifically acknowledges, stipulates and agrees as follows: (i) the protective covenants are reasonable and necessary to protect the goodwill, property and Proprietary Information of BIJ, and the operations and business of BIJ; and (ii) the time duration of the protective covenants is reasonable and necessary to protect the goodwill and the operations and business of BIJ, and does not impose a greater restrain than is necessary to protect the goodwill or other business interests of BIJ. Nevertheless, if any of the restrictions set forth in this Exhibit is found by a court having jurisdiction to be unreasonable or overly-broad as to geographic area, scope or time or to be otherwise unenforceable, the parties intend for the restrictions set forth in this Exhibit to be reformed, modified and redefined by such court so as to be reasonable and enforceable and, as so modified by such court, to be fully enforced.

### 6. **<u>Remedies for Breach</u>**

Employee acknowledges that the legal remedies for breach of the provisions of this Exhibit may be found inadequate and therefore agrees that, in addition to all of the remedies available to BIJ in the event of a breach or a threatened breach of any of such provisions, BIJ may also, in addition to any other remedies which may be available under applicable law, obtain temporary, preliminary and permanent injunctions against any and all such actions.

#### 7. Intent of Parties

Employee recognizes and agrees that: (i) this Exhibit is necessary and essential to protect the business of BIJ and to realize and derive all the benefits, rights and expectations of conducting BIJ's business; (ii) the area and duration of the protective covenants contained herein are in all things reasonable; and (iii) good and valuable consideration exists under the Agreement, for Employee's agreement to be bound by the provisions of this Exhibit.

## TRANSLATION FROM HEBREW

## Exhibit C

## To Personal Employment Agreement by and between BioLine Innovations Jerusalem, L.P. and the Employee whose name is set forth herein.

#### Agreement under Section 14 of the Severance Pay Law

I, the undersigned, hereby confirm that I agree to incorporate the terms and conditions detailed in the foregoing regarding only ongoing payments of the employee to the insurance fund (Managers Insurance) for an allowance and/or severance fund, as published in the Official Announcement Gazette of the State of Israel 4659 on June 30, 1998, on page 4394 (Last Amended as — Official Announcement Gazette of the State of Israel 4970, on 1949):

By virtue of my power under Section 14 of the Severance Pay Law, 5723-1963 (hereinafter: the "Law"), I certify that payments made by an employer commencing from the date of the publication of this approval for the sake of his employee to a comprehensive pension provident fund that is not an insurance fund within the meaning set forth in the Income Tax Regulations (Rules for the Approval and Conduct of Provident Funds), 5724-1964 (hereinafter: the "Pension Fund") or to managers' insurance which includes the possibility to receive annuity payments under an insurance fund as aforesaid, (hereinafter: the "Insurance Fund"), including payments made by the employer by a combination of payments to a Pension Fund and an Insurance Fund (hereinafter: "Employer's Payments"), shall be made in lieu of severance pay due to said employee with respect to the salary from which said payments were made and for the period they were paid (hereinafter: the "Exempt Salary"), provided that all the following conditions are fulfilled:

(1) The Employer's Payments –

(a) to the Pension Fund are not less than  $14\frac{1}{3}\%$  of the Exempt Salary or 12% of the Exempt Salary if the employer pays, for the sake of his employee, in addition thereto, payments to supplement severance pay to a severance pay provident fund or to an Insurance Fund in the employee's name, in the amount of  $2\frac{1}{3}\%$  of the Exempt Salary. In the event that the employer has not paid the above mentioned  $2\frac{1}{3}\%$  in addition to said 12%, his payments shall come in lieu of only 72% of the employee's severance pay;

(b) to the Insurance Fund are not less than one of the following:

(i) 13<sup>1</sup>/<sub>3</sub>% of the Exempt Salary, provided that, in addition thereto, the employer pays, for the sake of his employee, payments to secure monthly income in the event of disability, in a plan approved by the Commissioner of the Capital Market, Insurance and Savings Department of the Ministry of Finance, in an amount equivalent to the lower of either an amount required to secure at least 75% of the Exempt Salary or in an amount of 2<sup>1</sup>/<sub>2</sub>% of the Exempt Salary (hereinafter: "Disability Insurance Payment");

(ii) 11% of the Exempt Salary, if the employer paid, in addition, the Disability Insurance Payment; and in such case, the Employer's Payments shall come in lieu of only 72% of the employee's severance pay. In the event that the employer has made payments in the employee's name, in addition to the foregoing payments, to a severance pay provident fund or to an Insurance Fund in the employee's name, to supplement severance pay in an amount of 2<sup>1</sup>/<sub>3</sub>% of the Exempt Salary, the Employer's Payments shall come in lieu of 100% of the employee's severance pay.

(2) No later than three months from the commencement of the Employer's Payment, a written agreement was executed between the employer and the employee, which includes:

(a) the employee's consent to an arrangement pursuant to this approval, in an agreement specifying the Employer's Payments, the Pension Fund and the Insurance Fund, as the case may be; said agreement shall also incorporate the text of this approval;

(b) an advance waiver by the employer of any right which he may have to a refund of monies from his payments, except in cases in which the employee's right to severance pay was denied by a final judgment pursuant to Section 17 of the Law, and in such a case or in cases in which the employee withdrew monies from the Pension Fund or Insurance Fund, other than by reason of an entitling event; for these purposes an "Entitling Event" means death, disability or retirement at or after the age of 60.

#### -10-

(3) This approval shall not derogate from the employee's right to severance pay pursuant to any law, collective agreement, extension order or employment agreement with respect to compensation in excess of the Exempt Salary.

15th Sivan 5758 (June 9th, 1998).

Dr. Leah Klapper 11 Shapira St. Apartment #38 Ramat-Gan, 52506

Dear Dr. Klapper,

## Re: <u>Engagement with BioLine Innovations Jerusalem, L.P.</u>

Further to our discussions, this is to set forth in writing our agreement with respect to the termination of your employment with BioLineRx Ltd. ("BLRX") and your engagement with BioLine Innovations Jerusalem, L.P. ("BIJLP"), a limited partnership in which BLRX is a limited partner.

1. Your employment with BLRX pursuant to the employment agreement between BLRX and yourself, a copy of which is attached as <u>Schedule A</u> to this letter agreement (the "**BLRX Employment Agreement**") shall terminate as of the date of December 31, 2004 (the "**Effective Date**"), and immediately as of such date you shall commence employment with BIJLP, in accordance with the terms and conditions set forth in the employment agreement between BIJLP and yourself, a copy of which is attached as <u>Schedule B</u> to this letter agreement (the "**BIJLP Employment Agreement**").

BIJLP takes upon itself all rights accrued to your benefit during the term of your employment with BLRX, as if, with respect to such rights, you were employed with BIJLP as of the date on which you commenced employment with BLRX.

2. You agree and confirm that no prior notice and Notice Period (as such term is defined in the BLRX Employment Agreement) are due, since you are immediately continuing your employment with BIJLP.

3. As of the Effective Date, BLRX shall take all required action in order to transfer the Insurance Scheme referred to in Section 11 of the BLRX Employment Agreement to BIJLP, and BIJLP shall continue all payments related to such Insurance Scheme in accordance with Section 11 of the BIJLP Employment Agreement.

4. As of the Effective Date, BLRX shall take all required action in order to transfer the advanced study fund referred to in Section 11 of the BLRX Employment Agreement to BIJLP, and BIJLP shall continue all contributions related to such advanced study fund in accordance with Section 11 of the BIJLP Employment Agreement.

5. You shall continue to be entitled to all options granted to you in accordance with the provisions of Section 15 of the BLRX Employment Agreement, in accordance with the provisions of Section 15 of the BIJLP Employment Agreement. For the avoidance of any doubt, the number of options specified in the BIJLP Employment Agreement refers and relates to the number of options granted to you under and pursuant to the BLRX Employment Agreement, and **DOES NOT** constitute an additional grant of options.

6. You shall continue to be entitled to the Leased Car made available to you pursuant to Section 16 of the BLRX Employment Agreement, at the responsibility of BIJLP.

7. You agree and confirm that you shall continue to be bound by the provisions of BLRX's Proprietary Information, Confidentiality and Non-Competition Agreement attached in Exhibit B to the BLRX Employment Agreement, which provisions shall continue to apply in accordance with their terms.

8. On the Effective Date, you shall return to BLRX all property, assets and materials of BLRX which are in your possession, as well as any and all documents, files, records, memoranda, computer hardware and software, and all other property or information provided by BLRX, and you shall not retain any BLRX property.

9. By signing below, you shall represent and warrant that upon the performance of the BLRX's undertakings set forth above, you shall have been paid in full all payments owed to you due to your employment with BLRX, in accordance with the BLRX Employment Agreement and/or in accordance with the provisions of any collective agreement, and/or any statute, and/or regulation applicable to her, including but not limited to employment wages, supplements to wages, additional hours, grants, vacation redemption, recreation pay, reimbursements, expenses, and any other payment in accordance with any other right, even if not specifically mentioned in this letter agreement, and you shall declare and affirm that you do not have now and will not have in the future any claims and/or prosecutions against BLRX, and its shareholders, directors, officers, managers, employees and agents, in connection with your employment with BLRX and/or its termination. Please indicate your acceptance to the terms of this letter by signing and dating them and returning a counterpart hereof to us.

Sincerely yours,

BioLineRx Ltd.

By: /s/ Yuri Shoshan

Title: Yuri Shoshan, VP Finance

BioLine Innovations Jerusalem, L.P.

By its General Partner, BioLine Innovations Jerusalem Ltd.

By: /s/ Yuri Shoshan

Title: Yuri Shoshan, Director

I, the undersigned, Leah Klapper hereby agree to all terms of this letter agreement, and in witness hereof have signed this letter agreement on this date of 17/2, 2005.

Signature: <u>/s/ Leah Klapper</u>

## CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. ASTERISKS DENOTE OMISSIONS.

## PAYMENT DATE EXTENSION AMENDMENT

Ikaria Development Subsidiary One LLC, a Delaware limited liability company having a principal place of business at 6 State Route 173, Clinton, NJ 08809, USA ("<u>Ikaria</u>"), BioLineRx Ltd., a corporation organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel ("<u>BioLineRx Ltd.</u>"), and BioLine Innovations Jerusalem L.P., a limited partnership organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel ("BioLineRx Ltd."), and BioLine Innovations Jerusalem L.P., a limited partnership organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel ("BioLine Innovations"; together with BioLineRx Ltd., "<u>BioLineRx</u>") are party to an Amended and Restated License and Commercialization Agreement dated as of the 26th day of August, 2009 (the "<u>Agreement</u>"). Any defined terms used herein shall have them meaning ascribed thereto in the Agreement.

Pursuant to <u>Section 4.1(a)</u> the Agreement, Ikaria is required to make a milestone payment to BioLineRx of USD \$10,000,000 upon the Successful Completion of the On-Going Phase I/II Trial (the "<u>Second Milestone Payment</u>") on or before [\*\*\*]. BioLine and Ikaria are currently in discussions to determine whether Ikaria is required to withhold United States federal income taxes from the Second Milestone Payment. In order to enable the parties to complete those discussions, Ikaria and BioLine hereby agree that the due date for the Second Milestone Payment is hereby extended to [\*\*\*].

Sections 10.2 ("Governing Law") and 10.3 ("Submission to Jurisdiction") of the Agreement are hereby incorporated herein by reference.

## Acknowledged, Agreed, and Confirmed

/s/ Daniel Tassé Daniel Tassé Chief Executive Officer Ikaria Development Subsidiary One LLC /s/ Kinneret Savitsky

Kinneret Savitsky, Chief Executive Officer On behalf of, and as authorized representative of, both BioLineRx Ltd. and BioLine Innovations Jerusalem L.P.

[\*\*\*] Omitted pursuant to a confidential treatment request. The confidential portion has been filed separately with the SEC.

## AMENDMENT TO THE AMENDED AND RESTATED LICENSE AND COMMERCIALIZATION AGREEMENT

This Amendment (this "<u>Amendment</u>") is entered into this 21st day of April 2010 (the "<u>Amendment Effective Date</u>") by and between **Ikaria Development Subsidiary One LLC**, a Delaware limited liability company with a place of business at 6 Route 173, Clinton, NJ, 08809 USA ("<u>Ikaria</u>"), and **BiolineRx Ltd.**, a corporation organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel ("<u>BioLineRx Ltd.</u>"), and **BioLine Innovations Jerusalem L.P.**, a limited partnership organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, P.O. Box 45158 Jerusalem 91450, Israel ("<u>BioLine Rx Ltd.</u>"). This Amendment amends the Amended and Restated License and Commercialization Agreement entered into by and between Ikaria and BioLineRx dated as of the 26th day of August 2009 (the "<u>Agreement</u>"). Any defined term used in this Amendment not expressly defined herein shall have the meaning ascribed thereto in the Agreement.

1. <u>Modification of Payee</u>. All payments to be made under the Agreement shall be made to BiolineRx Ltd. or any Third Party assignee of BioLineRx Ltd. permitted under Section 10.4 of the Agreement.

2. <u>Modification of Assignment</u>. The last two sentences of <u>Section 10.4</u> of the Agreement are hereby amended and restated as follows:

"BioLineRx Ltd. may assign its right to receive payments hereunder to a Third Party, in its sole discretion, provided that BioLineRx Ltd. provides Ikaria with prior written notice of the assignment and the name and address of the assignee. Any such Third Party assignee may not further assign the right to receive payments hereunder without providing Ikaria with prior written notice of the assignment and the name and address of the assignee. Ikaria shall maintain a written record of any such assignments. The parties intend that this Agreement shall be considered to be in "registered form" as defined in United States Treasury Regulations Section 5f.103-1(c). BiolineRx shall not otherwise be permitted to assign this Agreement, in whole or in part, without the prior written consent of Ikaria, which approval shall not be unreasonably withheld, conditioned, or delayed. Any assignment in contravention of this Section 10.4 shall be null and void."

3. <u>Ratification of Agreement</u>. Except as set forth in this Amendment, all of the other terms and conditions of the Agreement are hereby ratified and confirmed to be of full force and effect, and shall continue in full force and effect. This Amendment is hereby integrated into and made a part of the Agreement.

4. <u>Counterparts</u>. This Amendment may be executed in two or more counterparts, each of which shall be effective as of the Amendment Effective Date, and all of which shall constitute one and the same instrument. Each such counterpart shall be deemed an original, and it shall not be necessary in making proof of this Amendment to produce or account for more than one such counterpart.

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5. <u>Execution and Delivery</u>. This Amendment shall be deemed executed by the parties when any one or more counterparts hereof, individually or taken together, bears the signatures of each of the parties hereto.

## Acknowledged and Agreed to:

# **BIOLINERX LTD.**

Signature	By: /s/ Kinneret L. Savitsky
Printed Name	Kinneret L. Savitsky
Title	CEO
	April 21, 2010
Signature	By: /s/ Philip Serlin
Printed Name	Philip Serlin
Title	CFO
	April 21, 2010

## BIOLINE INNOVATIONS JERUSALEM L.P., BY ITS GENERAL PARTNER BIOLINE INNOVATIONS JERUSALEM, LTD.

Signature	By:	/s/ Kinneret L. Savitsky
Printed Name		Kinneret L. Savitsky
Title		CEO
		April 21, 2010
Signature	Bv	/s/ Philip Serlin
Printed Name	<i>Dj</i> .	Philip Serlin
Title		CFO
11110		
		April 21, 2010

## IKARIA DEVELOPMENT SUBSIDIARY ONE LLC

Signature Printed Name Title By: /s/ Matthew M. Bennett

Matthew M. Bennett Vice President and Secretary April 21, 2010

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# Subsidiaries of BioLineRx Ltd.

Entity Name	State or Country of Organization
BioLine Innovations Jerusalem Ltd.	Israel
BioLine Innovations Jerusalem Limited Partnership	Israel
BioLineRx USA, Inc.	Delaware

# CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Registration Statement on Form F-1 of our report dated March 24, 2010, relating to the financial statements of BIOLINERX LTD, which appears in such Registration Statement. We also consent to the reference to us under the headings "Experts" in such Registration Statement.

/s/ Kesselman & Kesselman

Tel Aviv, Israel September 24, 2010