

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

FORM 20-F

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2018**

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report

For the transition period from _____ to _____

Commission file number _____

BioLineRx Ltd.

(Exact name of Registrant as specified in its charter)
(Translation of Registrant's name into English)

Israel

(Jurisdiction of incorporation or organization)

**2 HaMa'ayan Street
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(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Title of each class	Name of each exchange on which registered
American Depositary Shares, each representing 1 ordinary share, par value NIS 0.10 per share	Nasdaq Capital Market
Ordinary shares, par value NIS 0.10 per share	Nasdaq Capital Market*

*Not for trading; only in connection with the registration of American Depositary Shares.

Securities registered or to be registered pursuant to Section 12(g) of the Act.

None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act.

None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report. 114,933,144

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes No

Note — Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act.

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP International Financial Reporting Standards as issued by the International Accounting Standards Board Other

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. N/A

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. N/A

Yes No

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INTRODUCTION

Certain Definitions

In this Annual Report on Form 20-F, unless the context otherwise requires:

- references to “BioLineRx,” the “Company,” “us,” “we” and “our” refer to BioLineRx Ltd., an Israeli company, and its consolidated subsidiaries;
- references to “ordinary shares,” “our shares” and similar expressions refer to the Company’s ordinary shares, NIS 0.10 nominal (par) value per share;
- references to “ADS” or “ADSs” refer to the Company’s American Depositary Shares;
- references to “dollars,” “U.S. dollars” and “\$” are to United States Dollars;
- references to “shekels” and “NIS” are to New Israeli Shekels, the Israeli currency;
- references to the “Companies Law” are to Israel’s Companies Law, 5759-1999, as amended; and
- references to the “SEC” are to the U.S. Securities and Exchange Commission.

Forward-Looking Statements

Some of the statements under the sections entitled “Item 3. Key Information – Risk Factors,” “Item 4. Information on the Company” and “Item 5. Operating and Financial Review and Prospects” and elsewhere in this Annual Report on Form 20-F 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, but these are not the only ways these statements are identified. 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 section of this Annual Report on Form 20-F entitled “Item 4. Information on the Company” contains information obtained from independent industry and other 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. Readers are encouraged to consult the Company’s filings made on Form 6-K, which are periodically filed with or furnished to the SEC.

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;
- our ability to integrate new therapeutic candidates and new personnel;
- 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 and 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;
- risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere;
- competitive companies, technologies and our industry; and
- statements as to the impact of the political and security situation in Israel on our business.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected 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 the Company should be read in conjunction with “Item 5. Operational and Financial Review and Prospects” and other information provided elsewhere in this Annual Report on Form 20-F 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.

In June 2015, we effected a 1:10 reverse split of our ordinary shares. All share and per share amounts in this report have been retroactively adjusted to reflect the reverse split as if it had been effected prior to the earliest financial statement period referred to herein. Following the reverse split, one ordinary share traded on the Tel-Aviv Stock Exchange, or the TASE, is equivalent to one ADS traded on The Nasdaq Capital Market, or Nasdaq (prior to the split, the ratio of ordinary shares to ADSs was 10:1).

The selected consolidated statements of operations data for the years ended December 31, 2016, 2017 and 2018, and the selected consolidated balance sheet data as of December 31, 2017 and 2018, have been derived from our audited consolidated financial statements set forth elsewhere in this Annual Report on Form 20-F. The selected consolidated statements of operations data for the years ended December 31, 2014 and 2015, and the selected consolidated balance sheet data as of December 31, 2014, 2015 and 2016, have been derived from our audited consolidated financial statements not included in this Annual Report on Form 20-F.

Our consolidated financial statements included in this Annual Report on Form 20-F were prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, and reported in dollars.

Consolidated Statements of Operations Data: ^{(1) (2)}	Year Ended December 31,				
	2014	2015	2016	2017	2018
	(in thousands of U.S. dollars, except share and per share data)				
Research and development expenses	(11,866)	(11,489)	(11,177)	(19,510)	(19,808)
Sales and marketing expenses	(1,589)	(1,003)	(1,352)	(1,693)	(1,362)
General and administrative expenses	(3,800)	(3,704)	(3,984)	(4,037)	(4,435)
Operating loss	(17,255)	(16,196)	(16,513)	(25,240)	(25,605)
Non-operating income (expenses), net	3,061	1,445	214	(260)	2,397
Financial income	3,566	457	480	1,169	719
Financial expenses	(448)	(106)	(22)	(21)	(473)
Net loss	(11,076)	(14,400)	(15,841)	(24,352)	(22,962)
Other comprehensive income (loss):					
Currency translation differences	(2,834)	–	–	–	–
Comprehensive loss	(13,910)	(14,400)	(15,841)	(24,352)	(22,962)
Net loss per ordinary share	(0.34)	(0.28)	(0.28)	(0.27)	(0.21)
Number of ordinary shares used in computing loss per ordinary share	32,433,883	51,406,434	56,144,727	89,970,713	108,595,702

Consolidated Balance Sheet Data:	As of December 31,				
	2014	2015	2016	2017	2018
	(in thousands of U.S. dollars)				
Cash and cash equivalents	5,790	5,544	2,469	5,110	3,404
Short-term bank deposits	28,890	42,119	33,154	44,373	26,747
Property, plant and equipment, net	721	2,909	2,605	2,505	2,227
Total assets	36,211	51,302	38,939	60,965	56,233
Total liabilities	4,406	3,692	3,912	8,084	14,912
Total shareholders' equity	31,805	47,610	35,027	52,881	41,321

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

(2) In June 2015, we effected a 1:10 reverse split of our ordinary shares. All share and per share amounts have been retroactively adjusted to reflect the reverse split as if it had been effected prior to the earliest financial statement period included herein.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should carefully consider the risks we describe below, in addition to the other information set forth elsewhere in this Annual Report on Form 20-F, including our consolidated financial statements and the related notes beginning on page F-1, before deciding to invest in our ordinary shares and ADSs. These material risks could adversely impact our results of operations, possibly causing the trading price of our ordinary shares and ADSs 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. Only one of our therapeutic candidates has begun to be commercialized. We, or our licensees, as applicable, will be required to conduct significant additional clinical trials before we or they can seek the regulatory approvals necessary to begin commercial sales of our other 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 recorded net losses of \$15.8 million in 2016, \$24.4 million in 2017 and \$23.0 million in 2018. As of December 31, 2018, we had an accumulated deficit of \$222.5 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 assure investors that our existing cash and investment balances will be sufficient to meet our future capital requirements.

As of December 31, 2018, we held cash and short-term investments of \$30.2 million. In February 2019, we completed a public offering of ADSs and warrants for net proceeds of \$14.1 million. We believe that our existing cash and investment balances (including the proceeds from our February 2019 public offering) and other sources of liquidity, not including potential milestone and royalty payments under our existing out-licensing and other collaboration agreements, will be sufficient to meet our capital requirements into 2021. We have funded our operations primarily through public and private offerings of our securities, payments received under our strategic licensing and collaboration arrangements and interest earned on investments. 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 expect to continue to explore alternative financing sources, including the possibility of future securities offerings and 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 expect to also continue to 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, as well as grants from government agencies and foundations. 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.

We may be unable to make payments due under our secured loan agreement.

On October 2, 2018, we entered into a \$10 million loan agreement with Kreos Capital V (Expert Fund) L.P., or Kreos Capital. As security for the loan, Kreos Capital received a first-priority secured interest in all of our assets, including intellectual property. The loan has a 12-month interest-only period followed by a 36-month repayment period. Borrowings under the loan bear interest at a fixed rate of 9.5% per annum.

Our ability to make the scheduled payments under the loan agreement or to refinance our debt obligations with Kreos Capital depends on numerous factors including, but not limited to, the amount of our cash reserves, our capital requirements and our ability to raise additional capital. We may be unable to maintain a level of cash reserves sufficient to permit us to pay the principal and accrued interest on the loan. If our cash reserves, cash flows and capital resources are insufficient to fund our debt obligations to Kreos Capital, we may be required to seek additional capital, restructure or refinance our indebtedness, or delay or abandon our research and development projects or other capital expenditures, which could have a material adverse effect on our business, financial condition, prospects or results of operations. There is no assurance that we would be able to take any of such actions, or that such actions would permit us meet our scheduled debt obligations under the Kreos Capital loan agreement.

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, only one of our products, BL-5010, a legacy asset for the treatment of benign skin lesions, has been approved for marketing and sale. Currently, we have two clinical-stage therapeutic candidates in development: BL-8040, a novel peptide for the treatment of hematological malignancies, solid tumors and stem cell mobilization, and AGI-134, an immuno-oncology agent in development for solid tumors. 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 other of our therapeutic candidates in a timely manner or at all. In connection with the clinical trials for BL-8040 and AGI-134 and other therapeutic candidates that we are may seek to develop in the future, either on our own or through out-licensing or co-development 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 U.S. Food and Drug Administration, or 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 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.

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 necessarily 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 to delay the analysis of data from completed or ongoing clinical trials. In addition, because some of our clinical trials are investigator-initiated studies (i.e., we are not the study sponsor), we may have less control over these studies. 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.

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 outcome 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.

We generally rely on third parties to conduct our preclinical studies and clinical trials and to 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 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 or add more sites to the studies. 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 and/or additional costs. 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.

We generally depend on out-licensing arrangements for late-stage development, marketing and commercialization of our therapeutic candidates.

We generally depend on out-licensing arrangements for late-stage development, marketing and commercialization of our therapeutic candidates. We have limited experience in late-stage development, marketing and commercializing therapeutic candidates. Dependence on out-licensing arrangements subjects us to a number of risks, including the risk that:

- we have limited control over 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 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 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.

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

We employ a number of methods to identify therapeutic candidates that we believe are likely to achieve commercial success. In certain instances, disease-specific third-party advisors evaluate therapeutic candidates as we deem necessary. However, there can be no assurance that our internal research efforts or our screening system will accurately or consistently select among various therapeutic candidates those that have the highest likelihood to achieve, and that 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. Recently, a number of global pharmaceutical companies and life sciences-focused investment funds have set up operations in Israel, both with and without Israeli government funding, in order to identify and in-license new technologies. The presence of these global companies with significantly greater resources than we have may increase the competition with respect to the in-licensing of promising therapeutic candidates. 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 our therapeutic candidates. We have in-licensed rights from Biokine Therapeutics Ltd., or Biokine, with respect to our BL-8040 therapeutic candidate; from the University of Massachusetts and from Kode Biotech Limited, or Kode Biotech, with respect to our AGI-134 therapeutic candidate; and from Innovative Pharmaceutical Concepts, Inc., or IPC, with respect to our BL-5010 therapeutic candidate. See “Item 4. Information on the Company — Business Overview — In-Licensing Agreements.” 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 range from 20% to 29.5% of the consideration we receive from sublicensing the applicable therapeutic candidate and a substantially lower percentage (generally less than 5%) if we elect to commercialize the subject therapeutic candidate independently. Due to the relatively advanced stage of development of the compound licensed from Biokine, our license agreement with Biokine provides for royalty payments of 10% of net sales, subject to certain limitations, should we independently sell products. These in-license agreements last either throughout the life of the patents that are 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.

If we do not meet the requirements under our agreement with the Agalimmune selling shareholders, we could lose the rights to the therapeutic candidates in Agalimmune's pipeline, including, but not limited to, AGI-134.

In March 2017, we acquired substantially all the outstanding shares of Agalimmune Ltd., or Agalimmune, a privately-held company incorporated in the United Kingdom. In conjunction with the acquisition, we entered into a development agreement with Agalimmune and its selling shareholders, or the Agalimmune Development Agreement, which, among other things, grants us an option to purchase any remaining Agalimmune shares. If we do not exercise this option within a certain period of time after achieving certain milestones or we commit a material breach of the Agalimmune Development Agreement, the selling shareholders have a reversionary option to acquire all the Agalimmune shares we hold for nominal consideration. If the exercise of this reversionary option is completed and our development work subsequently generates revenues for Agalimmune, we will only be entitled to a percentage of Agalimmune's net proceeds, until such time as we have recouped the expenses we incurred in connection with the Agalimmune Development Agreement. Completion of the exercise of the reversionary option would result in the loss of our rights in the proprietary technology held by Agalimmune, which could 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 effect 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 EU, we or our licensees, as applicable, must notify the applicable EU Notified Body, an organization appointed by a member state of the EU 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.

If our competitors develop and market products that are more effective, safer or less expensive than our current or future therapeutic candidates, our 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 other companies that currently market and/or are in the process of developing products that address stem cell mobilization, acute myeloid leukemia, or AML, solid malignancies and skin lesions.

An important element of our strategy for identifying future products is maintaining relationships with universities, medical institutions and biotechnology companies in order to in-license potential therapeutic candidates, and we compete with respect to this in-licensing with a number of global pharmaceutical companies. The presence of these global companies with significantly greater resources than we have may increase the competition with respect to the in-licensing of promising therapeutic candidates. Our failure to license or otherwise acquire necessary technologies could materially and adversely affect our business, financial condition and results of operations.

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 practices, 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. 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, financial condition and results of operations.

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.

If we decide to market any of our other therapeutic candidates on our own, 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, we 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.

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.

We rely upon third-party manufacturers to produce therapeutic supplies for the clinical trials, and commercialization, of our 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 do not currently have laboratories that are compliant with cGMP and therefore cannot independently manufacture drug products for our current clinical trials. We rely on third-party manufacturers to produce the therapeutic supplies that will enable us to perform clinical trials and, if we choose to do so, commercialize therapeutic candidates ourselves. 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 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 that guarantee the supply of any of our therapeutic candidates. When 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, it is likely that 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, which would have a material adverse effect on our business, financial condition and results of operations.

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;
- significant changes in pricing due to pressure from public opinion, non-governmental organizations or governmental authorities;
- 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.

Healthcare reforms and related reductions in pharmaceutical pricing, reimbursement and coverage by governmental authorities and third-party payors may adversely affect our business.

The continuing increase in expenditures for healthcare has been the subject of considerable government attention, particularly as public resources have been stretched by financial and economic crises in the United States, Western Europe and elsewhere. Both private health insurance funds and government health authorities continue to seek ways to reduce or contain healthcare costs, including by reducing or eliminating coverage for certain products and lowering reimbursement levels. In many countries and regions, including the United States, Western Europe, Israel, Russia, certain countries in Central and Eastern Europe and several countries in Latin America, pharmaceutical prices are subject to new government policies designed to reduce healthcare costs. These changes frequently adversely affect pricing and profitability and may cause delays in market entry. We cannot predict which additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for our approved products, if any of our therapeutic products are approved.

Significant developments that may adversely affect pricing in the United States include (i) the enactment of federal healthcare reform laws and regulations, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the Patient Protection and Affordable Care Act of 2010, or PPACA, and (ii) trends in the practices of managed care groups and institutional and governmental purchasers, including the impact of consolidation of our customers. Changes to the healthcare system enacted as part of healthcare reform in the United States, as well as the increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, may result in increased pricing pressure by influencing, for instance, the reimbursement policies of third-party payors. Healthcare reform legislation has increased the number of patients who would have insurance coverage for our approved products, if any of our therapeutic products are approved, but provisions such as the assessment of a branded pharmaceutical manufacturer fee and an increase in the amount of the rebates that manufacturers pay for coverage of their drugs by Medicaid programs may have an adverse effect on us. It is uncertain how current and future reforms in these areas will influence the future of our business operations and financial condition, as federal, state and foreign governmental authorities are likely to continue efforts to control the price of drugs and reduce overall healthcare costs. These efforts could have an adverse impact on our ability to market products and generate revenues in the United States and foreign countries.

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.

Regardless of the impact of the PPACA on us, the U.S. government, other governments and commercial payors have shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could cause significant pressure on the pricing of healthcare products and services, including those biopharmaceuticals currently being developed by us or our licensees, in the United States and internationally, as well as the amount of reimbursement available from governmental agencies or other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors to contain or reduce healthcare costs may compromise our ability to set prices at commercially attractive levels for our products that we may develop, which in turn could adversely impact how much or under what circumstances healthcare providers will prescribe or administer our products, if approved. Changes in healthcare policy, such as the creation of broad limits for diagnostic products, could substantially diminish the sale of or inhibit the utilization of diagnostic tests, increase costs, divert management's attention and adversely affect our ability to generate revenues and achieve consistent profitability. 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. Claims could be made against us based on the use of our therapeutic candidates in clinical trials and in marketed products. We currently carry life science liability insurance covering general liability with an annual coverage amount of \$30.0 million per occurrence and product liability and clinical trials coverage with an annual coverage amount of \$30.0 million each claim and in the aggregate. The annual aggregate as well as the maximum indemnity for a single occurrence, claim or circumstances under this insurance is \$30.0 million. 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 to 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.

Significant disruptions of our information technology systems or breaches of our data security could adversely affect our business.

A significant invasion, interruption, destruction or breakdown of our information technology systems and/or infrastructure by persons with authorized or unauthorized access could negatively impact our business and operations. We could experience business interruption, information theft and/or reputational damage from cyber-attacks or cyber-intrusions over the Internet, computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, and attachments to emails. Any of the foregoing may compromise our systems and lead to data leakage either internally or at our third-party providers. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Our systems have been, and are expected to continue to be, the target of malware and other cyber-attacks. Although we have invested in measures to reduce these risks, we cannot assure you that these measures will be successful in preventing compromise and/or disruption of our information technology systems and related data.

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, as well as cytotoxic, biologic, radio-labeled 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 unforeseen, sudden 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 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 in-licensing 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 therapeutic candidates that are in development or being commercialized. In 2012, we in-licensed the rights to BL-8040 under a license agreement from Biokine. Under the BL-8040 license agreement, we are obligated to make commercially reasonable, good faith efforts to sublicense or commercialize BL-8040 for fair consideration. Agalimmune in-licensed rights to AGI-134 under a license from the University of Massachusetts in 2013 and under a license from Kode Biotech in 2015. Under each of those license agreements, Agalimmune is obligated to use diligent efforts or cause its affiliates and sublicensees to use diligent efforts to develop the respective licensed technology and introduce licensed products into the commercial market. In 2007, we in-licensed the rights to BL-5010 under a license agreement with IPC. Under the BL-5010 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 foregoing in-licensing agreements, or the obligation to pay royalties thereunder, will generally remain in effect until the expiration, under the applicable agreement, of all 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 the BL-8040 in-licensing agreement upon 90 days' prior written notice to Biokine. Agalimmune may terminate each of the in-licensing agreements with University of Massachusetts and Kode Biotech relating to AGI-134, on 90 days' notice. We may terminate the BL-5010 in-licensing agreement upon 30 days' prior written notice to IPC.

Any party to any of the foregoing 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 an agreed-upon period, generally 30 days to 90 days, after receiving written notice of the breach from the non-breaching party.

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 March 15, 2019, we owned or exclusively licensed for uses within our field of business 29 patent families that collectively contain over 71 issued patents, four allowed patent applications and over 104 pending patent applications relating to our therapeutic candidates.

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. 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 could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and 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 from a third party accusing us of patent infringement.

Our license agreements with our licensees contain, and any contract that we enter into with licensees in the future will likely contain, indemnity provisions that obligate us to indemnify the licensee against any losses arising from infringement of 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 employee 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.

Risks Related to our Ordinary Shares and ADSs

We may be a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for our taxable year ending December 31, 2019 or in any subsequent year. There may be negative tax consequences for U.S. taxpayers that are holders of our ordinary shares or our ADSs if we are a PFIC.

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. We believe that we were a PFIC during certain prior taxable years and, although we have not determined whether we will be a PFIC for our taxable year ending December 31, 2019, or in any subsequent year, our operating results for any such years may cause us to be a PFIC. If we are a PFIC for our taxable year ending December 31, 2019, or any subsequent year, and a U.S. Investor (as defined below) does not make an election to treat us as a “qualified electing fund,” or QEF, or make a “mark-to-market” election, then “excess distributions” to a U.S. Investor, and any gain realized on the sale or other disposition of our ordinary shares or ADSs will be subject to special rules. Under these rules: (i) the excess distribution or gain would be allocated ratably over the U.S. Investor’s holding period for the ordinary shares (or ADSs, as the case may be); (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, or the IRS, 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. Investor to make a timely QEF or mark-to-market election. U.S. Investors who hold our ordinary shares or ADSs 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. Investors who made a timely QEF or mark-to-market election. A U.S. Investor can make a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. A QEF election generally may not be revoked without the consent of the IRS. 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.

The market prices of our ordinary shares and ADSs are subject to fluctuation, which could result in substantial losses by our investors.

The stock market in general and the market prices of our ordinary shares on the TASE and ADSs on Nasdaq, in particular, are subject to fluctuation, and changes in these prices may be unrelated to our operating performance. We expect that the market prices of our ordinary shares and ADSs will continue to be subject to wide fluctuations. The market price of our ordinary shares and ADSs are and will be subject to a number of factors, including:

- announcements of technological innovations or new products by us or others;
- announcements by us of significant acquisitions, strategic partnerships, in-licensing, out-licensing, joint ventures or capital commitments;
- expiration or terminations of licenses, research contracts or other collaboration agreements;
- public concern as to the safety of drugs we, our licensees or others develop;
- general market conditions;
- the volatility of market prices for shares of biotechnology companies generally;

- success of research and development projects;
- departure of key personnel;
- 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 or ADSs are covered by analysts;
- statements about the Company made in the financial media or by bloggers on the Internet;
- statements made about drug pricing and other industry-related issues by government officials;
- 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 ADSs, 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, even if we are successful.

Our ordinary shares are traded on the TASE and our ADSs are listed on Nasdaq. Trading in our securities on these markets takes place in different currencies (dollars on Nasdaq 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 securities on these two markets may differ due to these factors, the factors listed above, or other factors. Any decrease in the price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

We have received a deficiency letter from Nasdaq regarding the current bid price of the ADSs; there can be no assurance that we will continue to meet the requirements for the ADSs to trade on Nasdaq.

We received a notification letter from Nasdaq on December 3, 2018, notifying us that, because the closing bid price for the ADSs listed on Nasdaq was below \$1.00 for 30 consecutive trading days, we no longer meet the minimum bid price requirement for continued listing on Nasdaq, requiring a minimum bid price of \$1.00 per share (the "Minimum Bid Price Requirement").

In accordance with Nasdaq rules, we have a period of 180 days from the date of notification, or until June 3, 2019, to regain compliance with the Minimum Bid Price Requirement during which the stock will continue to list on Nasdaq. If at any time before June 3, 2019 the bid price of the ADSs closes at or above \$1.00 per share for a minimum of ten consecutive business days, Nasdaq will provide written notification that we have achieved compliance with the Minimum Bid Price Requirement.

The notification letter also disclosed that in the event we do not regain compliance with the Minimum Bid Price Requirement by June 3, 2019, we may be eligible for additional time for compliance. To qualify for additional time, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. If we meet these requirements, Nasdaq will inform us that we have been granted an additional 180 days to regain compliance. However, if it appears to the staff of Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, the staff would notify us that our shares will not be granted an additional 180 days for compliance and be subject to delisting at that time. In the event of such notification, we may appeal the staff's determination to delist our shares, but there can be no assurance the staff would grant our request for continued listing.

If the ADSs were delisted from Nasdaq, it would likely lead to a number of negative implications, including an adverse effect on the price of the ADSs, reduced liquidity in the ADSs, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In the event of a delisting, we would expect to take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow the ADSs to become listed again, stabilize the market price or improve the liquidity of the ADSs or prevent future non-compliance with Nasdaq's listing requirements.

Future sales of our ordinary shares or ADSs could reduce the market price of our ordinary shares and ADSs.

Substantial sales of our ordinary shares or ADSs, either on the TASE or on Nasdaq, may cause the market price of our ordinary shares or ADSs to decline. Sales by us or our securityholders of substantial amounts of our ordinary shares or ADSs, or the perception that these sales may occur in the future, could cause a reduction in the market price of our ordinary shares or ADSs.

As a result of previous financings, we have warrants outstanding (i) for the purchase of 2,973,451 ADSs at an exercise price of \$2.00 per ADS, (ii) for the purchase of 2,973,451 ADSs at an exercise price of \$4.00 per ADS, (iii) for the purchase of 957,549 ADSs at an exercise price of \$0.94 per ADS and (iv) for the purchase of 28,000,000 ADSs at an exercise price of \$0.75 per ADS. In addition, as of March 25, 2019, in the framework of our Share Incentive Plan, there are outstanding stock options, restricted stock units and performance stock units (granted to directors, employees and consultants) for the purchase of 10.9 million ordinary shares with a weighted average exercise price of \$1.10 per ordinary share.

In October 2017, we entered into an at-the-market sales agreement with BTIG, LLC, or BTIG, pursuant to which we may, in our discretion and from time to time, offer and sell through BTIG, acting as sales agent, our ADSs having an aggregate offering price up to \$30 million, through an "at-the-market" program, or the ATM Program.

The issuance of any additional ordinary shares, any additional ADSs, or any securities that are exercisable for or convertible into our ordinary shares or ADSs, may have an adverse effect on the market price of our ordinary shares and ADSs 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;
- our success in effecting out-licensing arrangements with third parties;
- our success in establishing other out-licensing or co-development 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 or ADSs could reduce the market price of our ordinary shares and ADSs.”

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 are permitted to follow certain home country corporate governance practices instead of those otherwise required under the Listing Rules of the Nasdaq Stock Market, or the Nasdaq Rules, for U.S. 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, composition of the compensation committee, approval of compensation of officers, and quorum at shareholders’ meetings. In addition, we will follow our home country law, instead of the Nasdaq Rules, 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. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on Nasdaq may provide less protection than is accorded to investors under the Nasdaq Rules applicable to U.S. domestic issuers. See “Item 16G — Corporate Governance — Nasdaq Listing Rules and Home Country Practices.”

In addition, as a foreign private issuer, we are 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 are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not 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.

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 and its region.

Our headquarters, 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 and the surrounding region 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 autumn of 2012, Israel was engaged in armed conflicts with Hamas, a militia group and political party operating in the Gaza Strip; during the summer of 2014, another escalation in violence among Israel, Hamas and other groups took place; and since October 2015, and to a lesser extent since August 2016, Israel has been facing another escalation in violence with the Palestinian population. These conflicts involved missile strikes against civilian targets in various parts of Israel, as well as civil insurrection of Palestinians in the West Bank, on the border with the Gaza Strip and in Israeli cities, and negatively affected business conditions in Israel. In addition, Israel faces threats from more distant neighbors, in particular Iran. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah (a Lebanese Islamist Shiite militia group and political party), and various rebel militia groups in Syria. Recent political uprisings and social unrest in various countries in the Middle East and North Africa are affecting the political stability of those countries. The year 2014 saw the rise of an Islamic fundamentalist group known as ISIS. Following swift operations, ISIS gained control of large areas in the Middle East, including in Iraq and Syria, which have contributed to the turmoil experienced in these areas. As a result, the United States and Russian armed forces have engaged in limited operations in Syria, resulting in the defeat of ISIS and other rebel groups and their withdrawal in 2017 from most of the areas they had previously held in Syria, including places along the Israeli-Syrian border. Iranian forces have supported operations of the Syrian army during the years of fighting in Syria, adding to the instability in the area. This instability may lead to deterioration of the political relationships that exist between Israel and these countries, and has raised concerns regarding security in the region and the potential for armed conflict. These situations may escalate in the future to more violent events that may affect Israel and us. Among other things, this instability may affect the global economy and marketplace through changes in oil and gas prices. 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. If the BDS Movement, the movement for boycotting, divesting and sanctioning Israel and Israeli institutions (including universities) and products become increasingly influential in the United States and Europe, this may also adversely affect our financial condition.

Due to a significant portion of our expenses and revenues being denominated in non-dollar currencies, our results of operations may be harmed by currency fluctuations.

Our reporting and functional currency is the dollar. However, we pay a significant portion of our expenses in NIS and in euro, and we expect this to continue. If the dollar weakens against the NIS or the euro in the future, there may be a negative impact on our results of operations. The revenues from our current out-licensing and co-development arrangements are payable in dollars and euros. Although we expect our revenues from future licensing arrangements to be denominated primarily in dollars, we are exposed to the currency fluctuation risks relating to the recording of our revenues in currencies other than dollars. For example, if the euro strengthens against the dollar, our reported revenues in dollars may be lower than anticipated. From time to time, we engage in 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 dollar. These measures, however, may not adequately protect us from material adverse effects.

We have received Israeli government grants and loans 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.

Our research and development efforts were previously financed, in part, through grants and loans that we received from the Israel Innovation Authority, or the IIA (formerly the Office of the Chief Scientist of Israel's Ministry of Economy and Industry, or the OCS). In addition, before we in-licensed BL-8040, Biokine had received funding for the project from the IIA, and as a condition to IIA consent to our in-licensing of BL-8040, we were required to agree to abide by any obligations resulting from such funding. We therefore must comply with the requirements of the Israeli Law for the Encouragement of Industrial Research, Development and Technological Innovation, 1984, and related regulations, as amended, or the Research Law, with respect to these projects. Through December 31, 2018, we received approximately \$22.0 million in funding from the IIA and paid the IIA approximately \$7.0 million in royalties under our approved programs. As of December 31, 2018, we have no contingent obligation to the IIA other than for BL-8040 as agreed when we in-licensed the project. The contingent liability to the IIA assumed by us relating to this transaction (which liability has no relation to the funding actually received by us) amounts to \$3.2 million as of December 31, 2018. We have a full right of offset for amounts payable to the IIA from payments that we may owe to Biokine in the future. Therefore, the likelihood of any payment obligation to the IIA with regard to the Biokine transaction is remote.

The transfer or licensing to third parties of know-how or technologies developed under the programs submitted to the IIA and derivatives thereof and as to which we or our licensors received grants, or manufacturing or rights to manufacture based on and/or incorporating such know-how to third parties, might require the consent of the IIA, and may require certain payments to the IIA. There is no assurance that we will be able to obtain such consent on terms acceptable to us, or at all. Although such restrictions do not apply to the export from Israel of our products developed with such know-how, without receipt of the aforementioned consent, such restrictions may prevent or limit us from engaging in transactions with our affiliates, customers or other third parties outside Israel, involving transfer or licensing of manufacturing rights or other know-how or assets that might otherwise be beneficial to us.

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 the approval of at least 95% of the issued share capital (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved the tender offer, except that if the total votes to reject the tender offer represent less than 2% of the company's issued and outstanding share capital, in the aggregate, approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer), and the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, claim that the consideration for the acquisition of the shares did not reflect their fair market value and petition the court to alter the consideration for the acquisition accordingly (unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights, and the acquirer or the company published all required information with respect to the tender offer prior to the date indicated for response to the tender offer).

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.

We have received Israeli government grants and loans 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 "Business — 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 annual report in Israel or the United States, or to serve process on our officers and directors.

We are incorporated in Israel. All of our executive officers and the majority of our directors 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 any of our executive officers and 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.

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.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our legal and commercial name is BioLineRx Ltd. We are a company limited by shares organized under the laws of the State of Israel. Our principal executive offices are located at 2 HaMa'ayan Street, Modi'in 7177871, Israel, and our telephone number is +972 (8) 642-9100.

We were founded in 2003 by leading institutions in the Israeli life sciences industry. We completed our initial public offering in Israel in February 2007 and our ordinary shares are traded on the TASE under the symbol "BLRX." In July 2011, we listed our ADSs on Nasdaq and they are traded under the symbol "BLRX."

In March 2017, we acquired Agalimmune Ltd., a private U.K.-based company, and its U.S. subsidiary, Agalimmune Inc. Agalimmune Inc. was dissolved on December 31, 2017.

Our capital expenditures for the years ended December 31, 2016 and 2018 were immaterial. For the year ended December 31, 2017, our capital expenditures were \$0.3 million. Our current capital expenditures involve acquisitions of laboratory equipment, computers and communications equipment.

The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers like BioLineRx that file electronically with the SEC. The address of that site is www.sec.gov. We maintain a corporate website at www.bioglinerx.com

B. Business Overview

We are a clinical-stage biopharmaceutical development company with a strategic focus on oncology. Our current development and commercialization pipeline consists of two clinical-stage therapeutic candidates – BL-8040, a novel peptide for the treatment of hematological malignancies, solid tumors and stem cell mobilization, and AGI-134, an immuno-oncology agent in development for solid tumors. In addition, we have an off-strategy, legacy therapeutic product called BL-5010 for the treatment of skin lesions. We generate our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a high probability of therapeutic and commercial success. To date, except for BL-5010, none of our therapeutic candidates have been approved for marketing or sold commercially. 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.

In January 2016, we entered into a collaboration with MSD (a tradename of Merck & Co., Inc., Kenilworth, New Jersey) in the field of cancer immunotherapy and in September 2016, we entered into a collaboration with Genentech, Inc., a member of the Roche Group, in the field of cancer immunotherapy. In addition, since December 2014 we have been collaborating with Novartis Pharma AG, or Novartis, for the co-development of selected Israeli-sourced novel drug candidates.

Therapeutic Candidates

BL-8040

Our clinical-stage lead therapeutic candidate, BL-8040, is a novel, short peptide that functions as a high-affinity antagonist for CXCR4. We are developing BL-8040 for the treatment of solid tumors, AML and stem cell mobilization. CXCR4 is expressed by normal hematopoietic cells and overexpressed in various human cancers where its expression correlates with disease severity. CXCR4 is a chemokine receptor that mediates the homing and retention of hematopoietic stem cells, or HSCs, in the bone marrow, and also mediates tumor progression, angiogenesis (growth of new blood vessels in the tumor), metastasis (spread of tumor to other organs) and survival.

Inhibition of CXCR4 by BL-8040 leads to the mobilization of HSCs from the bone marrow to the peripheral blood, enabling their collection for subsequent autologous or allogeneic transplantation in cancer patients. Clinical data has demonstrated the ability of BL-8040 to mobilize higher numbers of long-term engrafting HSCs (CD34⁺CD38⁻CD45RA⁻CD90⁺CD49f⁺) as compared to G-CSF.

BL-8040 also mobilizes cancer cells from the bone marrow, detaching them from their survival signals and sensitizing them to chemotherapy. In addition, BL-8040 has demonstrated a direct anti-cancer effect by inducing apoptosis (cell death) and inhibiting proliferation in various cancer cell models (multiple myeloma, non-Hodgkin's lymphoma, leukemia, non-small-cell lung carcinoma, neuroblastoma and melanoma).

In the field of immuno-oncology, BL-8040 mediates infiltration of T-cells while reducing immune regulatory cells in the tumor microenvironment. In clinical studies, the combination of BL-8040 with immune checkpoint inhibitors, such as anti PD-1, has shown T-cell activation and a reduction in tumor cell numbers.

In September 2013, the FDA granted an Orphan Drug Designation to BL-8040 as a therapeutic for the treatment of AML; and in January 2014, the FDA granted an Orphan Drug Designation to BL-8040 as a treatment for stem cell mobilization. In January 2015, the FDA modified this Orphan Drug Designation for BL-8040 for use either as a single agent or in combination with granulocyte colony-stimulating factor, or G-CSF. In February 2019, the FDA granted Orphan Drug Designation to BL-8040 as a therapeutic for the treatment of pancreatic cancer.

The following paragraphs are a summary of the clinical trials being carried out with BL-8040.

Solid tumors

Ø In January 2016, we entered into a collaboration with MSD (a tradename of Merck & Co., Inc., Kenilworth, New Jersey) in the field of cancer immunotherapy. Based on this collaboration, in September 2016 we initiated a Phase 2a study, known as the COMBAT/KEYNOTE-202 study, focusing on evaluating the safety and efficacy of BL-8040 in combination with KEYTRUDA[®] (pembrolizumab), MSD's anti-PD-1 therapy, in 37 patients with metastatic pancreatic adenocarcinoma. The study was an open-label, multicenter, single-arm trial designed to evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T-cells into the tumor and their reactivity. Top-line results from the initial dual combination arm of the trial showed that the combination demonstrated encouraging disease control and overall survival in patients with metastatic pancreatic cancer. In addition, assessment of patient biopsies supported BL-8040's ability to induce infiltration of tumor-reactive T-cells into the tumor, while reducing the number of immune regulatory cells. In July 2018, we announced the expansion of the COMBAT/KEYNOTE-202 study under the collaboration to include a triple combination arm investigating the safety, tolerability and efficacy of BL-8040, KEYTRUDA and chemotherapy. We initiated this arm of the trial in December 2018. Top-line results from the new triple combination arm of the study are expected in the second half of 2019, with overall survival results expected in 2020.

- Ø In August 2016, in the framework of an agreement with MD Anderson Cancer Center, we entered into an additional collaboration for the investigation of BL-8040 in combination with KEYTRUDA in pancreatic cancer. The focus of this study, in addition to assessing clinical response, is the mechanism of action by which both drugs might synergize, as well as multiple assessments to evaluate the biological anti-tumor effects induced by the combination. We are supplying BL-8040 for this Phase 2b study, which commenced in January 2017. Partial results from this study are anticipated in the first half of 2019, with top-line results expected in 2020.
- Ø In September 2016, we entered into a collaboration with Genentech, Inc., or Genentech (a member of the Roche Group), in the framework of which both companies would carry out Phase 1b/2 studies investigating BL-8040 in combination with TECENTRIQ® (atezolizumab), Genentech's anti-PDL1 cancer immunotherapy, in various solid tumors and hematologic malignancies. The clinical study collaboration between us and Genentech is part of MORPHEUS, Roche's novel cancer immunotherapy development platform. Genentech commenced a Phase 1b/2 study for the treatment of pancreatic cancer in July 2017, as well as a Phase 1b/2 study in gastric cancer in October 2017. These studies will evaluate the clinical response, safety and tolerability of the combination of these therapies, as well as multiple pharmacodynamic parameters.

AML

- Ø During 2016, we completed and reported on a Phase 2a proof-of-concept trial for the treatment of relapsed or refractory acute myeloid leukemia, or r/r AML, which was conducted on 42 patients at six world-leading cancer research centers in the United States and at five premier sites in Israel. The study included both a dose-escalation and a dose-expansion phase. Results from the trial showed detailed, positive safety and response rate data for subjects treated with a combination of BL-8040 and high-dose cytarabine (Ara-C), or HiDAC. At the annual meeting of the European Hematology Association, or EHA, in June 2018, we presented positive overall survival data from the long-term follow-up part of this study. We continue to monitor long-term survival data for patients in the study and, in parallel, are planning our next clinical development steps in this indication.
- Ø We are currently investigating BL-8040 as a consolidation treatment together with cytarabine (the current standard of care) for AML patients who have responded to standard induction treatment and are in complete remission and, in this regard, are conducting a significant Phase 2b trial in Germany, in collaboration with the German Study Alliance Leukemia Group. The Phase 2b trial is a double-blind, placebo-controlled, randomized, multi-center study aimed at assessing the efficacy of BL-8040 in addition to standard consolidation therapy in AML patients. Up to 194 patients will be enrolled in the trial. We continue to discuss with our collaboration partners the potential conduct of an interim analysis on this study based on various factors, including the occurrence of a minimum number of reported relapse events and/or exposure to provide a reasonable statistical powering for the analysis. Our current best estimate for the timing of such potential interim analysis is the second half of 2019, with top-line results from the trial expected in 2021.
- Ø In September 2017, we initiated a Phase 1b/2 trial in AML, known as the BATTLE trial, under the collaboration with Genentech referred to above in "— Solid tumors." The trial will focus on the maintenance treatment of patients with intermediate- and high-risk AML who have achieved a complete response following induction and consolidation therapy. Top-line results from this study are expected in 2021.

Stem cell mobilization

- Ø In March 2015, we reported successful top-line safety and efficacy results from a Phase 1 safety and efficacy trial for the use of BL-8040 as a novel stem cell mobilization treatment for allogeneic bone marrow transplantation at Hadassah Medical Center in Jerusalem.

- Ø In March 2016, we initiated a Phase 2 trial for BL-8040 in allogeneic stem cell transplantation, conducted in collaboration with the Washington University School of Medicine, Division of Oncology and Hematology, or WUSM. In May 2018, we announced positive top-line results of this study showing, among other things, that a single injection of BL-8040 mobilized sufficient amounts of CD34+ cells required for transplantation at a level of efficacy similar to that achieved by using 4-6 injections of G-CSF, the current standard of care.
- Ø In December 2017, we commenced a randomized, controlled Phase 3 registrational trial for BL-8040, known as the GENESIS trial, for the mobilization of HSCs for autologous transplantation in patients with multiple myeloma. The trial began with a lead-in period for dose confirmation, which was to include 10-30 patients and progress to the placebo-controlled main part, which is designed to include 177 patients in more than 25 centers. Following review of the positive results from treatment of the first 11 patients, the Data Monitoring Committee recommended that the lead-in part of the study should be stopped and that we should move immediately to the second part. Top-line results of this randomized, placebo-controlled main part of the study are expected in the second half of 2020.

Other matters

- Ø In addition to the above, we are currently conducting, or planning to conduct, a number of investigator-initiated, open-label studies in a variety of indications to support the interest of the scientific and medical communities in exploring additional uses for BL-8040. These studies serve to further elucidate the mechanism of action for BL-8040.

AGI-134

AGI-134, a clinical therapeutic candidate in-licensed by Agalimmune, is a synthetic alpha-Gal glycolipid immunotherapy in development for solid tumors. AGI-134 harnesses the body's pre-existing, highly abundant, anti-alpha-Gal antibodies to induce a hyper-acute, systemic, specific anti-tumor response to the patient's own tumor neo-antigens. This response not only kills the tumor cells at the site of injection, but also brings about a durable, follow-on, anti-metastatic immune response. In August 2018, we initiated a Phase 1/2a clinical study for AGI-134 that is primarily designed to evaluate the safety and tolerability of AGI-134, given both as monotherapy and in combination with an immune checkpoint inhibitor, in unresectable metastatic solid tumors. The multi-center, open-label study will take place in the United Kingdom and Israel, with possible expansion to the United States and additional countries in Europe in 2019. Initial safety results from the first part of the study are expected in the second half of 2019; initial efficacy results of the monotherapy arm from the second part of the study are expected by the end of 2020.

BL-5010

Our commercialized, legacy therapeutic product, BL-5010, is a customized, proprietary pen-like applicator containing a novel, acidic, aqueous solution for the non-surgical removal of skin lesions. In December 2014, we entered into an exclusive out-licensing arrangement with Perrigo Company plc, or Perrigo, for the rights to BL-5010 for over-the-counter, or OTC, indications in Europe, Australia and additional selected countries. In March 2016, Perrigo received CE Mark approval for BL-5010 as a novel OTC treatment for the non-surgical removal of warts. The commercial launch of this first OTC indication (warts/verruccas) commenced in Europe in the second quarter of 2016. Since then, Perrigo has invested in improving the product and expects to launch an improved version of the product during 2019.

Our Strategy

Our objective is to become a leader in the development of novel therapeutics for the treatment of cancer. We have successfully advanced a number of therapeutic candidates into clinical development. We intend to commercialize our two clinical candidates, BL-8040 and AGI-134, and any future candidates through out-licensing or co-development arrangements with third parties that may perform any or all of the following tasks: completing development, securing regulatory approvals, securing reimbursement codes from insurance companies and health maintenance organizations, manufacturing and/or marketing. If appropriate, we may also enter into co-development and similar arrangements with respect to any therapeutic candidate with third parties or commercialize a therapeutic candidate ourselves.

Stem cell mobilization. High-dose chemotherapy followed by stem cell transplantation has become an established treatment modality for a variety of hematologic malignancies, including multiple myeloma, as well as various forms of lymphoma and leukemia. Stem cells are mobilized from the bone marrow of the patient (i.e., autologous transplant) or donor (i.e., allogeneic transplant) using granulocyte-colony stimulating factor, or G-CSF, harvested from the peripheral blood by apheresis, and infused to the patient after chemotherapy. G-CSF is approved only for autologous use, although it is also used to mobilize and collect stem cells in the allogeneic setting on an off-label basis. This type of treatment often replaces the use of traditional surgical bone marrow harvesting, because the stem cells are easier to collect, and the treatment allows for a quicker recovery time and fewer complications.

Regulatory Approvals. In September 2013, the FDA granted an Orphan Drug Designation to BL-8040 as a therapeutic for the treatment of AML. In January 2014, the FDA granted an Orphan Drug Designation to BL-8040 for use, in combination with G-CSF, in mobilizing human stem cells from the bone marrow to the peripheral blood for collection for autologous or allogeneic (donor-based) transplantation. In January 2015, the FDA modified this Orphan Drug Designation for BL-8040 for use either as a single agent or in combination with G-CSF. In February 2019, we announced that the FDA granted Orphan Drug Designation to BL-8040 for use in the treatment of pancreatic cancer. Orphan Drug Designation is granted to therapeutics intended to treat rare diseases that affect not more than 200,000 people in the United States. Orphan Drug Designation entitles the sponsor to a seven-year marketing exclusivity period and clinical protocol assistance with the FDA, as well as federal grants and tax credits.

Preclinical Results.

In vitro and in vivo studies have shown that BL-8040 binds CXCR4 with high affinity (7.9 pM) and occupies it for prolonged periods of time (>48h). These studies have shown that BL-8040 mobilizes cancer cells from the bone marrow and may therefore detach these cells from survival signals in the bone marrow microenvironment as well as sensitize them to chemo- and bio-based anti-cancer therapies. In addition, BL-8040 directly induces apoptosis of cancer cells. BL-8040 was efficient, both alone and in combination with chemotherapy, in reducing malignant bone marrow cells and stimulating their cell death.

In August 2013, we announced that BL-8040 has been shown in preclinical trials to be effective for the treatment of thrombocytopenia, or reduced platelet production.

In December 2013, we presented preclinical data at the annual meeting of the American Society of Hematology (ASH), showing that BL-8040 directly inhibits AML cell growth and induces cell death, both in cell cultures and in mice engrafted with human AML cells. In addition, BL-8040 showed the ability to induce mobilization of AML cells from the bone marrow into the blood circulation, thereby enhancing the chemotherapeutic effect of ARA-C (one of the standard-of-care chemotherapies for AML). The data also showed that BL-8040's effects were even more robust in cells harboring the FLT3 mutation, and a synergistic effect was observed when BL-8040 was combined with the FLT3 inhibitor AC220 (Quizartinib).

At the annual meeting of ASH in December 2016, detailed preclinical data on the mechanism-of-action by which BL-8040 directly induces apoptosis of AML cells was presented by Prof. Amnon Peled of the Hadassah Medical Center and Biokine. The results of the preclinical studies showed that BL-8040 treatment in vivo triggered mobilization of AML blasts from their protective bone marrow microenvironment and induced their terminal differentiation, further supporting the data we presented at the American Association for Cancer Research annual conference earlier in 2016. In addition, the studies illustrate how BL-8040 increases the expression and activity of a special class of microRNA precursors termed miR-15a/16-1. These microRNA molecules have been previously linked to cancer, and shown to suppress the activity of several tumor-related pro-survival proteins. Therefore, by increasing the expression of miR-15a/16-1 microRNA molecules, BL-8040 decreases the expression of tumor-survival proteins and promotes tumor cell death. Importantly, in both in vitro and in vivo experiments, BL-8040 was found to synergize with a selective Bcl-2 inhibitor (Venetoclax) and an FLT3 inhibitor (Quizartinib, also known as AC220) in inducing AML cell death, pointing at potential drug combination treatments.

At the ASCO-SITC symposium in January 2018, we presented preclinical data showing that BL-8040 augments the ability of the immune system to fight cancer by increasing the infiltration of anti-tumor-specific T-cells into the TME, resulting in decreased tumor growth and prolonged survival in a murine model of cancer. In the preclinical study, a murine model of cancer was used to assess the effects of BL-8040 in combination with a cancer vaccine that primes the immune system against the tumor. The results of the study show that combining BL-8040 with the cancer vaccine leads to a significantly enhanced anti-tumor immune response, which attenuates tumor growth and prolongs mouse survival better than either agent administered alone. The results go on to demonstrate that BL-8040 significantly increases the abundance of tumor-specific T-cells in the TME, suggesting an explanation for the enhanced efficacy of the combination over either agent when administered alone.

Clinical Trials.

Solid tumors

In January 2016, we entered into a collaboration with MSD in the field of cancer immunotherapy. In the framework of this collaboration, in September 2016 we initiated a Phase 2a study, known as the COMBAT study, focusing on evaluating the safety and efficacy of BL-8040 in combination with KEYTRUDA, MSD's anti-PD-1 therapy, in patients with metastatic pancreatic adenocarcinoma. Findings in the field of immuno-oncology suggest that CXCR4 antagonists such as BL-8040 may be effective in inducing the migration of anti-tumor T-cells into the tumor micro-environment. KEYTRUDA is a humanized monoclonal antibody that works by blocking co-inhibitory T-cell activation signals, thereby increasing the ability of the body's immune system to help detect and fight tumor cells. KEYTRUDA blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes, which may affect both tumor cells and healthy cells. The study is an open-label, multicenter, single-arm trial designed to evaluate the clinical response, safety and tolerability of the combination of BL-8040 and KEYTRUDA as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T-cells into the tumor and their reactivity. According to the terms of our collaboration agreement with MSD, we are sponsoring and performing the COMBAT study and MSD is supplying its compound for purposes of the study. Upon completion of the study, or at any earlier point, both parties will have the option to expand the collaboration to include a pivotal registration study.

Partial results from the BL-8040 monotherapy portion of this trial were presented at ASCO-GI in January 2018. These results show that BL-8040 was safe and well-tolerated, and that it induced an increase in the number of total immune cells in the peripheral blood, while the frequency of peripheral blood regulatory T-cells (Tregs), known to impede the anti-tumor immune response, was decreased. In addition, analysis of available biopsies (N=7) showed infiltration of effector T-cells, known to attack cancer cells, into the tumor periphery and tumor micro-environment (TME). In this regard, the results show up to a 15-fold increase in CD3+ T-cells, and up to a two-fold increase in CD8+ T-cells, in the TME of 43% (3/7) of the patients, after five days of BL-8040 monotherapy.

In October 2018, we announced encouraging top-line results from the dual combination arm of the Phase 2a COMBAT/KEYNOTE-202 study at the European Society for Medical Oncology 2018 Congress. The data show that the treatment regimen was safe and well tolerated. The disease control rate (patients exhibiting a response or stable disease) was 34.5% for the evaluable population (N=29), including one patient (3.4%) with a partial response showing a 40% reduction in tumor burden, as well as nine patients (31%) with stable disease, with a median treatment time of 72 days (37-267). Median overall survival (OS) in all patients (N=37) was 3.3 months with a six-month survival rate of 34.4%. A significant observation was made in the subpopulation of patients receiving the study drugs as a second-line treatment (N=17), where the median overall survival was 7.5 months, with a six-month survival rate of 51.5%. This compares favorably with historical median overall survival data of 6.1 months for the only currently approved second-line PDAC treatment (a chemotherapy combination of Onivyde®, 5-FU and leucovorin). Additional data from in-depth analyses of biopsies taken at screening and following monotherapy or combination treatment of BL-8040 and KEYTRUDA demonstrate that in 75% of the available biopsies, BL-8040 treatment promotes an increase in the number of infiltrating CD4+, CD8+ and CD8+Granzyme B+ cytotoxic T-cells. The greatest improvement in T-cell infiltration was observed following combination treatment of BL-8040 and KEYTRUDA and was correlated with stable disease for eight cycles of treatment. Furthermore, increased infiltration of activated CD4 and CD8 T-cells was accompanied by a pronounced decrease in the number of tumor cells, as well as by a decrease in myeloid-derived suppressor cells, a cell type known to impede the antitumor immune response.

As a result of the encouraging data, the collaboration with MSD was expanded to include an additional cohort that will test the effect of the triple combination of BL-8040, KEYTRUDA and chemotherapy (Onivyde[®]/5-fluorouracil/leucovorin, the only second-line approved treatment for pancreatic cancer). We initiated this additional arm of the trial in December 2018 to investigate the safety, tolerability and efficacy of this triple combination. The triple combination arm will focus on second-line pancreatic cancer patients and will include approximately 40 patients with unresectable metastatic pancreatic adenocarcinoma who have progressed following first-line therapy prior to enrollment. Patients will receive BL-8040 monotherapy priming treatment for five days, followed by repeat cycles of the combination of chemotherapy, KEYTRUDA and BL-8040 until progression. The primary endpoint of the study is the objective response rate (ORR) assessed by RECIST v1.1 criteria. Secondary endpoints will include overall survival, progression free survival, and the disease control rate. Top-line results from this arm of the study are expected in the second half of 2019, with overall survival results expected in 2020.

In August 2016, we entered into an agreement with MD Anderson Cancer Center in regard to an additional collaboration for the investigation of BL-8040 in combination with KEYTRUDA in pancreatic cancer. The study is being conducted as an investigator-sponsored study, as part of a strategic clinical research collaboration between Merck and MD Anderson Cancer Center aimed at evaluating KEYTRUDA in combination with various treatments and novel drugs, including BL-8040. The open-label, single center, single-arm Phase 2b study will focus on the mechanism of action by which both drugs might synergize. In addition to assessing clinical response, the study will include multiple assessments to evaluate the biological anti-tumor effects induced by the combination. We are supplying BL-8040 for the study, which commenced in January 2017. Partial results from this study are anticipated in the first half of 2019, with top-line results expected in 2020.

In September 2016, we entered into a collaboration with Genentech to support several Phase 1b/2 studies investigating BL-8040 in combination TECENTRIQ, Genentech's anti-PDL1 cancer immunotherapy, in multiple cancer indications. Research findings in the field of immuno-oncology suggest that CXCR4 antagonists such as BL-8040 may be effective in inducing the migration of anti-tumor T-cells into the tumor micro-environment. TECENTRIQ is a humanized monoclonal antibody designed to bind with a protein called PD-L1. TECENTRIQ is designed to bind to PD-L1 expressed on tumor cells and tumor-infiltrating immune cells, blocking its interactions with both PD-1 and B7-1 (CD80) receptors. By inhibiting PD-L1, TECENTRIQ may enable the activation of T-cells, whose migration into the tumor may be enhanced by BL-8040. The clinical study collaboration between us and Genentech is part of MORPHEUS, Roche's novel cancer immunotherapy development platform. MORPHEUS is a phase 1b/2 adaptive platform to assess the efficacy and safety of combination cancer immunotherapies. Upon completion of the planned Phase 1b/2 studies, both parties will have the option to expand the collaboration to include a pivotal registration study.

In July 2017, Genentech commenced a Phase 1b/2 trial to evaluate the combination of TECENTRIQ and BL-8040 in metastatic pancreatic ductal adenocarcinoma. In September 2017, Genentech commenced an additional Phase 1b/2 trial to evaluate the combination of TECENTRIQ and BL-8040 in gastric cancer. Up to 40 patients are planned to be enrolled in each of these studies. Each study will be multicenter, randomized, controlled and open-label, intended to evaluate the clinical response, safety and tolerability, as well as multiple pharmacodynamic parameters, of the drug combination. Initially, patients will receive BL-8040 injections as priming monotherapy, after which they will receive both BL-8040 and TECENTRIQ, and continue with multiple treatment cycles for up to two years or until disease progression, clinical deterioration or unacceptable toxicity.

AML

During 2016, we completed and reported on the results of a Phase 2a clinical trial studying the use of BL-8040 for the treatment of relapsed/refractory AML, or r/r AML. The study was conducted at six sites in the United States, including MD Anderson Cancer Center in Houston, Memorial Sloan-Kettering Cancer Center in New York, Mayo Clinic in Jacksonville, Johns Hopkins University in Baltimore, Northwestern Memorial Hospital in Chicago and Washington University in St. Louis, as well as at five well-known sites in Israel. The study was an open-label study under an IND, designed to evaluate the safety and efficacy profile of repeated escalating doses of BL-8040 in combination with HiDAC in adult subjects with r/r AML. The study was comprised of two parts – a dose escalation Phase and an expansion Phase at the highest tolerated dose found during the escalation Phase. The primary endpoints of the study were the safety and tolerability of the drug. Secondary endpoints included the pharmacokinetic profile of the drug and an efficacy evaluation, indicated by the extent of mobilization of cancer cells from the bone marrow to the peripheral blood, the level of cancer cell death (apoptosis) and clinical responses.

Final results for the Phase 2a trial were presented at the annual meetings of the Society of Hematologic Oncology and ASH in September and December 2016, respectively. The reported data set includes 45 patients, including three compassionate-use patients treated at the study sites under the identical treatment protocol. The majority of patients in the study were heavily pretreated, with 45% of patients being refractory to one or two remission induction treatments, 19% of patients having relapsed after a short first remission of less than 12 months, and 17% of patients having undergone two or more relapses. In addition, the treated patient population included patients that had relapsed post allogeneic stem cell transplantation (17%), as well as secondary AML patients (24%), both conditions which represent difficult-to-treat populations with poor prognoses.

The results showed that treatment with BL-8040 in combination with HiDAC, was safe and well tolerated at all doses tested up to and including the highest dose level of 2.0 mg/kg. Response to treatment was associated with efficient CXCR4 inhibition, resulting in high mobilization of blasts. The composite complete remission rate, including both CR and CRi, was 38% in subjects receiving up to two cycles of BL-8040 treatment at doses of 1 mg/kg and higher (n=39). In the 1.5 mg/kg dose selected for the expansion Phase of the study (n=23), the composite complete remission rate was 39%. These response rates are superior to the historical response rate of approximately 19% reported for high-risk AML patients treated with Ara-C alone in Phase 3 randomized trials. The ongoing follow-up of patients participating in the study's expansion Phase and responding to the combination treatment suggests long durability of the remissions achieved, with two-thirds of these patients still alive, based on a follow-up period to date of up to 12 months. Results further show that BL-8040 monotherapy had a substantial therapeutic effect. Treatment with BL-8040 as a single agent triggered robust mobilization of AML blasts from the bone marrow to the peripheral blood stream, and the extent of mobilization was correlated with a positive response to treatment. The preferential mobilization of AML blasts over normal cells (4.7-fold vs. 1.4-fold, respectively) was further confirmed by analysis using the fluorescence in situ hybridization, or FISH, technique in a subset of patients. In addition, BL-8040 monotherapy resulted in a 40% increase in AML blast apoptosis.

In June 2018, at the 23rd Congress of the EHA in Stockholm, Sweden, we reported long-term survival data from the study that showed significantly enhanced overall survival of r/r AML patients treated with a combination of BL-8040 and HiDAC. The response rate for all dosing levels was 29% and median overall survival was 9.1 months, compared with historical data on overall survival of 6.1 months for HiDAC alone. In addition, a statistically significant correlation between patient response and the mobilization of AML blasts was reported. Responding patients demonstrated a clear and significant increase in the number of AML blasts in the peripheral blood following BL-8040 treatment, whereas non-responding patients were largely unaffected. In patients receiving the 1.5 mg/kg dose selected for expansion (n=23), the response rate was 39% and median overall survival was 10.7 months with one-year, two-year and three-year survival rates of 38.1%, 23.8% and 23.8%, respectively. Furthermore, median overall survival for responding patients at the 1.5 mg/kg dose (n=9) was 21.8 months, with one-year, two-year and three-year survival rates of 66.7%, 44.4% and 44.4%, respectively. Responding patients also demonstrated a statistically significant mean 6.3-fold increase (p=0.003) in the number of AML blasts in the peripheral blood following BL-8040 monotherapy treatment, whereas in non-responding patients the mean-fold increase was minor and non-significant (1.66-fold; p=0.21).

We are also investigating a second AML treatment line – consolidation therapy – in a large randomized, controlled Phase 2b trial in Germany. This study is examining BL-8040 as part of a second-stage treatment, termed consolidation therapy, to improve outcomes for the approximately 70% of AML patients who have achieved remission after the standard initial treatment regimen, known as induction therapy. The consolidation therapy is aimed at eliminating the minimal residual disease left in the bone marrow after induction therapy that can lead to relapse in 40-60% of the patients within 12-18 months after entering remission.

The Phase 2b trial, which is being conducted in collaboration with the University of Halle as sponsor and with the participation of two large leukemia study groups in Germany, is a double-blind, placebo-controlled, randomized, multi-center study aimed at assessing the efficacy of BL-8040 in addition to standard consolidation therapy in AML patients. The primary endpoint of the study is to compare the RFS time in AML subjects in their first remission during a minimum follow-up time of 18 months after randomization. In addition, pharmacodynamic measurements will be conducted in order to assess the minimal residual disease, and biomarker analyses will be performed to identify predictors of BL-8040 response. The study, which is being carried out at 29 sites in Germany, will enroll up to 194 patients. AML patients between 18 and 75 years of age with documented first remission will be randomized in a 1:1 ratio to receive HiDAC, either with BL-8040 or with a matching placebo, as consolidation therapy. We continue to discuss with our collaboration partners the potential conduct of an interim analysis on this study based on various factors, including the occurrence of a minimum number of reported relapse events and/or exposure to provide a reasonable statistical powering for the analysis. Our current best estimate for the timing of such potential interim analysis is the second half of 2019, with top-line results from the trial expected in 2021.

In September 2017, we initiated a Phase 1b/2 trial in AML as part of the collaboration with Genentech referred to above in “— Solid tumors.” The trial, known as the BATTLE study, will focus on the maintenance treatment of patients with intermediate- and high-risk AML who have achieved a complete response following induction and consolidation therapy. Up to 60 patients are planned to be enrolled in this multicenter, single arm, open-label study, to evaluate the relapse-free survival, minimal residual disease status, safety and tolerability of the combination of BL-8040 and TECENTRIQ for maintenance treatment in AML patients. The study’s primary endpoint is to assess whether the combination of BL-8040 and TECENTRIQ prolongs relapse free survival. In addition, the effect of the combination therapy on minimal residual disease, multiple immunological parameters, and potential biomarkers will be evaluated. The trial is planned to take place at approximately 22 sites in the United States, Europe and Israel. Top-line results from this study are expected in 2021.

Stem cell mobilization

In a Phase 1/2a, open-label, dose escalation, safety and efficacy clinical trial in 18 multiple myeloma patients, BL-8040 demonstrated an excellent safety profile at all doses tested and was highly effective in combination with G-CSF, in the mobilization of hematopoietic stem cells from the bone marrow to the peripheral blood for autologous transplantation. All patients receiving transplants (n=17) exhibited rapid engraftment, with median time to neutrophil and platelet recovery of 12 and 14 days, respectively, at the highest dose given (0.9 mg/kg).

In March 2015, we announced successful top-line results from a Phase 1 trial for BL-8040 as a novel treatment for the mobilization of stem cells from the bone marrow to the peripheral blood circulation in healthy volunteers, where they can be potentially harvested for allogeneic transplant supporting the treatment of hematological indications. The study was conducted at the Hadassah Medical Center in Jerusalem, and consisted of two parts. The first part of the study was a randomized, double-blind, placebo-controlled, dose-escalation study in three cohorts of eight participants each, with each participant receiving two consecutive injections of BL-8040. Results show that BL-8040 is safe and well tolerated up to the maximal tested dose of one mg/kg, and that dramatic mobilization of CD34+ hematopoietic stem and progenitor cells, or HSPCs, was observed across all doses tested. The robust mobilization supports the further use of a single injection of BL-8040 for HSPC collection.

In the second part of the Phase 1 study, eight healthy participants received a single injection of BL-8040 at the highest tested dose of 1 mg/kg, and four hours later underwent a single, standard leukapheresis procedure. Robust and rapid stem cell mobilization was evident in all treated participants, supporting a novel approach to stem cell collection. The median level of collected stem cells was higher than 11×10^6 cells per kg, which is more than two-fold higher than the target concentration, and five-fold higher than the minimum concentration, necessary for transplantation. In addition, the level of HPSCs in the peripheral blood circulation 24 hours after injection of BL-8040 enabled an additional apheresis on Day 2, if needed. These data support the use of BL-8040 as a single-agent, single-injection, one-day regimen for the collection of stem cells.

In March 2016, we announced the initiation of a Phase 2 trial for BL-8040 as a novel approach for the mobilization and collection of bone marrow stem cells from the peripheral blood circulation for allogeneic bone marrow transplantation. The open-label study was conducted in collaboration with the Washington University School of Medicine, Division of Oncology and Hematology, and enrolled up to 24 donor/recipient pairs, aged 18-70. The trial was designed to evaluate the ability of BL-8040, as a single agent, to promote stem cell mobilization for allogeneic transplantation. On the donor side, the primary endpoint of the study was the ability of a single injection of BL-8040 to mobilize 2×10^6 CD34 cells for transplantation following up to two apheresis collections. On the recipient side, the study aimed to evaluate the functionality and engraftment following transplantation of the BL-8040 collected graft. The study also evaluated the safety and tolerability of BL-8040 in healthy donors, as well as graft durability, the incidence of grade 2-4 acute graft versus host disease (GVHD), chronic GVHD, relapse and other recipient-related parameters in patients who have undergone transplantation of hematopoietic cells mobilized with BL-8040.

In May 2018, we announced positive results from the study. Single-agent treatment with BL-8040 showed efficacy similar to standard of care (currently, a four- to five-day treatment cycle with G-CSF and a one- to two-day apheresis procedure) in only one administration of BL-8040. In addition, BL-8040 showed non-inferiority to standard of care in recipient engraftment, with all transplanted recipients successfully engrafting with BL-8040-mobilized grafts. Of the 21 evaluable donors that have been enrolled in the study, 11 out of 13 donors (85%) treated at the 1 mg/kg dose and 8/8 donors (100%) treated at the 1.25 mg/kg dose of BL-8040 reached the primary goal of $\geq 2 \times 10^6$ CD34 cells/kg of recipient weight in up to two leukapheresis sessions. BL-8040 was safe and well tolerated, with adverse events consisting of injection site reactions and transient systemic reactions, all of which were resolved. No related serious adverse events were observed. All 19 transplanted recipients were successfully engrafted with BL-8040-mobilized grafts, 13 of whom had reached the secondary endpoint of 100 days post-transplant. Preliminary graft-versus-host disease (GVHD) data are in line with current standard-of-care incidence rates. The full effect of BL-8040 on acute and chronic GVHD, as well as on relapse rates, await longer follow-up periods and will be reported at a later stage once available.

In December 2017, we initiated a Phase 3 registration study for BL-8040 in autologous stem cell mobilization. The trial, known as the GENESIS study, is a randomized, placebo-controlled, multicenter study, evaluating the safety, tolerability and efficacy of BL-8040 and G-CSF, compared to placebo and G-CSF, for the mobilization of HSCs for autologous transplantation in multiple myeloma patients. The study began with an open-label, single-arm lead-in period, which was to include 10-30 patients in order to assess safety and efficacy following treatment with BL-8040 plus G-CSF. Results of the first 11 patients showed that BL-8040 in combination with standard G-CSF treatment is safe and tolerable. In addition, the data showed that 9/11 patients (82%) reached the primary endpoint threshold of $\geq 6 \times 10^6$ CD34 cells/kg with only one dose of BL-8040 and in up to 2 apheresis sessions. Furthermore, seven of the 11 patients (64%) reached the threshold of $\geq 6 \times 10^6$ CD34 cells/kg in a single apheresis session only. These data demonstrated the potential of BL-8040 treatment to reduce the number of administrations and apheresis sessions, as well as hospitalization costs, related to the preparation of multiple myeloma patients for autologous HSC transplantation. Following review of these positive results, the Data Monitoring Committee recommended that the lead-in part of the study should be stopped and that we should move immediately to the placebo-controlled main part, which is designed to include 177 patients in more than 15 centers. Additional positive results from the lead-in period were reported at the annual meeting of the European Society for Blood and Marrow Transplantation held in March 2019, where it was announced that HSCs mobilized by BL-8040 in combination with G-CSF were successfully engrafted in all 11 patients. Treatment in the main part of the study will include five to eight days of G-CSF, with a single dose of BL-8040 or placebo on Day 4 and an optional additional dose of BL-8040 or placebo on Day 6. Apheresis for stem cell collection will be performed on day 5. Further apheresis sessions may be conducted if needed in order to reach the benchmark of $\geq 6 \times 10^6$ mobilized CD34⁺ cells. The primary objective of the study is to demonstrate that BL-8040 on top of G-CSF is superior to G-CSF alone in the ability of mobilize $\geq 6 \times 10^6$ CD34⁺ cells in up to two apheresis sessions. Secondary objectives include time to engraftment of neutrophils and platelets and durability of engraftment, as well as other efficacy and safety parameters. Top-line results of this study are expected in the second half of 2020.

At the annual meeting of ASH in December 2017, clinical data supporting BL-8040 as a robust mobilizer of HSCs associated with long-term engraftment was presented by Prof. Amnon Peled. HSCs are cells found in the bone marrow, peripheral blood or umbilical cord blood that are responsible for generation and replenishment of all blood cell progenitors and eventually mature cells. It is therefore believed to be beneficial for a variety of therapeutic purposes, such as transplantation for people with hematological malignancies or for the therapy of blood or immune system disorders. The success of long-term HSC engraftment depends largely on the amount and quality of HSCs (CD34⁺ CD38⁻ CD45RA⁻ CD90⁺ CD49f⁺). The data presented demonstrate that human CD34⁺ cells from BL-8040-mobilized grafts contain high numbers of HSC (CD34⁺, CD38⁻, CD45RA⁻, CD90⁺, CD49f⁺) associated with long-term engraftment, compared to cells mobilized by granulocyte colony stimulating factor (G-CSF). An associated in vivo study further showed that BL-8040-mobilized HSCs can successfully engraft the bone marrow and spleen of immunodeficient mice. In addition, a robust long-term engraftment of BL-8040-mobilized human CD34⁺ cells was seen in these mice in primary and secondary transplants.

AGI-134

AGI-134 entered our pipeline following our acquisition of Agalimmune in March 2017. The compound is a synthetic alpha-gal immunotherapy in development for solid tumors. AGI-134 harnesses the body's pre-existing, highly abundant, anti-alpha-gal, or anti-Gal, antibodies to induce a systemic, specific anti-tumor response to the patient's own tumor neo-antigens. This response not only kills the tumor cells at the site of injection, but also brings about a durable, follow-on, anti-metastatic immune response. Alpha-gal is a cell-surface carbohydrate antigen that is not expressed by humans, unlike virtually all other mammals and bacteria. Therefore, humans universally produce and maintain high levels of anti-Gal antibodies, due to exposure to alpha-gal on bacteria in the digestive system.

AGI-134 is injected into the tumor, where it coats the tumor cell membranes, resulting in alpha-gal being exposed on the tumor cell surface. Anti-Gal antibodies bind to the alpha-gal part of AGI-134 to produce an initial immune response that activates complement-dependent and antibody-dependent cellular cytotoxicity (cell death). This cytotoxicity generates immune-tagged cells and cellular debris that trigger an uptake of tumor-associated antigens by antigen-presenting cells (APCs). These APCs induce a follow-on systemic immune response by the activation and clonal expansion of T-cells to the patient's own neo-antigens. This approach not only targets the primary injectable tumor, but has also demonstrated efficacy against existing distant secondary tumors. Furthermore, the mechanism of action suggests the potential of long-term protection against future metastases.

AGI-134 has completed numerous proof-of-concept studies, demonstrating regression of established primary tumors after injection with AGI-134 and robust protection against the development of secondary tumors in a model of melanoma with a single dose only. Synergy has also been demonstrated in the same model when combined with a PD-1 immune checkpoint inhibitor, offering the potential to broaden the utility of such immunotherapies and improve the rate and duration of responses in multiple cancer types. A 28-day, repeated-administration GLP toxicology study in monkeys with AGI-134 has also been successfully completed.

At ASCO-SITC in January 2018, we presented preclinical findings demonstrating successful results in the treatment of primary tumors. Intratumoral administration of AGI-134 induced regression of established tumors in two murine melanoma models. Moreover, treatment with AGI-134 showed a beneficial effect on survival, compared to the control group, with fewer mice dying or requiring euthanasia due to tumor burden. In addition, the results show that injection of AGI-134 into the tumors induces activation of the complement system, an important component of the innate immune system. Activation of the complement system within tumors by AGI-134 is predicted to destroy tumor cells and create a pro-inflammatory tumor microenvironment that attracts and activates other immune cells, ultimately resulting in adaptive anti-tumor immunity.

In August 2018, we initiated a Phase 1/2a clinical study for AGI-134 that is primarily designed to evaluate the safety and tolerability of AGI-134, given both as monotherapy and in combination with an immune checkpoint inhibitor, in unresectable metastatic solid tumors. Additional objectives are to perform a wide array of biomarker studies, to demonstrate the mechanism of AGI-134 and to assess its efficacy by clinical and pharmacodynamic parameters. The multicenter, open-label study will take place in the United Kingdom and Israel, with possible expansion to the United States and additional countries in Europe in 2019.

The study will be comprised of two parts: (i) an accelerated dose-escalation part to assess the safety and tolerability of intratumorally injected AGI-134 as a monotherapy, as well as to determine the maximum tolerated dose and the recommended dose for part 2 of the study and (ii) a dose expansion part at the recommended dose, comprised of three cohorts and designed to assess the safety, tolerability and anti-tumor activity of AGI-134 as a monotherapy in a basket cohort of multiple solid tumor types, as well as in two additional cohorts in combination with an immune checkpoint inhibitor – in metastatic colorectal cancer and head and neck squamous cell carcinoma. Initial safety results from the first part of the study are expected in the second half of 2019; initial efficacy results of the monotherapy arm from the second part of the study are expected by the end of 2020.

In November 2018, we announced that the FDA had granted the Biological Product Designation for AGI-134. This designation provides the Company with eligibility to obtain 12 years of market exclusivity upon approval of the product for commercial use by the FDA. This regulatory market exclusivity adds an incremental layer of protection in addition to that afforded by existing patents granted in the United States and Europe, and pending in other countries, covering the use of AGI-134 for the treatment of solid cancer tumors.

Commercialized Product

BL-5010

BL-5010 is a novel medical device containing an acidic, aqueous solution and applicator for the non-surgical removal of benign skin lesions. It offers an alternative to painful, invasive and expensive removal treatments including cryotherapy, laser treatment and surgery. Since the treatment is non-invasive, it poses minimal infection risk and eliminates the need for anesthesia, antiseptic precautions and bandaging. The pre-filled device controls and standardizes the volume of solution applied to a lesion, ensuring accurate administration directly on the lesion and preventing both accidental exposure of the healthy surrounding tissue and unintentional dripping. It has an ergonomic design, making it easy to handle, and has been designed with a childproof cap. BL-5010 is applied topically on a skin lesion in a treatment lasting a few minutes with the pen-like applicator and causes the lesion to gradually dry out and fall off within one to four weeks. We received European confirmation from British Standards Institute of the regulatory pathway classification of BL-5010 as a Class IIa medical device. We in-licensed the exclusive, worldwide rights to develop, market and sell BL-5010 from IPC in November 2007.

Development and Commercialization Arrangement. In December 2014, we entered into an exclusive out-licensing arrangement with Perrigo for the rights to BL-5010 for OTC indications in Europe, Australia and additional selected countries. We retain the OTC rights to BL-5010 in the United States and the rest of the world, as well as the non-OTC rights on a global basis. Under our out-licensing arrangement with Perrigo, Perrigo is obligated to use commercially reasonable best efforts to obtain regulatory approval in the licensed territory for at least two OTC indications and to commercialize BL-5010 for those two OTC indications. In addition, Perrigo will sponsor and manufacture BL-5010 in the relevant regions. Compensation by Perrigo for the exclusive license includes an agreed amount for each unit sold. In addition, we will have full access to all clinical and research and development data generated during the performance of the development plan and may use these data in order to develop or license the product in other territories and fields of use where we retain the rights. In March 2016, Perrigo received CE Mark approval for BL-5010 as a novel OTC treatment for the non-surgical removal of warts. The commercial product launch of this first OTC indication (warts/verruca) commenced in Europe in the second quarter of 2016. Since then, Perrigo has invested in improving the product and expects to launch the improved product during 2019.

As a result of our out-licensing arrangement, as well as the previous discussions with other potential partners for this product, the commercialization activities for BL-5010 are currently focused on OTC indications. However, we may decide to seek collaboration partners for development of BL-5010 for non-OTC indications, or for OTC indications in territories not out-licensed to Perrigo, primarily the U.S.

Termination of Therapeutic Candidates

During 2018 and the period subsequent thereto through the date of this report, we terminated one clinical-stage and three preclinical-stage therapeutic candidates.

BL-1040 was a novel, resorbable polymer solution for use in the prevention of ventricular remodeling that may occur in patients who have suffered an acute myocardial infarction, or AMI. We in-licensed BL-1040 from B.G. Negev Technologies and Applications Ltd., or B.G. Negev, in 2005. We entered into an out-licensing arrangement for BL-1040 with the predecessor of Bellerophon Therapeutics, Inc., or Bellerophon, in 2009. Bellerophon renamed the compound “Bioabsorbable Cardiac Matrix,” or BCM, and developed it as a medical device. In July 2015, Bellerophon reported top-line results from PRESERVATION I, a CE mark registration clinical trial for BCM, showing no statistically significant difference between patients treated with BCM versus placebo for both the primary and the secondary endpoints of the study. In August 2018, after the project had not been active in any significant way since 2015, Bellerophon exercised its contractual right to terminate the licensing arrangement based on its determination that the results of the clinical trial it had carried out did not warrant further development of BL-1040. As a result of Bellerophon’s decision, we terminated our in-license agreement with B.G. Negev.

BL-1220 was an orally administered, novel composition of sodium alginate, intended as a treatment for various liver failure conditions such as end-stage liver disease and for conditions potentially leading to liver failure such as NASH. BL-9020 was a novel monoclonal antibody treatment designed to prevent immune-mediated destruction of insulin-producing beta cells in the pancreas. The treatment was developed to treat Type 1 diabetes in early stage patients, during what is known as the “honeymoon period,” where the pancreatic beta cells have not been completely destroyed and continue to secrete insulin. BL-1230 was a cannabinoid receptor type 2 intended as a novel anti-inflammatory treatment for Dry Eye Syndrome (DES). These preclinical projects were terminated due to lack of efficacy and other scientific considerations as well as market considerations.

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 three therapeutic candidates.

We have established close relationships with various universities, academic and research institutions and biotechnology companies that permit us to identify and select compounds at various stages of clinical and pre-clinical development. 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.

Collaboration and Out-Licensing Agreements

Collaboration Agreements with MSD and Genentech

See “—Therapeutic Candidates — BL-8040 — Clinical Trials — Solid tumors” for details regarding our collaborations with MSD and Genentech.

Investment and Collaboration Agreement with Novartis

In December 2014, we entered into a multi-year strategic collaboration agreement with Novartis designed to facilitate development and commercialization of Israeli-sourced drug candidates. As part of the collaboration agreement, Novartis made an initial equity investment in us of \$10 million. We in-licensed three pre-clinical projects in the framework of the collaboration. All those projects were subsequently terminated due to lack of efficacy and other scientific considerations, as well as market considerations. As of December 31, 2018, we do not have any on-going projects under the collaboration.

Out-Licensing Agreement with Perrigo

In December 2014, we entered into an exclusive out-licensing arrangement with Perrigo for the rights to BL-5010 for OTC indications in Europe, Australia and additional selected countries, or collectively, the Territory. We retain all OTC rights to BL-5010 in the United States and the rest of the world, as well as all non-OTC rights on a global basis. Perrigo fulfilled its obligation to launch a licensed product commercially in the Territory in 2016. In addition, Perrigo is obligated to use commercially reasonable best efforts to obtain regulatory approval in the Territory for at least one more OTC indication and to commercialize BL-5010 for that indication.

Perrigo has the right to sublicense BL-5010 in arm’s-length transactions consistent with the terms and conditions of its license agreement with us. In certain agreed-on countries in the Territory, Perrigo is obligated to commercialize licensed products itself, through its affiliates or through sublicensees approved by us; in other countries in the Territory, Perrigo does not need our prior written approval for sublicensing but must provide us with a copy of the executed sublicense agreement.

Compensation by Perrigo for the exclusive license includes an agreed amount for each unit sold. We must pay a portion of all net consideration we receive from Perrigo, within our standard range of sublicense receipt consideration, to IPC, the company from which we initially in-licensed the development rights to BL-5010. See “— In-Licensing Agreements — BL-5010.”

We have the right to prosecute and maintain the patents for BL-5010 in the Territory, and Perrigo will bear the cost of all renewal fees for patents and the other costs of prosecution and maintenance up to an agreed limit.

We will have full access to all clinical and research and development data generated during the performance of the development plan and may use these data in order to develop or license the product in other territories and fields of use where we retain the rights.

Our agreement with Perrigo will continue in effect until the cessation of all commercialization in the Territory. After the fifth anniversary of the first commercial sale of a licensed product, either party may terminate the agreement by giving at least 18 months’ prior written notice to the other party. Either party may terminate the agreement (a) by providing 60 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 or (b) with immediate effect on written notice to the other party if there is a change of control of the other party. The parties have agreed that the announced acquisition of Perrigo by Perrigo Company Plc is a change of control event that will not give rise to a right on our part to terminate the license agreement. In addition, we have the right to terminate the agreement if Perrigo does not fulfill any of its obligations of diligence with respect to launching a licensed product or obtaining regulatory approval for, and commercializing, licensed products as described above.

Other Out-licensing/Collaboration Agreements

iPharma

In 2016, we established a joint venture with I-Bridge Capital, a Chinese venture capital fund focused on developing innovative therapies in China, with each party contributing initial seed capital to the venture of \$1.0 million. The joint venture, named iPharma, focused on the development of innovative clinical and pre-clinical therapeutic candidates to serve the Chinese and global healthcare markets. During 2018, we determined that the joint venture's activities were no longer part of our current strategic focus. Accordingly, in April 2018, we sold our holdings in the joint venture to I-Bridge Capital for cash consideration of \$1.5 million.

JHL

In January 2014, we signed an agreement with JHL Biotech, or JHL, a biopharmaceutical company that develops, manufactures, and commercializes biologic medicines, pursuant to which we collaborated with JHL in the development and commercialization of BL-9020. As a result of our termination of the BL-9020 project during 2018, by its terms the collaboration agreement with JHL ended as well.

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.

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 sub-licensing 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 sublicenses.
- **Milestone payments.** These payments are generally linked to the successful achievement of milestones in the development and approval of drugs, such Phases 1, 2 and 3 of clinical trials and approvals of new drug applications, or NDAs.
- **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 decreases 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 sublicenses 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 in most cases range from 20% to 29.5% of the consideration we receive from sublicensing the applicable therapeutic candidate. We are required to pay a substantially lower percentage, generally less than 5%, if we elect to commercialize the subject therapeutic candidate independently. Due to the relatively advanced stage of development of the compound licensed from Biokine, our license agreement with Biokine provides for royalty payments of 10% of net sales, subject to certain limitations, should we independently sell products. In addition, milestone payments are not generally payable if the revenue-sharing from an out-licensing transaction is greater than any relevant payments due under our in-licensing agreements.

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

BL-8040

In September 2012, we in-licensed the rights to BL-8040 under a license agreement with Biokine. Pursuant to the agreement, Biokine granted us an exclusive, worldwide, sublicensable license to develop, manufacture, market and sell certain technology relating to a short peptide that functions as a high-affinity antagonist for CXCR4 and the uses thereof.

There were no upfront payments due under the agreement. We are obligated to pay a monthly development fee of \$27,500 for certain development services that Biokine has committed to provide to us under the agreement. The payment of this monthly fee will continue until the completion of the last clinical trial in which BL-8040 is planned to be tested, or is being tested with, at least 20 subjects.

We are responsible for paying all development costs incurred by the parties in carrying out the development plan.

Should we independently develop manufacture and sell products (excluding sublicensing) containing the licensed technology, we are obligated to make royalty payments of 10% of net sales, subject to certain limitations.

The agreement also grants us the right to grant sublicenses for the licensed technology. Initially, we were required to pay Biokine a royalty payment of 40% of the amounts we receive as consideration in connection with any sublicensing, development, manufacture, marketing, distribution or sale of the licensed technology. In October 2018, Biokine agreed to reduce the royalty payment for sublicensing to 20% in return for the payment by us of \$10 million in cash plus \$5 million in our restricted shares. Biokine is also eligible to receive up to a total of \$5 million in future milestone payments. The royalty rate of 20% is subject to an increase of an additional 10% under certain conditions.

Before we in-licensed BL-8040, Biokine had received funding for the project from the IIA, and as a condition to IIA giving its consent to our in-licensing of BL-8040, we were required to agree to abide by any obligations resulting from such funding. However, if we become legally required to make payments to the IIA in respect of grants made to Biokine, we have the right to offset the full amount of such grants from any payments otherwise due to Biokine as sublicensing royalties as described above.

We are obligated under the agreement with Biokine to make commercially reasonable, good faith efforts to sublicense or commercialize BL-8040 for fair consideration. If we do not fulfill this obligation within 24 months after completion of the development plan, all of the rights and responsibilities with respect to commercialization of the licensed technology will revert to Biokine, and our obligation to pay royalties for sales of any licensed products or sublicensing as described above will revert to Biokine.

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 we are required to consult with Biokine 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 all the expenses of any patent infringement suit that we bring, including any expenses incurred by Biokine in connection with such suits, with such expenses reimbursable from any sums recovered in such suit or in the settlement thereof for. After such reimbursement, if any funds remain, both we and Biokine are each entitled to a certain percentage of any remaining sums.

The agreement will remain in effect until the expiration of all of our royalty and sublicense revenue obligations to Biokine, determined on a product-by-product and country-by-country basis. We may terminate the agreement for any reason on 90 days' prior written notice to Biokine. Either party may terminate the agreement for a 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 non-breaching party. With respect to any termination for a 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 drug and the licensed technology, which will revert to Biokine. In addition, any sublicense of ours will terminate provided that, upon such termination and at the request of the sublicensee, Biokine will be required to enter into a separate license agreement with the sublicensee on substantially the same terms as those contained in the applicable sublicense agreement.

AGI-134

Acquisition Agreements with Agalimmune

In March 2017, we acquired substantially all of the outstanding shares of Agalimmune and entered into the Agalimmune Development Agreement with the selling shareholders. We control the Agalimmune board of directors, and subject to the protections in favor of the selling shareholders, we will direct and be responsible for the planning, execution and day-to-day management of Agalimmune and its pipeline, including AGI-134.

The Agalimmune Development Agreement provides the selling shareholders with a reversionary option, in the event of a breach of that agreement and certain other limited triggering events, that permits the selling shareholders to re-acquire our equity interests in Agalimmune for nominal consideration. See "Risk Factors — Risks Related to Our Business Regulatory Matters — If we do not meet the requirements under our agreement with the Agalimmune selling shareholders, we could lose the rights to the therapeutic candidates in Agalimmune's pipeline, including but not limited to AGI-134."

License from the University of Massachusetts

In 2013, Agalimmune entered into an exclusive license agreement with the University of Massachusetts which was amended and restated in February 2017, for rights to intellectual property related to AGI-134. Pursuant to the agreement, Agalimmune has an exclusive, worldwide, royalty-bearing, sublicensable license to develop, manufacture, use, import and sell licensed products. Agalimmune is obligated to use diligent efforts to develop the licensed products and to introduce them into the commercial market. The agreement sets forth specific development milestones that Agalimmune is required to fulfill. In consideration of the grant of the license, Agalimmune is obligated to pay upfront license fees, annual maintenance fees, milestone payments, and low, single digit royalty payments on the net sales of licensed products. In addition, the agreement provides that following a change of control event, Agalimmune will allot to the University 6% of its shares on a fully diluted basis. The agreement will remain in full effect until the later of expiration or abandonment of all valid claims in the licensed patents or 10 years from the date of first sale of a licensed product. Agalimmune may terminate the agreement for any reason on 90 days' prior written notice to the University.

License from Kode Biotech

In March 2015, Agalimmune entered into an evaluation license and option agreement with Kode Biotech for the rights to intellectual property related to certain water dispersible glycan-lipid conjugates (the "KODE™ Constructs"), including AGI-134. Pursuant to the agreement, Agalimmune had an exclusive license to pursue preclinical assessment of the use of the KODE™ Constructs in Agalimmune's method of promoting tumor anticancer therapy, and the exclusive right to require Kode Biotech to grant Agalimmune an exploitation license to pursue clinical development and commercialization of the use of the KODE™ Constructs in its method.

In September 2017, Agalimmune exercised its option to enter into the exploitation license agreement with Kode Biotech that grants Agalimmune a worldwide, exclusive, royalty-bearing transferable license to develop, manufacture, use, import and sell licensed products, including AGI-134. Agalimmune is obligated to use reasonable, diligent efforts to develop licensed products and to introduce licensed products into the commercial market. In consideration of the grant of the license, Agalimmune paid a license issue fee and is obligated to pay annual maintenance fees, milestone payments and low, single-digit royalty payments on the net sales of the licensed products. Agalimmune also has the right to grant sublicenses for the licensed technology and is required to pay Kode Biotech a payment based on the revenues from sublicense net sales. The agreement will remain in effect, unless terminated earlier in accordance with its terms, until the later of expiration or abandonment of all enforceable patent claims within the licensed patents.

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 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 payment, within our standard range of sublicense receipt consideration, 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. 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 would 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.

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, as well as on regulatory exclusivity, such as Orphan Drug designation or new chemical entity (NCE) protection, to develop and maintain our proprietary position.

Patents

As of March 15, 2019, we owned or exclusively licensed for uses within our field of business 29 patent families that collectively contain over 71 issued patents, four allowed patent applications and over 104 pending patent applications relating to the three candidates listed below. 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 therapeutic candidates are described below and include both issued patents and pending patent applications we exclusively license. We vigorously defend our intellectual property to preserve our rights and gain the benefit of our investment.

- With respect to BL-8040, we have an exclusive license to two patent families that cover the molecule that is the active ingredient of our proprietary drug. Patents and patent applications of these families have been granted or are pending in the U.S., Europe, Japan and Canada. The patents and any patents to issue in the future based on pending patent applications in these families will expire in 2023 (in the U.S.) and 2021 (in other countries), not including any applicable patent term extension, which may add an additional term of up to five years on the patents. In addition, we have an exclusive license to eighteen other patent families pending or granted worldwide directed to methods of use of BL-8040 either alone or in combination with other drugs for the treatment of certain types of cancer and other indications. Furthermore, we have Orphan Drug status for AML, pancreatic cancer and stem cell mobilization, as well as data exclusivity protection afforded to BL-8040 as a new chemical entity, or NCE.

- With respect to AGI-134, Agalimmune owns or has an exclusive license to three patent families that cover the AGI-134 compound and its use for treating cancer. Patents have been granted in the family that covers the use of AGI-134 for treating solid tumors in the United States and Europe and will expire in 2035. Applications in these families are pending in China, Japan and other countries that would have the same expiration, if granted. Patents have been granted in the families that cover a genus of compounds including AGI-134 in the United States, Europe, Japan and other countries and will expire in 2025. In addition, the future drug product is eligible for obtaining regulatory Biological Product exclusivity (12 years of market exclusivity in the U.S.).
- With respect to BL-5010, we have an exclusive license to a patent family directed to a novel applicator uniquely configured for applying the BL-5010 composition to targeted skin tissue safely and effectively. Patent applications of this family are pending in the U.S., Israel, Europe, Japan, Canada, China, Russia and Australia. If granted, patents will expire in 2034.

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 invention 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.

Manufacturing

Our laboratories are located in our headquarters in Modi'in, Israel and are in part compliant with FDA regulations setting forth current good laboratory practices, or GLP. However, they are not compliant with cGMP and therefore we cannot independently manufacture drug products for our current clinical trials or, if we choose to do so, commercialize therapeutic candidates ourselves. The suppliers of the drug substances used for our current clinical trials do have these necessary approvals. 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 commercial scale.

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. Our contract manufacturers are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products or medical devices. Our contract manufacturers must ensure that all of the processes, methods and equipment are compliant with cGMP, for drugs 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 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. 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 do. In certain cases, 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-8040

There are a number of potentially competitive compounds under development that act as CXCR4 inhibitors, including, among others, Mozobil[®] (plerixafor), which is being marketed by Sanofi Genzyme as a stem cell mobilizer for autologous stem cell transplantation; LY-2510924, which is being developed by Eli Lilly & Co; BMS-936564 (MDX-1338; ulocuplumab) developed by Bristol-Myers Squibb; TG-0054 (burixafor) developed by TaiGen Biotechnology Co; POL-6326 (balixafortide) developed by Polyphor Ltd.; X4P-001 developed by X4 Pharmaceuticals Inc.; GMI-1359 developed by Glyco-Mimetics Inc; F-50067 developed by Pierre Fabre and USL-311 developed by Proximagen Group.

Immuno-oncology is an area of great interest in the pharmaceutical market, specifically, immuno-oncology combination therapies. Currently there are hundreds of immuno-oncology combination treatments being tested in clinical trials. Recently, there has been growing attention to the combination of immuno-oncology agents with chemokines such as CXCR4 antagonist. Such combination therapies currently in development are BMS-936564 in combination with Opdivo[®] (nivolumab marketed by Bristol-Myers Squibb); X4P-001 in combination with Opdivo and X4P-001 in combination with KEYTRUDA. These combination therapies, among others, could potentially compete with the combinations of BL-8040 with KEYTRUDA and BL-8040 and TECENTRIQ.

In the field of AML, BL-8040, if approved, will compete with currently approved treatments for AML that include chemotherapy (doxorubicin, cytarabine, vincristine), radiation therapy, stem cell transplantation and the hypomethylating agents Dacogen[®] (decitabine, Eisai and Johnson & Johnson) and Vidaza[®] (azacitidine, Celgene). Other approved drugs for AML are Vyxeos[®] (liposomal cytarabine and daunorubicin, Jazz Pharmaceuticals).

In addition there are a number of potentially competitive compounds in development to treat AML including, among others, Qinprezo (vosaroxin, Sunesis Pharmaceuticals); F-14512 (Pierre Fabre); pacritinib (CTI BioPharma Corp, pre-registration); Odomzo[®] (sonidegib), Mekinist (trametinib) and uprosertib developed by Novartis; Selinexor (Karyopharm Therapeutics and Ono Pharmaceutical Co Ltd.); Velcade (bortezomib, Janssen and Takeda); Revlimid (lenalidomide, Celgene and BeiGene Co Ltd.); Tarceva (erlotinib, Roche Astellas and Chugai); Zolinza (Vorinostat, Merck and Co.); SGI-110 (guadecitabine sodium, Astex Pharmaceuticals); Pracinostat (MEI Pharma); sapacitabine (Cyclacel Pharmaceuticals Inc.); idasanutlin (Ro-5503781, Roche Holding AG); and CX-01 (Cantex Pharmaceuticals). Some of these treatments are being developed for specific AML patient populations and lines of treatment and not for the entire AML population: e.g. quizartinib (Ambit Biosciences) as treatment for FLT3-ITD mutated AML patients; Nexavar (sorafenib, Bayer); midostaurin (Novartis, pre-registration); ASP-2215 (gilteritinib, Astellas Pharma Inc.); CPI-613 (Rafael Pharmaceuticals); alvocidib (Tolero Pharmaceuticals); BST-236 (Biosight); ELZONRIS[®] (Stemline Therapeutics). As well as treatment for FLT3 mutated AML patients including, among others: Quizartinib (Daiichi Sankyo); crenolanib (Arog Pharmaceuticals Inc.) and pacritinib (CTI BioPharma Corp). Some of these treatments can be developed for administration to AML patients in combination with BL-8040.

In the field of stem cell mobilization, in addition to the above-referenced Mozobil, there are a number of compounds under development that could potentially compete with BL-8040: Burixafor (TG-0054, TaiGen Biotechnology); Balixafortide (POL6326, Polyphor) and NOX-A12 (Noxxon Pharama).

AGI-134

The field of cancer immunotherapy is rapidly growing, targeting CTLA-4, PD1 or PDL1 via antibody blockade. In recent years, approval has been granted for use of these agents for various oncology-related indications such as melanoma, non-small cell lung cancer, renal cell carcinoma, head and neck, gastric and colorectal cancer, liver cancer and bladder cancer. As noted above, there are currently hundreds of immuno-oncology combination treatments being tested in clinical trials. Many of these combinations could be competitive with AGI-134.

In general, the competitive landscape is comprised of compounds that target tumor specific neoantigens and create adaptive, anti-tumor immune response. Examples of such therapeutic approaches include oncolytic viruses, dendritic cell vaccines, personalized neoantigen-based cancer vaccines, pathogen-associated molecular patterns (PAMPs), damage-associated molecular pattern (DAMPs) and cancer vaccines.

If approved, AGI-134 will compete with approved treatments such as the oncolytic viruses Imlygic® (T-VEC; Amgen) and dendritic cell cancer vaccine Provenge® (sipuleucel-T; Dendreon Corp). In addition, there are several potentially-competitive compounds that are currently under development, including, among others, Pexa-Vec (pexastimogene devacirepvec, SillaJen and Transgene); Reolysin (pelareorep, Adlai Nortye Pharmaceutical Co Ltd and Oncolytics Biotech Inc.); Cavatak (Viralytics); NeoVax (Neon Therapeutics); IVAC Mutanome (BioNTech AG); TLR9 agonists such as Idefitolimod (MGN-1703, Mologen Ag), tilsetolimod (IMO-2125, Idera Pharmaceuticals Inc.), SD-101 (Dynavax Technologies Corp) and CMP-001 (Checkmate Pharmaceuticals); ADU-S100 (Aduro BioTech Inc. and Novartis); imprime PGG® (Biothera Pharmaceuticals Inc), dorgemeltucel-L (NewLink Genetics Corp), MG1MA3 (Turnstone Biologics Inc) and ruxotemotide (LTX-315, Lytix Biopharma AS). Most of these competitors have ongoing combination trials with the approved checkpoint inhibitors.

BL-5010

BL-5010 will compete with a variety of approved destructive and non-destructive treatments for skin lesions. Both Endwarts® (Meda Health) and Eskata® (Aclaris therapeutics) are medical device-based treatments marketed for removal of warts.

Insurance

We maintain insurance for our offices and laboratory in Israel. This insurance covers approximately \$4.8 million of equipment, consumables and lease improvements against risk of fire, lightning, natural perils and burglary (the latter coverage limited to \$250,000), and \$1.5 million of consequential damages (covering fixed damages and extra expenses). For our clinical activities, we carry life science liability insurance covering general liability with an annual coverage amount of \$30.0 million per occurrence and product liability and clinical trials coverage with an annual coverage amount of \$30.0 million each claim and in the aggregate. The annual aggregate as well as the maximum indemnity for a single occurrence, claim or circumstances under this insurance is \$30.0 million. In addition, we maintain the following insurance: employer's liability with coverage of approximately \$10.0 million for each occurrence and in the aggregate; third-party liability with coverage of approximately \$5.0 million for each occurrence and in the aggregate; all risk coverage of approximately \$2.0 million for electronic and mechanical equipment; directors' and officers' liability with coverage of \$20.0 million for each occurrence and in the aggregate; and a global travel insurance policy.

We procure stock throughput insurance (cargo marine) coverage when we ship substances for our clinical studies. Such insurance is customized 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 “Business — Government Regulation and Funding — Israel Ministry of Environment — Toxin Permit.”

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 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 early 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, a trend toward harmonization of drug and medical device approval standards, starting in individual countries in Europe and then in the EU as a whole, in Japan, and in the United States under the aegis of what is now known as the International Council on Harmonisation, or ICH (created as the International Conference on Harmonisation in 1990), is gradually narrowing these differences. 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 including Canada, Hong Kong, Japan, Saudi Arabia, Singapore, South Africa, South Korea, Switzerland, Taiwan, Turkey and Australia.

Summaries of the United States, EU and Israeli regulatory processes follow 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 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 NDA process or subject to another regulatory procedure, the steps required before a drug may be marketed in the United States include:

- preclinical laboratory tests, animal studies and formulation development;
- submission to the FDA of a request for an IND to conduct human clinical testing;
- adequate and well controlled clinical trials to determine the safety and efficacy of the drug for each indication as well as to establish the exposure levels;
- submission to the FDA of an application for marketing approval;
- 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 drug for marketing.

Preclinical studies include laboratory evaluation of product chemistry, toxicity, formulation and stability, 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 study drug fails to meet cGMP 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 involve the administration of the investigational drug to people under the supervision of qualified investigators in accordance with the principles of good clinical practice, or GCP. 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 U.S. study protocol to the FDA as part of an IND. Foreign clinical trials may or may not be conducted under an IND. However, their safety assessments are included in an IND annual report.

We conduct clinical trials typically in three sequential Phases, but the Phases may overlap or be combined. An institutional review board, or IRB, must review and approve each trial before it can begin. Phase 1 includes the initial administration of a tested drug to 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 GLP, 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 ethnic diversity in the United States.

NDA and BLA

After successful completion of the required clinical testing, an 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 of 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. Although 505(b)(2) is a type of NDA, it has been used in the United States to obtain approval of follow-on biologics (also termed biosimilars) where limited clinical data is necessary to show that the follow-on is the same as the reference product. However, 505(b)(2) can be used to seek approval for a biologic only until March 23, 2020, and only for follow-on biologics of a class for which a product has already been approved under 505(b)(2). In this way, several natural source products and recombinant proteins have been approved as generic drugs under Section 505(b)(2) of the FDCA. An additional pathway for approval of follow-on biologics is discussed in the section "Generic Competition" below. 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. Separate fees are payable for an Abbreviated New Drug Application, or ANDA, and for Biosimilar Biological Product Development, or BPD.

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 or if the applicant submits a major amendment during the review. 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 GMP. If the FDA determines that the NDA or BLA is supported by adequate data and information, the FDA may issue an approval letter. During review, the FDA may request additional information via an information request, or IR letter, or state deficiencies via a deficiency letter, or DR letter. Upon compliance with the conditions stated, 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 complete response letter. The complete response letter indicates that the review cycle for an application is complete and that the application is not ready for approval. The complete response letter will describe specific deficiencies and, when possible, will outline recommended actions the applicant might take in order to place the application in condition for approval. Following receipt of a complete response letter, the company may submit additional information and start a new review cycle, withdraw the application or request a hearing. Failure to take any of the above actions may result in the FDA considering the application withdrawn following one year from issuance of the complete response letter. In such cases, the FDA will notify the company and the company will have 30 days to respond and request an extension of time in which to resubmit the application. The FDA may grant reasonable requests for extension. If the company does not respond within 30 days of the FDA's notification, the application will be considered withdrawn. Even with submission of additional information for a new review cycle, 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 and BLAs (or 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). In addition, under the Best Pharmaceuticals for Children Act, or BPCA, the FDA may issue a written request to the company to conduct clinical trials in the pediatric population that are related to the moiety and expand on the claimed indication. The studies are voluntary, but may award the company with 6 months of marketing exclusivity if conducted according to good scientific principles and address the written request. Finally, a sponsor can request that a product that must be studied under PREA to be studied also under the BPCA to allow the sponsor to be eligible for six-months of pediatric exclusivity. The pediatric studies requested under BPCA are usually more extensive and would generally also fulfill the PREA requirement; however, even if the sponsor does not complete the studies outlined in the BPCA written request, it is still required to complete any studies required under PREA.

Post-Marketing 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 filing of an ANDA, under section 505(j), of the Federal Food, Drug and Cosmetic Act which relies on bioequivalence studies that compare the generic drug to a reference listed drug to support approval. 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.

Section 7002 of the Patient Protection and Affordable Care Act, which is referred to as the Biologics Price Competition and Innovation Act of 2009, or BPCIA, amends Section 351 of the Public Health Service Act to create an abbreviated BLA for “highly similar” biological products; the abbreviated BLA permits a follow-on biological product to be evaluated against only a single reference biological product. To be considered for an abbreviated BLA, the biosimilar must have the same presumed mechanism of action, route of administration, dosage form and potency as the innovator product. It may only be reviewed and approved for indications for which the FDA already has approved the innovator product.

The BPCIA provides the manufacturer of the innovator product with economic protection by granting a period of “exclusivity” during which follow-on products may not be approved. A BLA for approval of a follow-on biological product may not be submitted for four years after the reference product was initially approved. The FDA may not approve a BLA for a follow-on biological product until 12 years after the reference product was first licensed. No additional period of exclusivity will be granted to a previously licensed biologic product when subsequent applications are made for a new indication, route of administration, dosage form, or dosing strength. However, each of the periods of exclusivity may be extended by six months if studies of the innovator biological product in the pediatric population are requested by the U.S. Secretary of Health and Human Services and carried out.

To encourage the development of biosimilars, the BPCIA grants 1 year of exclusive marketing rights to the first follow-on biological that is approved as being “interchangeable” with a reference product. If patent litigation between the manufacturers of the biosimilar and innovator products is ongoing, this period of exclusivity may be extended for up to 42 months.

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 QSRs. Some Class I medical devices require 510(k) pre-market notification although most are exempt;
- Class II: general controls, 510(k) pre-market notification, and specific controls such as performance standards, patient registries, and postmarket surveillance; and
- Class III: general controls and approval of a pre-market approval, or PMA.

All new devices are class III by operation of law unless the FDA (1) determines the new device to be substantially equivalent (SE) to a device previously classified in class I or class II, (2) grants a risk-based (“de novo”) classification request, or (3) reclassifies the device into class I or II.

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 post-approval 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, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA upon receipt of the respective IRB approvals. 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 do not 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

Clinical Trials

The European Medicines Agency, or the Agency, relies on the results of clinical trials carried out by pharmaceutical companies to reach its opinions on the authorization of medicines. Although the authorization of clinical trials occurs at member state level, the Agency plays a key role in ensuring that the standards of good clinical practice (GCP) are applied across the European Economic Area (EEA) in cooperation with the member states. It also manages a database of clinical trials carried out in the EU. Clinical trials are currently regulated under Directive 2001/20/EC. However, in April 2014 a new regulation on clinical trials on medicinal products for human use was adopted. Regulation 536/2014, or the Regulation, entered into force on in June 2014 and is scheduled to become effective in during 2020. The Regulation will apply to interventional clinical trials on medicines once the Regulation is in operation, and to all trials authorized under the previous legislation (Directive (EC) No. 2001/20/EC) and still ongoing three years (the transition period) after the Regulation has come into operation. The Regulation ensures that:

- the rules for conducting clinical trials are consistent throughout the EU; and
- transparent information is made publicly available on the authorization, conduct, and results of each clinical trial carried out in the EU.

Marketing Authorization Procedures

A medicinal product may only be placed on the market in the EEA composed of the 28 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 amended, or an authorization has been granted under the centralized procedure in accordance with Regulation (EC) No. 726/2004, as amended, or its predecessor, Regulation 2309/93. There are essentially three EU 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.

In 2016, the United Kingdom conducted a referendum and voted to leave the European Union, also known as “Brexit.” On March 29, 2017, the British government invoked Article 50 of the Treaty on the European Union and, as a result, the United Kingdom is scheduled to leave the European Union on March 29, 2019. The United Kingdom and European Union are currently in the process of defining their future relationship, and the steps we need to take, if any, in order to conform to the new circumstances will depend on the nature of that relationship.

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 EMA. That authorization is valid throughout the entire EEA 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 EMA 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 or veterinary products designed to promote animal growth or increase yield in accordance with Paragraph 2. The mandatory centralized procedure is applicable to: (a) medicinal products for human use containing an active substance authorized in the EU after May 20, 2004 for which the therapeutic indication is the treatment of acquired immune deficiency syndrome, or AIDS, cancer, neurodegenerative disorder or diabetes; (b) autoimmune diseases and other immune dysfunctions and viral diseases; (c) all medicinal products that are designated as orphan medicinal products pursuant to Regulation 141/2000; and (d) medicines derived from biotechnology processes or advanced therapy medicinal products, such as gene therapy, tissue engineered and somatic cell therapy products. 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 EU level. For each application submitted to the EMA for scientific assessment, the EMA 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 or within 150 days by means of an accelerated procedure. If the opinion is positive, the EMA is required to send the opinion to the European Commission, which is responsible for preparing the decision granting a marketing authorization, within 67 days. 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 EU.

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 EU 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)) in accordance with Article 28 of Directive 2001/83/EC. 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. In both procedures, national marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

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 EMA's scientific committee 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 for medicines and investigational medicines for human use or Directive 91/412/EEC for medicines for veterinary use and Volume 4 of the "Rules Governing Medicinal Products in the European Community" and distributed in accordance with Directive 92/25/EEC and current guidance. Moreover, EU law requires the clinical results in support of clinical safety and efficacy to be based upon clinical trials conducted in the EU in compliance with the requirements of Directives 2001/20/EC and 2005/28/EC, which implement good clinical practice in the conduct of clinical trials on medicinal products for human use. Clinical trials conducted outside the EU 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 EU.

National Procedure

In order to increase availability of medicinal products, in particular on smaller markets, Article 126a of Directive 2001/83/EC, or Article 126a, provides that, in the absence of a marketing authorization or of a pending application for authorization for a medicinal product, which has already been authorized in another member state, a member state may for justified public health reasons authorize the placing on the market of that medicinal product. In such cases, the competent authority of the member state has to inform the marketing authorization holder in the member state in which the medicinal product concerned is authorized, of the proposal to authorize the placing on the market under this Article.

When a member state avails itself of this possibility, it must adopt the necessary measures in order to ensure that the requirements for the labelling and package leaflet, classification of the medicinal product, advertising, pharmacovigilance and supervision and sanctions are complied with. For the specific mechanisms chosen by the member states to implement this provision, the relevant national legislation is referred to. The register of the medicinal products authorized under Article 126a is available at the European Commission website.

For medicinal products authorized in accordance with Article 126a of Directive 2001/83/EC, marketing authorization holders do not qualify for the pediatric development rewards as described in Regulation (EC) No. 1901/2006.

Types of Marketing Authorization Applications:

There are various types of applications for marketing authorizations. The legal basis for all types of application is set out in Directive 2001/83/EC and in Regulation (EC) No726/2004.

A. Full Applications. A full application is one that is made under any of the EU 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/EC, 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, as amended. 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.

B. 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 four 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 (used for generic medicines or similar biological medicinal products); (2) well-established use according to published literature; (3) fixed combination products; and (4) informed consent to refer to an existing dossier of research results filed by a previous applicant.

(1) Cross-referral to Innovator's Data

Generic Applications. 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 EU 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. For applications made after either October 30 or November 20, 2005 (depending on the approval route used), 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 has expired, be found on the originator's file and used for assessment of the generic medicinal product. The 10-year 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.

Hybrid Applications (equivalent to the U.S. 505(b)(2) NDA). 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.

Similar Biological Applications. Article 10(4) of Directive 2001/83/EC refers to a biological medicinal product which is similar to a reference biological product and does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product. For such products, the results of appropriate preclinical tests or clinical trials relating to these conditions must be provided in accordance with the criteria stated in the annex and related guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

(2) 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 well-established medicinal use within the EU 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 EU. 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 literature refers, additional preclinical and/or clinical results would have to be provided.

(3) Fixed Combination Application

Under Article 10(b) of Directive 2001/83/EC, as amended, and Annex I, Part II(5), fixed-combination applications are possible for medicinal products containing active substances used in the composition of authorized medicinal products (but not to be used in combination for therapeutic purposes). In that case, the results of new preclinical tests or new clinical trials relating to that combination shall be provided in accordance with Article 8(3) (i) of Directive 2001/83/EC, but it is not necessary to provide scientific references relating to each individual active substance. Moreover, any fixed combination may be considered a complete/full, independent application because it is a new and unique medicinal product requiring a separate SmPC.

(4) 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.

C. Mixed Marketing Authorization Applications

Annex I, Part II(7) of Directive 2001/83/EC, as amended, specifies that mixed marketing authorization applications, or MAAs, must present published scientific literature together with original results of tests and trials. Such applications must be submitted and processed following the complete, full and independent MAA dossier requirements. These requirements apply to the use of bibliographic references in mixed dossiers both as supporting data for the applicant's own tests and trials or in order to replace any tests or trials in Module 4 and/or 5. All other module(s) are in accordance with the structure described in Part I of the above-mentioned Annex 1. The Competent Authority will accept the applicant's proposed format on a case-by-case basis.

Law Relating to Pediatric Research

Regulation (EC) 1901/2006 (as amended by Regulation (EC) 1902/2006), or the Pediatric Regulation, 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 EU 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 or unless the product is excluded from the scope of Regulation 1902/2006 (generics, hybrid medicinal products, biosimilars, homeopathic and traditional (herbal) medicinal products and medicinal products containing one or more active substances of well-established medicinal use. 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 imposes 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 codified as Regulation (EC) no. 469/2009 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. If any of the non-centralized procedures for marketing authorization have been used, the six-month extension of the supplementary protection certificate is only granted if the medicinal product is authorized in all member states. 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, or PUMA, which, on approval, will provide eight years' protection for data and 10 years' marketing protection for the pediatric results.

In June 2013, the European Commission published a **report on the first five years of implementation of the Pediatric Regulation**. The report concludes that pediatric development has become a more integral part of the overall development of medicinal products in the EU, with the Regulation working as a major catalyst to improve the situation for young patients. In November 2016, the European Commission launched a public consultation in preparation for its second report on the Pediatric Regulation after nearly ten years of implementation. The European Commission published the final report in October 2017.

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 provision of a risk management plan and provision of annual periodic safety update reports, carrying out of post-authorization efficacy studies and/or post-authorization safety studies, maintenance of a pharmacovigilance system master file, adverse event reporting, signal detection and management and other pharmacovigilance activities conducted under an established quality system, 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.

Another relevant aspect in the EU regulatory framework is the “sunset clause”: a provision leading to the cessation of the validity of any marketing authorization if it is not followed by marketing within three years or, if marketing is interrupted for a period of three consecutive years.

Approval of Medical Devices

In the EEA there is a consolidated system for the authorization of medical devices. Currently applicable regulations are: Regulation 2017/745 on Medical Devices (amending Directive 2001/83/EC, Regulation 178/2002 and 1223/2009 and repealing Directives 93/42/EEC and Directive 90/385/EEC regarding active implantable medical devices), and Regulation 2017/746 regarding in vitro diagnostic medical devices (repealing Directive 98/79/EC and commission decision 2010/227/EU). The new regulations will apply after a 3-year transitional period (in May 2020) for the regulation of medical devices and a five-year transitional period (May 2022) for the regulation of in-vitro diagnostic medical devices. The EU requires that manufacturers of medical devices obtain the right to affix the CE mark to their products, which shows that the device has a Declaration of Conformity, before selling them in EU 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 EU without further conformance tests being required in other member states.

Israel

Israel Ministry of the Environment — Toxin Permit

In accordance with the Israeli Dangerous Substances Law - 1993, the Israeli 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 December 2021.

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. These regulations require authorization by the institutional ethics committee and general manager as well as from the Israeli Ministry of Health, except in certain circumstances, and in the case of genetic trials, special fertility trials and complex clinical trials, an additional authorization of the Israeli Ministry of Health's overseeing 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 in most cases, from the Israeli Ministry of Health.

Other Countries

In addition to regulations in the United States, the EU 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 EMA 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 EMA 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 Innovation Authority

Research and Development Grants. A number of our therapeutic products have been financed, in part, through funding from the IIA in accordance with Research Law. Through December 31, 2018 we have received approximately \$22.0 million in aggregate funding from the IIA and have paid the IIA approximately \$6.3 million in royalties under our approved programs. As of December 31, 2018, we have no contingent obligation to the IIA other than for BL-8040. In connection with the in-licensing of BL-8040 from Biokine, and as a condition to IIA consent to the transaction, we agreed to abide by any obligations resulting from funds previously received by Biokine from the IIA. The contingent liability to the IIA assumed by us relating to this transaction (which liability has no relation to the funding actually received by us) amounts to \$3.2 million as of December 31, 2018. We have a full right of offset for amounts payable to the IIA from payments that we may owe to Biokine in the future. Therefore, the likelihood of any payment obligation to the IIA with regard to the Biokine transaction is remote.

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 IIA were payable to the Israeli government, generally at the rate of 3% although these terms would be different if we were to receive IIA approval to manufacture or to transfer the rights to manufacture our products developed with IIA grants outside of Israel. The obligation to make these payments terminates upon repayment of the amount of the received grants as adjusted for fluctuation in the dollar/shekel exchange rate, plus interest and any additional amounts as described below. However, we could be required to pay an increased total amount of royalties (possibly up to 300% of the grant amounts plus interest) if we receive approval to manufacture or to transfer the rights to manufacture our products developed with IIA grants outside of Israel, depending on the portion of total manufacturing that was performed outside of Israel, as further described below, and we could be required to pay additional amounts in respect of the technology developed under these projects that was otherwise transferred outside of Israel, as further described below. The amounts received bear interest equal to the 12-month London Interbank Offered Rate applicable to dollar deposits that was published on the first business day of each calendar year.

Pursuant to the Research Law and the tracks published by the IIA, recipients of funding from the IIA are prohibited from manufacturing products developed using IIA grants or derived from technology developed with IIA grants outside of Israel and from transferring rights to manufacture such products outside of Israel. However, the IIA could, in special cases, approve the transfer of manufacture or of manufacturing rights of a product developed in an approved program or which resulted therefrom, outside of Israel. If we were to receive approval to manufacture or to transfer the rights to manufacture our products developed with IIA 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 was performed outside of Israel. In addition, the royalty rate applicable to us could possibly increase. Such increased royalties constituted the total repayment amount required in connection with the transfer of manufacturing rights of IIA-funded products outside Israel. The tracks published by the IIA do enable companies to seek prior approval for conducting manufacturing activities outside of Israel without being subject to increased royalties (but resulting in a lower grant amount); however, the IIA rarely granted such prior approval.

Under the Research Law and the tracks published by the IIA, we are prohibited from transferring or licensing our IIA-financed technologies, technologies derived therefrom and related intellectual property rights and know-how outside of Israel except under limited circumstances and only with the approval of the IIA and generally upon making a payment to the IIA. The required approvals may not be received for any proposed transfer and, if received, we could be required to pay the IIA an amount calculated in accordance with the applicable formula set out in the tracks published by the IIA. The scope of the support received, the royalties that we already paid to the IIA, the amount of time that elapsed between the date on which the technology was transferred and the date on which the applicable project performance period for the IIA grants was completed, and the sale price and the form of transaction are to be taken into account in order to calculate the amount of the payment to the IIA. The repayment amount is subject to a maximum limit calculated in accordance with a formula set forth in guidelines published by the IIA. 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 IIA with respect to the product or technology, could require us to notify, or to obtain the approval of, the IIA, and could result in increased royalty payments to the IIA 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 was performed outside of Israel.

Approval of the transfer or license of technology to residents of Israel is required and could be granted in specific circumstances, only if the recipient agreed to abide by the provisions of applicable laws, including the restrictions on the transfer of know-how and the obligation to pay royalties.

The State of Israel does not own intellectual property rights in technology developed with IIA funding and there is no restriction on the export of products manufactured using technology and know-how developed with IIA funding. The technology and know-how is, however, subject to transfer of technology and manufacturing rights restrictions as described above.

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 EMA, making it comparatively straightforward for studies conducted in Israel to satisfy FDA and the EMA requirements, thereby enabling medical technologies subjected to clinical trials in Israel to reach U.S. and EU 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 EU.

C. Organizational Structure

Our corporate structure consists of BioLineRx Ltd., a substantially wholly-owned U.K. subsidiary, Agalimmune Ltd., and one wholly-owned inactive subsidiary, BioLineRx USA Inc.

D. Property, Plant and Equipment

We are headquartered in Modi'in, Israel. The facility consists of 1,663 square meters (approximately 17,900 square feet) of space and lease payments are approximately \$31,000 per month, including maintenance fees and parking. This facility houses both our administrative and research operations and our central laboratory. The central laboratory consists of approximately 380 square meters (approximately 4,200 square feet) and includes a bioanalytical laboratory, a formulation laboratory and a tissue culture laboratory. Our bioanalytical laboratory has received GLP certification. All of our employees are based in this facility.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

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 Annual Report on Form 20-F. 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 Annual Report on Form 20-F, particularly those in “Item 3. Key Information — Risk Factors.”

We are a clinical-stage biopharmaceutical development company with a strategic focus on oncology. Our current development and commercialization pipeline consists of two clinical-stage therapeutic candidates – BL-8040, a novel peptide for the treatment of hematological malignancies, solid tumors and stem cell mobilization, and AGI-134, an immuno-oncology agent in development for solid tumors. In addition, we have an off-strategy, legacy therapeutic product called BL-5010 for the treatment of skin lesions. We have generated our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a high probability of therapeutic and commercial success. 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.

A. Operating Results

History of Losses

Since our inception in 2003, we have generated significant losses in connection with our research and development. As of December 31, 2018, we had an accumulated deficit of \$222.5 million. 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 expect to continue to incur operating losses, which may be substantial over the next several years, and we expect to need to obtain additional funds to further pursue our research and development programs.

We have funded our operations primarily through the sale of equity securities (both in public and private offerings), payments received under our strategic licensing and collaboration arrangements, interest earned on investments and funding received from the IIA. We expect to continue to fund our operations over the next several years through our existing cash resources, potential future upfront, milestone, royalty or other payments that we may receive from our existing out-licensing agreements, potential future upfront or milestone payments that we may receive from out-licensing transactions for our other therapeutic candidates, interest earned on our investments and additional capital to be raised through public or private equity offerings or debt financings. As of December 31, 2018, we held \$30.2 million of cash, cash equivalents and short-term bank deposits. In February 2019, we completed a public offering of ADSs and warrants for net proceeds of \$14.1 million.

Revenues

Our revenues to date have been generated primarily from milestone payments under current and previously existing out-licensing agreements.

We expect our revenues for the next several years to be derived primarily from payments under collaboration and partnering arrangements, including future royalties on product sales.

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 to remain our primary expense in the near future as we continue to develop our therapeutic candidates.

The following table identifies our current pipeline projects:

Project	Status	Expected Near Term Milestones
BL-8040	<ol style="list-style-type: none"> 1. Phase 2a study for relapsed or refractory AML completed 2. Phase 2b study in AML consolidation treatment line (BLAST) ongoing 3. Phase 2 study in allogeneic stem cell mobilization completed 4. Phase 2a in pancreatic cancer under Merck collaboration (COMBAT/KEYNOTE-202) ongoing; top-line results from dual combination arm announced in October 2018 5. Phase 2b study in pancreatic cancer, in collaboration with MD Anderson Cancer Center, ongoing 6. Phase 1b/2 study in AML, in collaboration with Genentech (BATTLE), ongoing 7. Phase 1b/2 studies in pancreatic and gastric cancer, under collaboration with Genentech (MORPHEUS) ongoing 8. Phase 3 registration study in autologous stem cell mobilization commenced (GENESIS); partial results from initial dose-confirmation, lead-in part of study announced August 2018 	<ol style="list-style-type: none"> 1. Follow-up for overall survival is ongoing; evaluation and decision regarding next clinical development steps 2. Possible interim results in H2 2019; top-line results expected in 2021 3. Follow-up on chronic GvHD by H2 2019 4. Top-line results from triple combination arm expected in H2 2019; overall survival results expected in 2020 5. Partial results from this study are anticipated in H1 2019; top-line results expected in 2020 6. Top-line results expected in 2021 7. Top-line results in 2019 8. Top-line results from randomized, placebo-controlled main part of study expected in H2 2020
AGI-134	Phase 1/2a study commenced in July 2018	Initial safety results from part 1 of study in H2 2019; initial efficacy results of monotherapy arm from part 2 of study expected by end of 2020
BL-5010	Out-licensed to Perrigo; CE mark approval obtained; commercial launch of first OTC indication in Europe	Launch of improved product during 2019; pursuit of potential out-licensing partner(s) for OTC and non-OTC rights still held by us

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 "Item 3. Key Information — 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 cost of drug substance/product manufacturing, storage and shipment;
- the number of patients that participate in the clinical trials;
- the duration of patient follow-up;
- whether the patients require hospitalization or can be treated on an out-patient basis;
- 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 remain our most significant cost 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. Due to 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.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of compensation for employees in business development and marketing functions. Other significant sales and marketing costs include costs for marketing and communication materials, professional fees for outside market research and consulting, legal services related to partnering transactions and travel costs.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and operational functions, including accounting, finance, legal, 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.

Non-Operating Expense and Income

Non-operating expense and income includes fair-value adjustments of derivative liabilities on account of the warrants issued in direct placements which we conducted in 2013 and 2017 and in a debt financing in 2018. These fair-value adjustments are highly influenced by our share price at each period end (revaluation date). Non-operating expense and income also includes the pro-rata share of issuance expenses from the private and direct placements related to the warrants, as well as the capital gain from realization of our investment in iPharma, a joint venture our holdings in which we sold in April 2018. Sales-based royalties and other revenue from the license agreement with Perrigo have also been included as part of non-operating income, as the out-licensed product is not an integral part of our strategy and the amounts are not material.

Financial Expense and Income

Financial expense and income consist of interest earned on our cash, cash equivalents and short-term bank deposits; interest expense related to our loan from Kreos Capital; bank fees and other transactional costs. In addition, it may also include gains/losses on foreign exchange hedging transactions, which we carry out from time to time to protect against a portion of our NIS-denominated expenses (primarily compensation) in relation to the dollar.

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, 2018. 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 using 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, including those described in greater detail below. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which impact the carrying value of our assets and liabilities that are not readily apparent from other sources. Actual results will differ from these estimates and such differences may be significant.

Revenue Recognition

We recognize revenues in accordance with International Financial Reporting Standards No. 15, or IFRS 15. IFRS 15, "Revenue from Contracts with Customers," which was issued in May 2014, amends revenue recognition requirements and establishes principles for reporting information about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The standard replaces International Auditing Standard, or IAS, 18, "Revenue" and IAS 11, "Construction Contracts" and related interpretations. The standard is effective for annual periods beginning on or after January 1, 2018, and we have adopted it as of that date.

IFRS 15 introduces a five-step model for recognizing revenue from contracts with customers, as follows:

- identify the contract with a customer;
- identify the performance obligations in the contract;
- determine the transaction price;
- allocate the transaction price to the performance obligations in the contract; and
- recognize revenue when (or as) the entity satisfies a performance obligation.

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 and on a semi-annual basis to the Investment Monitoring Committee of our Board of Directors. Any divergence from this investment policy requires approval from our Board of Directors.

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 the 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 stock-based compensation 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 ordinary shares are publicly traded on the TASE, we do not need to estimate their fair market value. Rather, we use the actual closing market price of our ordinary shares on the date of grant, as reported by the TASE.

Warrants

In connection with the direct placement to OrbiMed Israel Partners Limited Partnership of approximately 2.67 million of our ADSs in February 2013, we issued warrants to purchase 1.6 million of our ADSs at an exercise price of \$3.94, subject to typical adjustments. The warrants were exercisable for a period of five years from the date of issuance. Since the exercise price was not deemed to be fixed, the warrants did not qualify for classification as an equity instrument and were therefore classified as a non-current financial liability. The warrants expired in February 2018 without having been exercised.

In connection with the direct placement to BVF Partners L.P., or BVF Partners, of 8,495,575 ADSs in July 2017, we issued (i) Series A warrants to purchase 2,973,451 ADSs at an exercise price of \$2.00 per ADS and (ii) Series B warrants to purchase 2,973,451 ADSs at an exercise price of \$4.00 per ADS. All the warrants are exercisable for a period of four years from the date of issuance. Since the exercise price was not deemed to be fixed, the warrants are not qualified for classification as an equity instrument and have therefore been classified as a non-current financial liability.

In connection with a loan transaction entered into with Kreos Capital, we issued a warrant to purchase 957,549 ADSs at an exercise price of \$0.94 per ADS. The warrant is exercisable for a period of ten years from the date of issuance. Since the exercise price was not deemed to be fixed, the warrant is not qualified for classification as an equity instrument and has therefore been classified as a non-current financial liability.

In connection with a public offering we completed in February 2019, we issued warrants to purchase 28,000,000 ADSs at an exercise price of \$0.75 per ADS. The warrants are exercisable for a period of five years from the date of issuance. Since the exercise price was not deemed to be fixed, the warrant is not qualified for classification as an equity instrument and has therefore been classified as a non-current financial liability.

Recent Accounting Changes and Pronouncements

There were no changes in the accounting policies applied by the Company during 2018, other than adoption of IFRS 15, as discussed above under "Revenue Recognition."

For information concerning new standards and interpretations not yet adopted, see Note 2q to our consolidated financial statements for the year ended December 31, 2018 included elsewhere in this report.

Results of Operations -- Overview

Revenues

We did not record any revenues for the years ended December 31, 2016, 2017 and 2018.

Cost of revenues

We did not record any cost of revenues for the years ended December 31, 2016, 2017 and 2018.

Research and development expenses

At December 31, 2015, our drug development pipeline consisted of eight therapeutic candidates. During 2016, we added three compounds to our pipeline and discontinued the development of three compounds in our pipeline, so that our drug development pipeline as of December 31, 2016 consisted of eight therapeutic candidates. During 2017, we terminated two therapeutic candidates in our pipeline, and added one therapeutic candidate to the pipeline, so that our drug development pipeline as of December 31, 2017 consisted of seven therapeutic candidates. Subsequent to December 31, 2017, we terminated four therapeutic candidates in our pipeline, so that our drug development pipeline as of the date of this report consists of three therapeutic candidates.

Comparison of the Year Ended December 31, 2018 to the Year Ended December 31, 2017

Research and development expenses

Research and development expenses for the year ended December 31, 2018 were \$19.8 million, an increase of \$0.3 million, or 1.5%, compared to \$19.5 million for the year ended December 31, 2017. The small increase resulted primarily from an increase in share-based compensation.

Sales and marketing expenses

Sales and marketing expenses for the year ended December 31, 2018 were \$1.4 million, a decrease of \$0.3 million, or 19.6%, compared to \$1.7 million for the year ended December 31, 2017. The decrease resulted primarily from one-time legal fees related to AGI-134, as well as market research for BL-8040 and AGI-134 incurred in the 2017 period.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2018 were \$4.4 million, an increase of \$0.4 million, or 9.9% compared to \$4.0 million for the year ended December 31, 2017. The increase resulted primarily from an increase in share-based compensation.

Non-operating income (expense), net

We recognized net non-operating income of \$2.4 million for the year ended December 31, 2018, compared to net non-operating expenses of \$0.3 million for the year ended December 31, 2017. Non-operating income for the year ended December 31, 2018 primarily relate to fair-value adjustments of warrant liabilities on our balance sheet and the capital gain from realization of our investment in iPharma. Non-operating expenses for the year ended December 31, 2017 primarily relate to fair-value adjustments of warrant liabilities on our balance sheet. These fair-value adjustments were highly influenced by our share price at each period end (revaluation date).

Financial income (expense), net

We recognized net financial income of \$0.2 million for the year ended December 31, 2018 compared to net financial income of \$1.1 million for the year ended December 31, 2017. Net financial income for the year ended December 31, 2018 primarily relates to investment income earned on our bank deposits, offset by interest paid on loans. Net financial income for the year ended December 31, 2017 relates primarily to gains recorded on foreign currency hedging transactions and investment income earned on our bank deposits.

Comparison of the Year Ended December 31, 2017 to the Year Ended December 31, 2016

Research and development expenses

Research and development expenses for the year ended December 31, 2017 were \$19.5 million, an increase of \$8.3 million, or 74.6%, compared to \$11.2 million for the year ended December 31, 2016. The increase resulted primarily from higher expenses in 2017 associated with new BL-8040 clinical studies commenced during the third quarter of 2016 and during 2017, as well as spending on our new AGI-134 near-clinical project.

Sales and marketing expenses

Sales and marketing expenses for the year ended December 31, 2017 were \$1.7 million, an increase of \$0.3 million, or 25.2%, compared to \$1.4 million for the year ended December 31, 2016. The increase resulted primarily from one-time legal fees related to AGI-134.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2017 were \$4.0 million, similar to those for the year ended December 31, 2016.

Non-operating income (expense), net

We recognized net non-operating expenses of \$0.3 million for the year ended December 31, 2017 compared to net non-operating income of \$0.2 million for the year ended December 31, 2016. Non-operating expenses and income for both periods primarily relate to fair-value adjustments of warrant liabilities on our balance sheet. These fair-value adjustments were highly influenced by our share price at each period end (revaluation date).

Financial income (expense), net

We recognized net financial income of \$1.1 million for the year ended December 31, 2017 compared to net financial income of \$0.5 million for the year ended December 31, 2016. The increase in net financial income relates primarily to gains recorded on foreign currency hedging transactions and higher investment income due to higher levels of cash and short-term bank deposits.

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 statement 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
	2017				2018			
	(in thousands of U.S. dollars)							
Consolidated Statements of Operations								
Revenues	-	-	-	-	-	-	-	-
Cost of revenues	-	-	-	-	-	-	-	-
Research and development expenses	(3,590)	(4,062)	(5,654)	(6,204)	(5,070)	(4,484)	(5,027)	(5,227)
Sales and marketing expenses	(681)	(288)	(249)	(475)	(484)	(360)	(293)	(225)
General and administrative expenses	(1,030)	(844)	(1,154)	(1,009)	(1,075)	(883)	(892)	(1,585)
Operating loss	(5,301)	(5,194)	(7,057)	(7,688)	(6,629)	(5,727)	(6,212)	(7,037)
Non-operating income (expenses), net	(5)	(4)	(333)	82	462	663	(255)	1,527
Financial income	457	304	153	255	175	287	154	103
Financial expenses	(6)	(3)	(6)	(6)	(206)	(11)	(11)	(245)
Net loss	(4,855)	(4,897)	(7,243)	(7,357)	(6,198)	(4,788)	(6,324)	(5,652)

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.

B. Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through public and private offerings of our equity securities, payments received under our strategic licensing and collaboration arrangements, interest earned on investments and funding from the IIA. At December 31, 2018, we held \$30.2 million in cash, cash equivalents and short-term bank deposits. In February 2019, we completed a public offering of ADSs and warrants for net proceeds of \$14.1 million. We have invested substantially all of our available cash funds in short-term bank deposits.

Pursuant to the ATM program we executed with BTIG in October 2017, we may, in our discretion and from time to time, offer and sell through BTIG, acting as sales agent, our ADSs having an aggregate offering price of up to \$30 million. From the effective date of the agreement through December 31, 2018, we sold 5,439,203 of our ADSs under the program for total gross proceeds of approximately \$5.1 million, leaving an available balance under the facility of approximately \$24.9 million.

Net cash used in operating activities for the year ended December 31, 2018 was \$24.2 million, compared to \$20.5 million for the year ended December 31, 2017 and \$14.5 million for the year ended December 31, 2016. The \$3.7 million increase in 2018 was the result of a decrease in accounts payable and an increase in prepaid expenses and other receivables. The \$6.0 million increase in 2017 was primarily the result of increased research and development expenses.

Net cash provided by investing activities for the year ended December 31, 2018 was \$9.6 million, compared to net cash used in investing activities of \$15.9 million for the year ended December 31, 2017 and net cash provided by investing activities of \$9.3 million for the year ended December 31, 2016. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits during the respective periods, as well as the acquisition of Agalimmune in 2017, the acquisition of an additional 20% of the BL-8040 sublicense receipts in 2018, and the realization of our investment in iPharma during 2018 as well.

Net cash provided by financing activities for the year ended December 31, 2018 was \$13.1 million, compared to \$38.7 million for the year ended December 31, 2017 and \$2.1 million for the year ended December 31, 2016. The cash flows in 2018 primarily reflect the net proceeds of the loan from Kreos Capital, as well as net proceeds from the ATM program. The cash flows in 2017 primarily reflect the underwritten public offering of our ADSs in March 2017 and the direct placement of ADSs and warrants to BVF Partners in July 2017. The cash flows in 2016 primarily reflect the funding under a share purchase agreement with Lincoln Park Capital Fund, LLC.

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 and other resources will be sufficient to fund our projected cash requirements into 2021, 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;
- interest and principal payments on the loan from Kreos Capital;
- any cost that we may incur under current and future licensing arrangements relating to our therapeutic candidates; and
- payments to the IIA.

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.

C. Research and Development, Patents and Licenses

For our research and development policies, see “Item 4 — Information on the Company — Business Overview — Our Strategy.” For information regarding patents, see Item 4 — Information on the Company — Intellectual Property.” For information regarding licenses, see “Item 4 — Information on the Company — Collaboration and Out-Licensing Arrangements” and Item 4 — Information on the Company — In-Licensing Agreements.”

D. Trend Information

We are a biopharmaceutical company that focuses on the development of our therapeutic candidates. It is not possible for us to predict with any degree of accuracy the outcome of our research and development or commercialization efforts with regard to any of our therapeutic candidates. Our research and development expenditure is our primary expenditure, although we may incur substantial expenditure should we acquire any new therapeutic candidates. Increases or decreases in research and development expenditure are primarily attributable to the level and results of our preclinical and clinical trial activities and the amount of expenditure on those trials.

E. Off-Balance Sheet Arrangements

Since our inception, we have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

F. Contractual Obligations

The following table summarizes our significant contractual obligations at December 31, 2018:

	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>4-5 years</u>	<u>More than 5 years</u>
	(in thousands of U.S. dollars)				
Car leasing obligations	372	214	158	–	–
Premises leasing obligations	517	340	177	–	–
Purchase commitments	13,303	6,369	6,922	12	–
Total	<u>14,192</u>	<u>6,923</u>	<u>7,257</u>	<u>12</u>	<u>–</u>

The premises leasing obligations in the foregoing table include our commitments under the lease agreement for our facility in Modi’in. See “Item 4. Information on the Company — Property, Plant and Equipment.” The term of the lease began on June 15, 2015 and will end June 30, 2020. The lease agreement grants us three options to extend the lease at our discretion, allowing us to continue leasing for an additional 10 years through June 30, 2030. Currently, we are obligated to pay monthly rental payments of \$21,000 and monthly parking charges of \$2,000. We are furthermore obligated to pay building maintenance charges of approximately \$8,000 per month.

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 material financial milestone obligations to be achieved within the next 12 months. 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 90 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 “Item 4. Information on the Company — Business Overview — In-Licensing Agreements.”

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Executive Officers and Directors

The following table sets forth information for our executive officers and directors as of March 25, 2019. Unless otherwise stated, the address for our directors and officers is c/o BioLineRx Ltd., 2 HaMa'ayan Street, Modi'in 7177871, Israel.

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
Philip A. Serlin, CPA, MBA	58	Chief Executive Officer
Mali Zeevi, CPA	43	Chief Financial Officer
Hillit Mannor Shachar, M.D., MBA, M.S.F.S. ⁽¹⁾	48	Vice President Business Development
Ella Sorani, Ph.D.	51	Vice President Research and Development
Abi Vainstein-Haras, M.D.	44	Vice President Clinical Development
Aharon Schwartz, Ph.D.	76	Chairman of the Board
Michael J. Anghel, Ph.D.	79	Director
Nurit Benjamini, MBA	52	External Director
B.J. Bormann, Ph.D.	60	Director
Raphael Hofstein, Ph.D.	69	Director
Avraham Molcho, M.D.	61	External Director
Sandra Panem, Ph.D.	72	Director

- (1) As of April 3, 2019, Dr. Shachar will be departing the Company. Philip Serlin, our Chief Executive Officer, will manage our business development efforts on an interim basis. As of the date of this report, we are meeting with potential candidates in order to fill the position.

Philip A. Serlin, CPA, MBA, has served as our Chief Executive Officer since October 2016. From May 2009 to October 2016, Mr. Serlin served as our Chief Financial and Operating Officer. 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., 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 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.

Mali Zeevi, CPA, has served as our Chief Financial Officer since October 2016. Prior to becoming Chief Financial Officer, Ms. Zeevi served as our Senior Director of Finance and Reporting beginning in 2011 and as our Director of Finance and Reporting beginning in 2009. Before joining BioLineRx, Ms. Zeevi was employed by Tescom Software Systems Testing Ltd., her last position there being Vice President Finance. Ms. Zeevi also served as a CPA at Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited. She holds a B.A. in business and accountancy from the College of Management Academic Studies in Israel.

Ella Sorani, Ph.D., has served as our Vice President Research and Development since February 2017. Before joining BioLineRx, from 2000 through 2016, Dr. Sorani served in a number of management positions in the global R&D division at Teva Pharmaceutical Industries Ltd. In her most recent position as Senior Director and Global Project Leader, Dr. Sorani led the development of one of Teva's leading innovative late stage compounds. Dr. Sorani holds a B.Sc. in chemistry and an M.Sc. and Ph.D. in pharmacology, all from Tel Aviv University.

Abi Vainstein-Haras, M.D., has served as our Vice President Clinical Development since January 2017. From June 2014 to January 2017, Dr. Vainstein-Haras served as our Senior Medical Director responsible for the clinical development of all our clinical phase projects. Prior to joining the Company, from 2012 to 2014, she served as the Director and Clinical Program Leader for COPAXONE® at Teva, and from 2007 to 2012, she served in several medical positions in Innovative R&D at Teva. Dr. Vainstein-Haras holds an M.D. from the University of Buenos Aires and is licensed to practice medicine in Israel.

Aharon Schwartz, Ph.D., has served as the Chairman of our Board of Directors since 2004. He served in a number of positions in Teva from 1975 through 2011, the most recent being Vice President, Head of Teva Innovative Ventures from 2008. Dr. Schwartz is currently a member of the board of directors of Protalix Ltd. (NYSE American:PLX), Foamix Pharmaceuticals Ltd. (NASDAQ:FOMX) and Barcode Ltd. He also works as an independent consultant. Dr. Schwartz received his Ph.D. in organic chemistry from the Weizmann Institute, his M.Sc. in organic chemistry from the Technion and a B.Sc. in chemistry and physics from the Hebrew University of Jerusalem. In addition, Dr. Schwartz holds a Ph.D. from the Hebrew University of Jerusalem in the history and philosophy of science.

Michael J. Anghel, Ph.D., has served on our Board of Directors since 2010 and on our Investment Monitoring Committee since 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). Over the years Dr. Anghel has been involved in founding and managing various technology enterprises and has served on the Boards of Directors of various major Israeli corporations and financial institutions, many of them publicly traded in the U.S. and Israel. During the past fiscal year, he completed his tenure as director for 12 years on the board of Partner Communications Company, Ltd. (Nasdaq:PTNR, TASE:PTNR), and a tenure of 9 years as a director on the board of the Strauss Group Ltd. (TASE:STRS). Dr. Anghel currently continues to serve as a director of Orbotech Ltd. (Nasdaq:ORBK), and of LUMUS-Optical Ltd. Prior to launching his business career, Dr. Anghel served as a full-time member of the faculty 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.

Nurit Benjamini, MBA, has served as an external director on our Board of Directors and as the chairperson of our Audit Committee of our Board of Directors since 2010. In addition, Ms. Benjamini has served on our Investment Monitoring Committee since 2010 and on our Compensation Committee since 2012. Since December 2013, Ms. Benjamini has served as the Chief Financial Officer of TabTale Ltd. a company that creates fresh mobile content for everyone. From 2011 to 2013, Ms. Benjamini served as the Chief Financial Officer of Wix.com Ltd. (Nasdaq:WIX); from 2007 through 2011, she served as the Chief Financial Officer of CopperGate Communications Ltd. (now Sigma Designs Israel Ltd., a subsidiary of Sigma Designs Inc. (Nasdaq:SIGM)); and from 2000 through 2007, she served as the Chief Financial Officer of Compugen Ltd. (Nasdaq: CGEN). Prior to that, from 1993 through 1998, Ms. Benjamini served as the Chief Financial Officer of Aladdin Knowledge Systems Ltd. (formerly Nasdaq: ALDN, TASE:ALDN). Ms. Benjamini serves on the board of directors, and as chairperson of the audit committee, of Allot Communications Ltd. (Nasdaq:ALLT, TASE:ALLT), RedHill Biopharma Ltd. (Nasdaq:RDHL, TASE:RDHL) and Gamida Cell Ltd. (Nasdaq:GMDA). Ms. Benjamini holds a B.A. in economics and business and an M.B.A. in finance, both from Bar Ilan University, Israel.

BJ Bormann, Ph.D., has served on our Board of Directors since August 2013. Dr. Bormann currently serves as the Vice President of Translational Science and Network Alliances at The Jackson Laboratory, a non-profit organization focused on the genetic basis of disease. Dr. Bormann was previously the Chief Executive Officer of Supportive Therapeutics, LLC, a Boston based company that is developing two molecules for use in the supportive care of oncology patients. In the past several years Dr. Bormann has held executive positions in several biotechnology companies including NanoMedical Systems (Austin, Texas), Harbour Antibodies (Rotterdam, The Netherlands) and Pivot Pharmaceuticals (PVTX: OTC listed). Prior to these engagements, Dr. Bormann was Senior Vice President responsible for world-wide alliances, licensing and business development at Boehringer Ingelheim Pharmaceuticals, Inc. from 2007 to 2013. From 1996 to 2007, she served in a number of positions at Pfizer, Inc., the last one being Vice President of Pfizer Global Research and Development and world-wide Head of Strategic Alliances. Dr. Bormann serves on the board of directors of various companies, including Xeris Pharmaceuticals (NASDAQ:XERS). Dr. Bormann received her Ph.D. in biomedical science from the University of Connecticut Health Center and her B.Sc. from Fairfield University in biology. Dr. Bormann completed postdoctoral training at Yale Medical School in the department of pathology.

Raphael Hofstein, Ph.D., has served on our Board of Directors since 2003, our Audit Committee since 2007 and our Compensation Committee since 2012. Dr. Hofstein has served as the President and Chief Executive Officer of MaRS Innovation (a commercialization company for 15 of Toronto's universities, institutions and research institutes plus the MaRS Discovery District) since June 2009. From 2000 through June 2009, Dr. Hofstein was the President and Chief Executive Officer of Hadasit Medical Research Services and Development Ltd., or Hadasit, the technology transfer company of Hadassah University Hospitals. 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. 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.

Avraham Molcho, M.D., has served as an external director on our Board of Directors and on our Audit Committee since 2010. In addition, Dr. Molcho has served on our Compensation Committee since 2012. Dr. Molcho is the founder of Biologic Design Ltd., a technology platform that encourages human antibody discoveries, and is a venture partner at Forbion Capital Partners, a Dutch life sciences venture capital firm. In 2012, he became the co-founder, Chief Executive Officer and director of Ayana Pharma Ltd. (formerly DoxoCure), a privately-held company engaged in the manufacturing of liposome-based therapeutics. From 2006 through 2008, Dr. Molcho served as the Chief Executive Officer and Chairman of Neovasc Medical, a privately-held Israeli medical device company. 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. 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.

Sandra Panem, Ph.D., has served on our Board of Directors since February 2014. She is currently a managing partner at Cross Atlantic Partners, which she joined in 2000. She is also co-founder and President of NeuroNetworks Fund, a not-for-profit venture capital fund focusing on epilepsy, schizophrenia and autism. From 1994 to 1999, Dr. Panem was President of Vector Fund Management, the then asset management affiliate of Vector Securities International. Prior thereto, Dr. Panem served as Vice President and Portfolio Manager for the Oppenheimer Global BioTech Fund, a mutual fund that invested in public and private biotechnology companies. Previously, she was Vice President at Salomon Brothers Venture Capital, a fund focused on early and later-stage life sciences and technology investments. Dr. Panem was also a Science and Public Policy Fellow in economic studies at the Brookings Institution, and an Assistant Professor of Pathology at the University of Chicago. Dr. Panem currently serves on the board of directors of Acorda Therapeutics, Inc. (Nasdaq:ACOR). Previously, Dr. Panem served on numerous boards of public and private companies, including Martek Biosciences (Nasdaq:MATK), IBAH Pharmaceuticals (Nasdaq:IBAH), Confluent Surgical, Molecular Informatics and Labcyte, Inc. She received a B.S. in biochemistry and a Ph.D. in microbiology from the University of Chicago.

B. Compensation

Employment Agreements

We have entered into written employment agreements with each of our executive officers, the terms of which are consistent with the provisions of our Compensation Policy for Executives and Directors, or Compensation Policy, which was approved by our shareholders in July 2016. 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 to the extent that these liabilities are not covered by directors' and officers' insurance. The terms of these agreements and of our directors' and officers' insurance are consistent with the provisions of the Compensation Policy.

Compensation of Directors and Senior Management

The following table presents in the aggregate all compensation we paid to all of our directors and senior management as a group for the year ended December 31, 2018. The table does not include any amounts we paid to reimburse any of such persons for costs incurred in providing us with services during this period.

	<u>Salaries, fees, commissions and bonuses</u>	<u>Pension, retirement, options and other similar benefits</u>
	<i>(in thousands of U.S. dollars)</i>	
All directors and senior management as a group, consisting of 13 persons	1,470	1,479

In accordance with the Companies Law, the following table presents information regarding compensation actually received by our five most highly-paid executive officers during the year ended December 31, 2018.

Name and Position	Salary	Social Benefits ⁽¹⁾	Bonuses	Value of Options Granted ⁽²⁾	All Other Compensation ⁽³⁾	Total
<i>(in thousands of U.S. dollars)</i>						
Philip A. Serlin Chief Executive Officer	254	69	119	381	23	846
Mali Zeevi Chief Financial Officer	150	38	59	187	16	450
Hillit Mannor Shachar Vice President Business Development	125	34	0	85	13	257
Abi Vainstein-Haras Vice President Clinical Development	167	53	40	217	18	495
Ella Sorani Vice President Research and Development	174	50	44	158	19	445

- (1) “Social Benefits” include payments to the National Insurance Institute, advanced education funds, managers’ insurance and pension funds, vacation pay and recuperation pay as mandated by Israeli law.
- (2) Consists of amounts recognized as share-based compensation expense on the Company’s statement of comprehensive loss for the year ended December 31, 2018.
- (3) “All Other Compensation” includes automobile-related expenses pursuant to the Company’s automobile leasing program, telephone, basic health insurance and holiday presents.

For additional information concerning our equity compensation plan, see “— Beneficial Ownership of Executive Officers and Directors — Equity Compensation Plan.”

C. Board Practices

Board of Directors

According to the 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.

Under the Companies Law, we are not required to have a majority of independent directors. We are required to appoint at least two external directors, unless we qualify as an Eligible Company (*as defined below*) and opt to follow an exemption provided under the Relief Regulations (*as defined below*). See “— External Directors.”

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 seven directors, including two external directors as required by the Companies Law. Pursuant to our Articles of Association, other than the external directors, for whom special election requirements apply under the Companies Law (unless the company is an Eligible Company and opted to follow the exemption provided under the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees) 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 Companies Law and our Articles of Association. In addition, our Articles of Association allow our Board of Directors to appoint directors, other than external 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 elected, under certain conditions, to two additional terms, although the term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including Nasdaq, may be further extended under certain conditions. External directors may be removed from office only pursuant to the terms of the Companies Law. Our last annual meeting of shareholders was held in July 2017. For additional information concerning external directors, see “— External Directors.”

The 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 allowing such exculpation are included in its articles of association. See “— Exculpation, insurance and indemnification of office holders.” 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 follow the requirements of the Nasdaq Rules with regard to the process of nominating directors, and instead 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, in some circumstances, our shareholders may nominate candidates for election as directors by the shareholders’ general meeting.

In addition, under the Companies Law, our Board of Directors must determine the minimum number of directors who are required to have financial and accounting expertise. Under applicable regulations, a director with financial and accounting expertise is a director who, by reason of his or her education, professional experience and skill, has a high level of proficiency in and understanding of business accounting matters and financial statements. He or she must be able to thoroughly comprehend the financial statements of the listed company and initiate debate regarding the manner in which financial information is presented. In determining the number of directors required to have such expertise, a company’s 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 we require at least one director with the requisite financial and accounting expertise. Ms. Nurit Benjamini and Dr. Michael J. Anghel have such financial and accounting expertise.

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

Chairman of the Board. Under the Companies Law, a person cannot hold the role of both chairman of the board of directors and chief executive officer of a company, without shareholder approval by special majority and for periods of time not exceeding three years each. Furthermore, a person who is directly or indirectly subordinate to a chief executive officer of a company may not serve as the chairman of the board of directors of that company and the chairman of the board of directors may not otherwise serve in any other capacity in a company or in a subsidiary of that company other than as the chairman of the board of directors of such a subsidiary.

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 second terms expired in July 2016, at which time they were each re-elected by the shareholders of the Company for a third three-year term as external directors.

External directors must be elected by majority vote of the shares present and voting at a shareholders meeting, provided that either:

- the majority of the shares that are voted at the meeting, including at least a majority of the shares held by non-controlling shareholders who do not have a personal interest in the election of the external director (other than a personal interest not deriving from a relationship with a controlling shareholder) who voted at the meeting, excluding abstentions, vote in favor of the election of the external director; or
- the total number of shares held by non-controlling, disinterested shareholders (as described in the preceding bullet point) that are voted against the election of the external director does not exceed 2% of the aggregate voting rights in the company.

After an initial term of three years, external directors may be re-elected to serve in that capacity for up to two additional terms of three years provided that either (a) the board of directors has recommended such re-election and such re-election is approved by a majority vote at a shareholders' meeting, subject to the conditions described above for election of external directors, (b) (1) the re-election has been recommended by one or more shareholders holding at least 1% of the company's voting rights and is approved by a majority of non-controlling, disinterested shareholders who hold among them at least 2% of the company's voting rights; and (2) the external director who has been nominated in such fashion by the shareholders is not a linked or competing shareholder, and does not have or has not had, on or within the two years preceding the date of such person's appointment to serve as another term as external director, any affiliation with a linked or competing shareholder, or (c) the external director has proposed himself for reappointment and the reappointment was approved by the majority described in (b)(1) above. The term "linked or competing shareholder" means the shareholder(s) who nominated the external director for reappointment or a material shareholder of the company holding more than 5% of the shares in the company, provided that at the time of the reappointment, such shareholder(s) of the company, the controlling shareholder of such shareholder(s) of the company, or a company under such shareholder(s) of the company's control, has a business relationship with the company or are competitors of the company; the Israeli Minister of Justice, in consultation with the Israeli Securities Authority, or ISA, may determine that certain matters will not constitute a business relationship or competition with the company. The term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including Nasdaq, may be extended beyond the initial three terms permitted under the 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 re-election for such additional period(s) is beneficial to the company; (b) the re-election is approved by the shareholders by a special majority required for the re-election of external directors; and (c) the term of office of the external director, and the considerations of the audit committee and the board of directors in deciding to recommend re-election of the external director for such additional term of office, are presented to the shareholders prior to the vote on re-election. 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 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 (unless the company is an Eligible Company and opted to follow the exemption provided under the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees). Under the 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 Companies Law.

A person may not serve as an external director if (a) the person is a relative of a controlling shareholder of a company or (b) at the date of the person's appointment or within the prior two years, the person, the person's relatives, entities under the person's control, the person's partner, the person's employer, or anyone to whom that person is subordinate, whether directly or indirectly, have or have had any affiliation with (1) a company, (2) a company's controlling shareholder at the time of such person's appointment or (3) any entity that is either controlled by the company or under common control with the company at the time of such appointment or during the prior two years. If a company does not have a controlling shareholder or a shareholder who holds company shares entitling him to vote at least 25% of the votes in a shareholders meeting, then a person may not serve as an external director if, such person or such person's relative, partner, employer or any entity under the person's control, has or had, on or within the two years preceding the date of the person's appointment to serve as external director, any affiliation with the chairman of the company's board, chief executive officer, a substantial shareholder who holds at least 5% of the issued and outstanding shares of the company or voting rights which entitle him to vote at least 5% of the votes in a shareholders meeting, or the chief financial officer of the company.

The term “affiliation” includes:

- an employment relationship;
- a business or professional relationship even if not maintained on a regular basis (excluding insignificant relationships);
- 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.

The term “relative” is defined as a spouse, sibling, parent, grandparent or descendant; a spouse’s sibling, parent or descendant; and the spouse of each of such persons.

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 or if the person is an employee of the ISA or of an Israeli stock exchange. Furthermore, a person may not continue to serve as an external director if he or she received direct or indirect compensation from us for his or her role as a director. This prohibition does not apply to compensation paid or given for service as an external director in accordance with regulations promulgated under the Companies Law or amounts paid pursuant to indemnification and/or exculpation contracts or commitments and insurance coverage.

Following the termination of an external director’s service on a board of directors, such former external director and his or her spouse and children may not be provided a direct or indirect benefit by the company, its controlling shareholder or any entity under its controlling shareholder’s control. This includes engagement to serve as an executive officer or director of the company or a company controlled by its controlling shareholder or employment by, or providing services to, any such company for consideration, either directly or indirectly, including through a corporation controlled by the former external director, for a period of two years (and for a period of one year with respect to relatives of the former external director).

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.

The Companies Law provides that an external director must meet certain professional qualifications or have financial and accounting expertise and that at least one external director must have financial and accounting expertise. However, if at least one of our other directors (1) meets the independence requirements of the Exchange Act, (2) meets the standards of the Nasdaq Rules for membership on the audit committee and (3) has financial and accounting expertise as defined in the Companies Law and applicable regulations, then neither of our external directors is required to possess financial and accounting expertise as long as both possess other requisite professional qualifications. Our Board of Directors is required to determine whether a director possesses financial and accounting expertise by examining whether, due to the director’s education, experience and qualifications, the director is highly proficient and knowledgeable with regard to business-accounting issues and financial statements, to the extent that the director is able to engage in a discussion concerning the presentation of financial information in the company’s financial statements, among others. Furthermore, our Board of Directors is also required to take into consideration a director’s education, experience and knowledge in any of the following: (1) accounting issues and accounting control issues characteristic to the segment in which the company operates and to companies of the size and complexity of the company, (2) the functions of the external auditor and the obligations imposed on such auditor, and (3) preparation of financial reports and their approval in accordance with the Companies Law and the Israeli Securities Law, 5728-1968, or the Israeli Securities Law. The regulations define a director with the requisite professional qualifications as a director who satisfies one of the following requirements: (1) the director holds an academic degree in either economics, business administration, accounting, law or public administration; (2) the director either holds an academic degree in any other field or has completed another form of higher education in the company’s primary field of business or in an area which is relevant to the office of an external director; or (3) the director has at least five years of experience serving in any one of the following, or at least five years of cumulative experience serving in two or more of the following capacities: (1) a senior business management position in a corporation with a substantial scope of business; (2) a senior position in the company’s primary field of business; or (3) a senior position in public administration. Our Board of Directors has determined that Ms. Nurit Benjamini possesses “accounting and financial” expertise, and that both of our external directors possess the requisite professional qualifications.

In addition, the Companies Regulations (Relief for Companies the Shares of which are Registered for Trading Outside of Israel) – 2000, or the Relief Regulations, provides an exemption for companies the shares of which are listed for trading on specified exchanges outside of Israel, including Nasdaq, provided that: (i) such company does not have a controlling shareholder; and (ii) the company complies with the requirements of the foreign securities laws and stock exchange regulations applicable to companies which are incorporated under the laws of such foreign countries with regard to appointing independent directors and composition of the audit and compensation committees, or collectively, Eligible Companies. Any Eligible Company which opts to comply with the applicable foreign securities laws and stock exchange regulations shall be exempt from the following rules under the Companies Law: (i) the requirement to have at least two external directors appointed to serve in a public company; (ii) that at least one of the external directors is required to have financial and accounting expertise and the rest are required to have professional expertise; (iii) that the external directors shall be appointed by the general meeting and subject to certain voting thresholds; (iv) that if all of the board members who are not controlling shareholders are of one gender, the appointed external director shall be of the other gender; and (v) that all of the board committees which are empowered and authorized to exercise any of the board's authorities must consist of at least one external director. The exemption from these rules under the Relief Regulations requires that the board be composed of both male and female directors.

Audit Committee

Under the 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, and one of the external directors must serve as chairperson of the committee. The audit committee of a company may not include:

- the chairman of the company's board of directors;
- a controlling shareholder or a relative of a controlling shareholder of the company (as each such term is defined in the Companies Law); or
- any director employed by the company, by a controlling shareholder of the company or by any other entity controlled by a controlling shareholder of the company, or any director who provides services to the company, to a controlling shareholder of the company or to any other entity controlled by a controlling shareholder of the company on a regular basis (other than as a member of the board of directors), or any other director whose main source of income derives from a controlling shareholder of the company.

The term "controlling shareholder" is defined in the Companies Law as a shareholder with the ability to direct the activities of the company, other than by virtue of being an office holder. A shareholder is presumed to be a controlling shareholder if the shareholder holds 50% or more of the voting rights in a company or has the right to appoint the majority of the directors of the company or its general manager.

A majority of the total number of then-serving members of an audit committee shall constitute a quorum for the transaction of business at the audit committee meetings, provided, that the majority of the members present at such meeting are unaffiliated directors and at least one of such members is an external director.

The audit committee of a publicly traded company must consist of a majority of unaffiliated directors. An "unaffiliated director" is defined as either an external director or as a director who meets the following criteria:

- he or she meets the qualifications for being appointed as an external director, except for (i) the requirement that the director be an Israeli resident (which does not apply to companies such as ours whose securities have been offered outside of Israel or are listed outside of Israel) and (ii) the requirement for accounting and financial expertise or professional qualifications; and
- he or she has not served as a director of the company for a period exceeding nine consecutive years. For this purpose, a break of less than two years in the service shall not be deemed to interrupt the continuation of the service.

Any person who is not eligible to serve on the audit committee is further restricted from participating in its meetings and votes, unless the chairman of the audit committee determines that such person's presence is necessary in order to present a certain matter, provided however, that company employees who are not controlling shareholders or relatives of such shareholders may be present in the meetings but not for the actual votes, and likewise, company counsel or company secretary who are not controlling shareholders or relatives of such shareholders may be present in the meetings and for the decisions if such presence is requested by the audit committee.

The members of our Audit Committee are Ms. Nurit Benjamini (Chairperson), Dr. Avraham Molcho and Dr. Raphael Hofstein. Pursuant to Nasdaq Rules, 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 Ms Nurit Benjamini (Chairperson) qualifies as an audit committee financial expert as defined by rules of the SEC.

In November 2012, our Board of Directors adopted an audit committee charter that added to the responsibilities of our Audit Committee under the Companies Law, setting forth the responsibilities of the audit committee consistent with the rules of the SEC and the Nasdaq Rules, including the following:

- oversight of the company's independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of our independent registered public accounting firm to our Board of Directors in accordance with Israeli law;
- recommending the engagement or termination of the office of our internal auditor; and
- reviewing and pre-approving the terms of audit and non-audit services provided by our independent auditors.

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. Our Audit Committee also oversees the audit efforts of our independent accountants and takes those actions it deems necessary to satisfy itself that the accountants are independent of management. Pursuant to the Companies Law, the audit committee of a company shall be responsible for: (i) determining whether there are delinquencies in the business management practices of a company, including in consultation with an internal auditor or independent auditor, and making recommendations to the company's board of directors to improve such practices; (ii) determining whether to approve certain related party transactions (including compensation of office holders or transactions in which an office holder has a personal interest and whether such transaction is material or otherwise an extraordinary transaction); (iii) where the company's board of directors approves the working plan of the internal auditor, examining such working plan before its submission to the board and proposing amendments thereto; (iv) examining internal control and the internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of his responsibilities (taking into consideration the special needs and size of a company); (v) examining the scope of the auditor's work and compensation and submitting its recommendation with respect thereto to the corporate body considering the appointment thereof (either the board or the general meeting of shareholders); and (vi) establishing procedures for the handling of employees' complaints as to the management of the business and the protection to be provided to such employees. The responsibilities of the audit committee under the Companies Law also include the following matters: (i) the establishment of procedures to be followed in respect of related party transactions with a controlling shareholder (where such are not extraordinary transactions), which may include, where applicable, the establishment of a competitive process for such transaction, under the supervision of the audit committee, or individual, or other committee or body selected by the audit committee, in accordance with criteria determined by the audit committee; and (ii) to determine procedures for approving certain related party transactions with a controlling shareholder, which having been determined by the audit committee not to be extraordinary transactions, were also determined by the audit committee not to be negligible transactions. Under the 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."

Pursuant to the Relief Regulations, companies the shares of which are listed for trading on specified exchanges outside of Israel, including Nasdaq, and which qualify as Eligible Companies, are exempt from the following rules regarding the audit committee under the Companies Law: (i) the committee shall be comprised of at least three members, who shall include all of the external directors, and the majority of the members shall be independent; (ii) certain persons may not be members of the audit committee; (iii) the controlling shareholder or his relatives shall not be members of the audit committee; (iv) the chairman of the audit committee shall be an external director; (v) a person who is prohibited from being a member of the audit committee shall not be present at the committee's meetings; (vi) if the committee also serves as a financial reports committee, the rules applicable to the financial reports committee shall apply; and (vii) the legal quorum shall be the majority of the committee members, provided that the majority of directors present are independent, at least one of whom is an external director.

Compensation Committee

Pursuant to the Companies Law, the board of directors of an Israeli publicly-traded company is required to appoint a compensation committee comprised of at least three members, including all of the external directors of a company, and one of the external directors must serve as chairman of the committee. Such compensation committee may not include:

- the chairman of the company's board of directors;
- a controlling shareholder or a relative of a controlling shareholder of the company (as each such term is defined in the Companies Law); or
- any director employed by the company, by a controlling shareholder of the company or by any other entity controlled by a controlling shareholder of the company, or any director who provides services to the company on a permanent basis, to a controlling shareholder of the company or to any other entity controlled by a controlling shareholder of the company on a regular basis (other than as a member of the board of directors), or any other director whose main source of income derives from a controlling shareholder of the company.

The term "controlling shareholder" is defined in the Companies Law as a shareholder with the ability to direct the activities of the company, other than by virtue of being an office holder. A shareholder is presumed to be a controlling shareholder if the shareholder holds 50% or more of the voting rights in a company or has the right to appoint the majority of the directors of the company or its general manager.

A majority of the total number of then-serving members of a compensation committee shall constitute a quorum for the transaction of business at the compensation committee meetings. The compensation committee of a publicly-traded company must consist of a majority of external directors.

Pursuant to the Relief Regulations, companies the shares of which are listed for trading on specified exchanges outside of Israel, including Nasdaq and qualify as Eligible Companies are exempt from the following rules regarding the compensation committee under the Companies Law: (i) the board of a public company is required to appoint a compensation committee; and (ii) the compensation committee shall be comprised of at least three members, all of the external directors shall be members and shall constitute the majority of its members and the rest of the members shall be members whose terms of service are as required under the Companies Law.

Any person who is not eligible to serve on the compensation committee is further restricted from participating in its meetings and votes, unless the chairman of the compensation committee determines that such person's presence is necessary in order to present a certain matter, provided however, that company employees who are not controlling shareholders or relatives of such shareholders may be present in the meetings but not for the actual votes, and likewise, company counsel and secretary who are not controlling shareholders or relatives of such shareholders may be present in the meetings and for the decisions if such presence is requested by the compensation committee.

The responsibilities of the compensation committee include the following:

- to make recommendations to the board of directors as to a compensation policy for officers, as well as to recommend once every three years to extend the compensation policy, subject to receipt of the required corporate approvals;
- to make recommendations to the board of directors as to any updates to the compensation policy which may be required;
- to review the implementation of the compensation policy by the company;
- to approve transactions relating to terms of office and employment of certain company office holders, that require the approval of the compensation committee pursuant to the Companies Law; and
- to exempt, under certain circumstances, a transaction relating to terms of office and employment from the requirement of approval of the shareholders meeting.

In November 2012, in order to comply with certain requirements of the Companies Law, which had been enacted shortly prior to that, our Board of Directors established a Compensation Committee, comprised of Ms. Nurit Benjamini and Dr. Avraham Molcho, our two external directors, and Dr. Raphael Hofstein. Ms. Nurit Benjamini serves as the Chairperson of our Compensation Committee.

Under the Companies Law, a board of directors of an Israeli publicly-traded company, following the recommendation of the compensation committee, is required to establish a compensation policy, to be approved by the shareholders of the company, and pursuant to which the terms of office and compensation of the company's officer holders will be decided.

A company's compensation policy shall be determined based on, and take into account, certain parameters set forth in Section 267B(a) and Parts A and B of Annex 1A of the Companies Law, which were legislated as part of Amendment 20.

The board of directors of a publicly traded company is obligated to adopt a compensation policy after considering the recommendations of the compensation committee. The final adoption of the compensation policy is subject to the approval of the shareholders of the company, and such approval is subject to certain special majority requirements, as set forth in the Companies Law, pursuant to which one of the following must be met:

- (i) the majority of the votes includes at least a majority of all the votes of shareholders who are not controlling shareholders of the company or who do not have a personal interest in the compensation policy and participating in the vote; abstentions shall not be included in the total of the votes of the aforesaid shareholders; or
- (ii) the total of opposing votes from among the shareholders described in subsection (i) above does not exceed 2% of all the voting rights in the company.

Nonetheless, even if the shareholders of the company do not approve the compensation policy, the board of directors of a company may approve the compensation policy, provided that the compensation committee and, thereafter, the board of directors resolved, based on detailed, documented, reasons and after a second review of the compensation policy, that the approval of the compensation policy is for the benefit of the company.

In December 2013, a general meeting of our shareholders approved the Executive Compensation Policy which had been recommended by our Compensation Committee and approved by our Board of Directors. The term of this initial policy was for three years from the date of its approval, or until December 2016. In July 2016, a general meeting of our shareholders approved an extension and revision of the initial policy, which has been renamed the Compensation Policy for Executives and Directors, or Compensation Policy. The Compensation Policy governs the terms of compensation for our directors and office holders, in accordance with the requirements of the Companies Law. Below is a summary discussion of the provisions of the Compensation Policy:

The Compensation Policy includes, among other issues prescribed by the Companies Law, a framework for establishing the terms of office and employment of our office holders, a recoupment policy and guidelines with respect to the structure of the variable pay of our office holders.

Compensation is considered performance-based to the extent that a direct link is maintained between compensation and performance and that rewards are consistent with long-term stakeholder value creation. At the company level, we analyze the overall compensation trends of the market in order to make informed decisions about our compensation approach.

According to the Compensation Policy, the fixed components of our office holder compensation will be examined at least every two years and compared to the market. Our Board of Directors may change the amount of the fixed components for one or more of our office holders after receiving a recommendation for such from our compensation committee. The change may be made if our Board of Directors concludes that such a change would promote our goals, operating plans and objectives and after taking into account the business and legal implications of the proposed change and its impact on our internal labor relations. Any such changes are subject to formal approval by the relevant parties. The fixed component of compensation remunerates the specific role covered and scope of responsibilities. It also reflects the experience and skills required for each position, as well as the level of excellence demonstrated and the overall quality of the office holder's contribution to our business. The weighting of fixed compensation within the overall package is designed to reduce the risk of excessively risk-oriented behavior, to discourage initiatives focused on short-term results which might jeopardize our mid and long-term business sustainability and value creation, and to allow us a flexible compensation approach. We offer our employees benefit plans based on common practice in the local labor market of the office holder.

As for the variable components of compensation, the types and amounts of such components will be determined with an aim at creating maximum matching between the Compensation Policy and our operating plan and objectives. Variable components of compensation will be primarily based on measurable long-term criteria. Nevertheless, we are allowed to base a non-material part of variable compensation on qualitative non-measurable criteria which focus on the office holder's contribution to the Company. Our variable compensation aims to remunerate for achievements by directly linking pay to performance outcomes in the short and long term. To strengthen the alignment of shareholder interests and the interests of management and employees, performance measurements reflect our actual results overall, as well as of the individual office holder. To support the aforementioned principles, we provide two types of variable compensation: short-term - annual bonus; and long-term - stock option plans.

Annual bonuses will be based on achievement of the business goals set out in our annual operating plan approved by the board of directors at the beginning of each year. The operating plan encompasses all aspects of our activities and as such sets the business targets for each member of the management team. Consequently, our Compensation Committee and Board of Directors should be able to judge the suitability of a bonus payment by deliberating retrospectively at year end and comparing actual performance and target achievements against the forecasted operating plan. The annual bonus mechanism will be directly tied to meeting objectives - both our business objectives and the office holder's personal objectives. The Board of Directors' satisfaction with the officer's performance will also affect the bonus amount. Annual bonus payments are subject to the limitations set out in the Compensation Policy and also subject to the discretion of our Compensation Committee and approval by the Board of Directors. In order to maintain some measure of flexibility, after calculating the compensation amount, the Board of Directors may exercise discretion about the final amount of the bonus.

Equity-based compensation may be granted in any form permitted under our share incentive plan in effect from time to time and shall be made in accordance with the terms of such share incentive plan. Equity-based compensation to office holders shall be granted from time to time and be individually determined and awarded according to the performance, educational background, prior business experience, qualifications, role and the personal responsibilities of each officer. The vesting period will generally be four years, with the vesting schedule to be determined in accordance with market compensation trends. Our policy is to grant equity-based compensation with exercise prices at market value. Furthermore, in order to create a ceiling for the variable compensation: (1) the aggregate value of annual grants to any one office holder (based on the Black Scholes calculation on the date of grant) will be no more than the higher of 2% of our market capitalization at the end of the measurement period or \$1.5 million; and (2) it is our intention that the maximum outstanding equity awards under its share incentive plan will not exceed 12% of our total fully-diluted share capital. Our Board of Directors may, following approval by our Compensation Committee, make provisions with respect to the acceleration of the vesting period of any office holder's awards, including, without limitation, in connection with a corporate transaction involving a change of control.

We have also established a defined ratio between the variable and the fixed components of compensation, as well as a maximum amount for all variable components as of the date on which they are paid (or as of the grant date for non-cash variable equity components), and subject to the limitations on variable compensation components which are set out in the Compensation Policy.

In addition, we have established guidelines under which an office holder will refund to us part of the compensation received, if it was paid based on information that was retroactively restated in our financial reports. Office holders shall be required to make restitution for any payments made based on our operating performance, if such payments were based on false or restated financial statements prepared at any time during the three years preceding discovery of the error.

All compensation arrangements of office holders are to be approved in the manner prescribed by applicable law. Our Compensation Committee will review the Compensation Policy on an annual basis, and monitor its implementation, and recommend to our Board of Directors and shareholders to amend the Compensation Policy as it deems necessary from time to time. The term of the Compensation Policy is three years from the date of its adoption, or July 5, 2019. Following such three-year term, the Compensation Policy, including any revisions recommended by our Compensation Committee and approved by our Board of Directors, as applicable, will be brought once again to the shareholders for approval.

Nominating Committee

Our Board of Directors does not currently have a nominating committee, having availed BioLineRx of the exemption available to foreign private issuers under the Nasdaq Rules. See “Item 16G. Corporate Governance.”

Investment Monitoring Committee

Our Board of Directors has established an Investment Monitoring Committee which consists of the following four members: Directors Dr. Michael Anghel (Chairperson) and Ms. Nurit Benjamini; Ms. Mali Zeevi, our Chief Financial Officer; and Mr. Raziel Fried, our Budget Control Manager and Treasurer. The function of the Investment Monitoring Committee includes providing recommendations to our Board of Directors regarding investment guidelines and performing an on-going review of the fulfillment of established investment guidelines. The Investment Monitoring Committee convenes for a meeting in accordance with our needs, but in any event at least twice per year. The Investment Monitoring Committee reports to our Board of Directors on a semi-annual basis.

Internal Auditor

Under the 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 Touche Tohmatsu Limited).

Fiduciary duties of office holders

The Companies Law imposes a duty of care and a duty of loyalty on all office holders of a company. The duty of care of an office holder is based on the duty of care set forth in connection with the tort of negligence under the Israeli Torts Ordinance (New Version) 5728-1968. This duty of care requires an office holder to act with the degree of proficiency with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care includes a duty to use reasonable means, in light of the circumstances, to obtain:

- information on the advisability 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 requires an office holder to act in good faith and for the benefit of the company, and includes the duty to:

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

We may approve an act performed in breach of the duty of loyalty of an office holder provided that the office holder acted in good faith, the act or its approval does not harm the company, and the office holder discloses his or her personal interest, as described below.

Disclosure of personal interests of an office holder and approval of acts and transactions

The Companies Law requires that an office holder promptly disclose to the company any personal interest that he or she may have and all related material information or documents relating to any existing or proposed transaction by the company. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. An office holder is not obliged to disclose such information if the personal interest of the office holder derives solely from the personal interest of his or her relative in a transaction that is not considered as an extraordinary transaction.

The term personal interest is defined under the Companies Law to include the personal interest of a person in an action or in the business of a company, including the personal interest of such person's relative or the interest of any corporation in which the person is an interested party, but excluding a personal interest stemming solely from the fact of holding shares in the company. A personal interest furthermore includes the personal interest of a person for whom the office holder holds a voting proxy or the interest of the office holder with respect to his or her vote on behalf of the shareholder for whom he or she holds a proxy even if such shareholder itself has no personal interest in the approval of the matter. An office holder is not, however, obliged to disclose a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction.

Under the Companies Law, an extraordinary transaction which requires approval is defined as any of the following:

- a transaction other than in the ordinary course of business;
- a transaction that is not on market terms; or
- a transaction that may have a material impact on the company's profitability, assets or liabilities.

Under the Companies Law, once an office holder has complied with the disclosure requirement described above, a company may approve a transaction between the company and the office holder or a third party in which the office holder has a personal interest, or approve an action by the office holder that would otherwise be deemed a breach of duty of loyalty. However, a company may not approve a transaction or action that is adverse to the company's interest or that is not performed by the office holder in good faith.

Under the Companies Law, unless the articles of association of a company provide otherwise, a transaction with an office holder, a transaction with a third party in which the office holder has a personal interest, and an action of an office holder that would otherwise be deemed a breach of duty of loyalty requires approval by the board of directors. Our Articles of Association do not provide otherwise. If the transaction or action considered is (i) an extraordinary transaction or (ii) an action of an office holder that would otherwise be deemed a breach of duty of loyalty and may have a material impact on a company's profitability, assets or liabilities, then audit committee approval is required prior to approval by the board of directors.

Under the Companies Law, a transaction with an office holder in a public company regarding his or her terms of office and employment should be determined in accordance with the company's compensation policy. Nonetheless, provisions were established that allow a company, under special circumstances, to approve terms of office and employment that are not in line with the approved compensation policy. Accordingly, the approval requirements for the compensation and/or terms of office of a specific office holder may require the approval of each of the compensation committee, board of directors and the shareholders, in that order. As such, under the following approvals are required for the following transactions:

A transaction with an office holder in a public company that is neither a director nor the chief executive officer regarding his or her terms of office and employment requires approval by the (i) compensation committee; and (ii) the board of directors. Approval of terms of office and employment for such officers which do not comply with the compensation policy may nonetheless be approved subject to two cumulative conditions: (i) the compensation committee and thereafter the board of directors, approved the terms after having taken into account the various considerations and mandatory requirements set forth in the Companies Law with respect to office holder compensation, and (ii) the shareholders of the company have approved the terms by means of the following special majority requirements, or the Special Majority Requirements, as set forth in the Companies Law, pursuant to which the shareholder approval must either include at least one-half of the shares held by non-controlling and disinterested shareholders who actively participate in the voting process (without taking abstaining votes into account), or, alternatively, the total shareholdings of the non-controlling and disinterested shareholders who vote against the transaction must not represent more than 2% of the voting rights in the company.

A transaction with the chief executive officer in a public company regarding his or her terms of office and employment requires approval by the (i) compensation committee; (ii) the board of directors; and (iii) the shareholders of the company by the Special Majority Requirements. Approval of terms of office and employment for the chief executive officer which do not comply with the compensation policy may nonetheless be approved subject to two cumulative conditions: (i) the compensation committee and thereafter the board of directors, approved the terms after having taken into account the various considerations and mandatory requirements set forth in the Companies Law with respect to office holder compensation and (ii) the shareholders of the company have approved the terms by means of the Special Majority Requirements, as detailed above.

A transaction with an office holder in a public company (including the chief executive officer) who is not a director regarding his or her terms of office and employment may be approved despite shareholder rejection, provided that a company's compensation committee and thereafter the board of directors have determined to approve the proposal, based on detailed reasoning, after having re-examined the terms of office and employment, and taken the shareholder rejection into consideration. In addition, the compensation committee may exempt the transaction regarding terms of office and employment with a chief executive officer who has no relationship with the controlling shareholder or the company from shareholder approval if it has found, based on detailed reasons, that bringing the transaction to the approval of the shareholders meeting shall prevent the employment of such candidate by the company. Such approval may be given only in respect of terms of office and employment which are in accordance with the company's compensation policy.

A transaction with a director in a public company regarding his or her terms of office and employment requires approval by the (i) compensation committee; (ii) the board of directors; and (iii) the shareholders of the company. Approval of terms of office and employment for directors of a company which do not comply with the compensation policy may nonetheless be approved subject to two cumulative conditions: (i) the compensation committee and thereafter the board of directors, approved the terms after having taken into account the various considerations and mandatory requirements set forth in the Companies Law with respect to office holder compensation and (ii) the shareholders of the company have approved the terms by means of the Special Majority Requirements, as detailed above. In addition, pursuant to a relief provided under the Companies Regulations (Relief in Interested Party Transactions), 2000, the compensation committee may exempt the transaction regarding terms of office and employment with a director, if the compensation committee and board of directors determined that such terms of office are only for the benefit of the company, or if the compensation terms of the director do not exceed the maximum compensation paid to external directors pursuant to the applicable regulations.

A director who has a personal interest in a matter that is considered at a meeting of the board of directors or the audit committee may generally not be present at the meeting or vote on the matter unless a majority of the directors or members of the audit committee have a personal interest in the matter, or, unless the chairman of the audit committee or board of directors (as applicable) determines that he or she should be present to present the transaction that is subject to approval. If a majority of the directors have a personal interest in the matter, such matter also requires approval of the shareholders of the company.

Disclosure of personal interests of a controlling shareholder and approval of transactions

Under the Companies Law, the disclosure requirements that apply to an office holder also apply to a controlling shareholder of a public company. See “— Audit Committee” for the general definition of controlling shareholder under the Companies Law. The definition of “controlling shareholder” in connection with matters governing: (i) extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, (ii) certain private placements in which the controlling shareholder has a personal interest, (iii) certain transactions with a controlling shareholder or relative with respect to services provided to or employment by the company, (iv) the terms of employment and compensation of the general manager, and (v) the terms of employment and compensation of office holders of the company when such terms deviate from the compensation policy previously approved by the company’s shareholders, also includes shareholders that hold 25% or more of the voting rights if no other shareholder owns more than 50% of the voting rights in the company (and the holdings of two or more shareholders which each have a personal interest in such matter will be aggregated for the purposes of determining such threshold).

Under the Companies Law, extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, including a private placement in which a controlling shareholder has a personal interest, as well as transactions for the provision of services whether directly or indirectly by a controlling shareholder or his or her relative, or a company such controlling shareholder controls, require the approval of the audit committee, the board of directors and the shareholders, in that order. Extraordinary transactions concerning the terms of engagement of a controlling shareholder or a controlling shareholder’s relative, whether as an office holder or an employee, require the approval of the compensation committee, the board of directors and the shareholders, in that order. In addition, the approval of such extraordinary transactions by the shareholders require at least a majority of the shares voted by the shareholders of the company participating and voting in a shareholders’ meeting, provided that one of the following requirements is fulfilled:

- at least a majority of the shares held by shareholders who have no personal interest in the transaction and are voting at the meeting must be voted in favor of approving the transaction, excluding abstentions; or
- the shares voted by shareholders who have no personal interest in the transaction who vote against the transaction represent no more than 2% of the voting rights in the company.

If such extraordinary transaction concerns the terms of office and employment of such controlling shareholder, in his capacity as an office holder or an employee of the company, such terms of office and employment approved by the compensation committee and board of directors shall be in accordance with the compensation policy of the company. Nonetheless, the compensation committee and the board of directors may approve terms of office and compensation of a controlling shareholder which do not comply with the company’s compensation policy, provided that the compensation committee and, thereafter, the board of directors approve such terms, based on, among other things, the considerations listed under Section 267B(a) and Parts A and B of Annex 1A of the Companies Law, as those are described above. Following such approval by the compensation committee and board of directors, shareholder approval would be required.

To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years, approval, in the same manner described above, is required once every three years, unless, with respect to extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

Duties of shareholders

Under the Companies Law, a shareholder has a duty to refrain from abusing its power in the company and to act in good faith and in an acceptable manner in exercising its rights and performing its obligations to the company and other shareholders, including, among other things, voting at general meetings of shareholders on the following matters:

- an amendment to the articles of association;
- an increase in the company's authorized share capital;
- a merger; and
- the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from discriminating against other shareholders.

The remedies generally available upon a breach of contract will also apply to a breach of the above-mentioned duties, and in the event of discrimination against other shareholders, additional remedies are available to the injured shareholder.

In addition, any controlling shareholder, any shareholder that knows that its vote can determine the outcome of a shareholder vote and any shareholder that, under a company's articles of association, has the power to appoint or prevent the appointment of an office holder, or has another power with respect to a company, is under a duty to act with fairness towards the company. The 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 in the event of a breach of the duty to act with fairness, taking the shareholder's position in the company into account.

Exculpation, insurance and indemnification of office holders

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our Articles of Association include such a provision. An Israeli company may not exculpate a director from liability arising out of a prohibited dividend or distribution to shareholders.

An Israeli company may indemnify an office holder in respect of the following liabilities and expenses incurred for acts performed as an office holder, either in advance of an event or following an event, provided a provision authorizing such indemnification is contained in its articles of association:

- 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. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking 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 according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned events and amount or criteria;

- 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 (1) no indictment was filed against such office holder as a result of such investigation or proceeding; and (2) 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 an offense that does not require proof of criminal intent.

An Israeli company may insure an office holder against the following liabilities incurred for acts performed as an office holder if and to the extent provided in the company's articles of association:

- a breach of duty of loyalty to the company, 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 to the company or to a third party, including a breach arising out of the negligent conduct of the office holder; and
- a financial liability imposed on the office holder in favor 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 or forfeit levied against the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders must be approved by the audit committee and the board of directors and, with respect to directors, by shareholders.

An amendment to the Israeli Securities Law and a corresponding amendment to the Companies Law authorize the ISA to impose administrative sanctions against companies like ours, and their office holders for certain violations of the Israeli Securities Law or the Companies Law. These sanctions include monetary sanctions and certain restrictions on serving as a director or senior officer of a public company for certain periods of time. The amendments to the Israeli Securities Law and to the Companies Law provide that only certain types of such liabilities may be reimbursed by indemnification and insurance. Specifically, legal expenses (including attorneys' fees) incurred by an individual in the applicable administrative enforcement proceeding and certain compensation payable to injured parties for damages suffered by them are permitted to be reimbursed via indemnification or insurance, provided that such indemnification and insurance are authorized by the company's articles of association and receive the requisite corporate approvals.

Our Articles of Association allow us to indemnify and insure our office holders for any liability imposed on them as a consequence of an act (including any omission) which was performed by virtue of being an office holder. In November 2011, our shareholders approved (i) the amendment of our Articles of Association to authorize indemnification and insurance in connection with administrative enforcement proceedings, including without limitation, the specific amendments to the Israeli Securities Law and the Companies Law described above and (ii) a new form of indemnification letter for our directors and officers so as to reflect the amendment to our Articles of Association, which new form of letter was also approved in October 2011 by our Audit Committee and Board of Directors, and in November 2011 by our shareholders. The terms of such agreements are consistent with the provisions of the Compensation Policy which was approved by our shareholders in December 2013 and amended as described in the next paragraph.

Our office holders are currently covered by a directors and officers' liability insurance policy. The terms of such directors' and officers' insurance are consistent with the provisions of the Compensation Policy which was approved by our shareholders in July 2016. The purpose of the amendment was to clarify that we are authorized to purchase insurance policies (including run-off policies) to cover the liability of directors and office holders that are in office at such time and that shall be in office from time to time, including directors and office holders that may have a controlling interest in the Company. Such insurance policies are authorized within the following limits: (1) the premium for each policy period shall not exceed \$250,000, (2) the maximum aggregate limit of liability pursuant to the policies shall not exceed \$20 million for each insurance period, and (3) the maximum deductible shall not exceed \$250,000. In addition, the Compensation Committee is authorized to increase the coverage purchased and/or the premium paid for such policies by up to 20% per year, as compared to the previous year, or cumulatively for a number of years, without an additional shareholders' approval to the extent permitted under the Companies Law. As of the date of this Annual Report on Form 20-F, no claims for directors' and officers' liability insurance have been filed under this policy and we are not aware of any pending or threatened litigation or proceeding involving any of our directors or officers in which indemnification is sought. Pursuant to the approval of our shareholders at the annual general meeting held in September 2014, we carry directors' and officers' insurance covering each of our directors and executive officers for acts and omissions. See also "Related Party Transactions — Indemnification Agreements."

There is no pending litigation or proceeding against any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

For significant ways in which our corporate governance practices differ from those required by the Nasdaq Rules, see "Item 16G. Corporate Governance."

D. Employees

As of December 31, 2018, we had 48 employees, all of whom are employed in Israel. Of our employees, 17 hold M.D. or Ph.D. degrees.

	December 31,		
	2016	2017	2018
Management and administration	11	11	10
Research and development	28	36	34
Sales and marketing	4	4	4
Total	43	51	48

While none of our employees are party to any collective bargaining agreements, in Israel we are subject to certain labor statutes and national labor court precedent rulings, as well as to 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) which are applicable to our employees by virtue of expansion orders issued in accordance with relevant labor laws by the Israel Ministry of Labor and Welfare, and which apply such agreement provisions to our employees even though they are not directly part of a union that has signed a collective bargaining agreement. The laws and labor court rulings that apply to our employees principally concern the minimum wage laws, procedures for dismissing employees, determination of severance pay, leaves of absence (such as annual vacation or maternity leave), sick pay and other conditions for employment. The expansion orders which apply to our employees principally concern the requirement for length of the work day and work week, mandatory contributions to a pension fund, annual recreation allowance, travel expenses payment 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.

E. Share Ownership

The following table sets forth information regarding the beneficial ownership of our outstanding ordinary shares as of March 25, 2019 of each of our directors and executive officers individually and as a group.

	Number of Ordinary Shares Beneficially Held	Percent of Class
Directors		
Aharon Schwartz ⁽¹⁾	113,337	*
Michael J. Anghel ⁽²⁾	113,337	*
Nurit Benjamini ⁽³⁾	93,337	*
B.J. Bormann ⁽⁴⁾	113,337	*
Raphael Hofstein ⁽⁵⁾	113,337	*
Avraham Molcho ⁽⁶⁾	93,337	*
Sandra Panem ⁽⁷⁾	110,837	*
Executive officers		
Philip A. Serlin ⁽⁸⁾	843,225	1.0%
Mali Zeevi ⁽⁹⁾	383,973	*
Hillit Mannor Shachar ⁽¹⁰⁾	112,000	*
Ella Sorani ⁽¹¹⁾	217,985	*
Abi Vainstein-Haras ⁽¹²⁾	341,293	*
All directors and executive officers as a group (12 persons)⁽¹³⁾	2,649,335	1.8%

* Less than 1.0%.

- (1) Includes 113,337 ordinary shares issuable upon exercise of outstanding options within 60 days of March 25, 2019. Does not include 11,663 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 25, 2019.
- (2) Includes 113,337 ordinary shares issuable upon exercise of outstanding options within 60 days of March 25, 2019. Does not include 11,663 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 25, 2019.
- (3) Includes 93,337 ordinary shares issuable upon exercise of outstanding options within 60 days of March 25, 2019. Does not include 11,663 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 25, 2019.
- (4) Includes 113,337 ordinary shares issuable upon exercise of outstanding options within 60 days of March 25, 2019. Does not include 11,663 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 25, 2019.
- (5) Includes 113,337 ordinary shares issuable upon exercise of outstanding options within 60 days of March 25, 2019. Does not include 11,663 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 25, 2019.
- (6) Includes 93,337 ordinary shares issuable upon exercise of outstanding options within 60 days of March 25, 2019. Does not include 11,663 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 25, 2019.

- (7) Includes 110,837 ordinary shares issuable upon exercise of outstanding options within 60 days of March 25, 2019. Does not include 11,663 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 25, 2019.
- (8) Includes 843,225 issued ordinary shares upon exercise of outstanding options within 60 days of March 25, 2019. Does not include 1,183,522 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 25, 2019.
- (9) Includes 383,973 ordinary shares issuable upon exercise of outstanding options within 60 days of March 25, 2019. Does not include 462,246 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 25, 2019.
- (10) Includes 112,000 ordinary shares issuable upon exercise of outstanding options within 60 days of March 25, 2019. Does not include 368,000 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 25, 2019.
- (11) Includes 217,985 ordinary shares issuable upon exercise of outstanding options within 60 days of March 25, 2019. Does not include 404,815 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 25, 2019.
- (12) Includes 341,293 ordinary shares issuable upon exercise of outstanding options within 60 days of March 25, 2019. Does not include 496,707 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 25, 2019.
- (13) Includes 2,649,335 ordinary shares issuable upon exercise of outstanding options within 60 days of March 25, 2019. Does not include 2,996,931 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 25, 2019.

Equity Compensation Plan

2003 Share Incentive Plan

In 2003, we adopted the BioLineRx Ltd. 2003 Share Incentive Plan, or the Plan. The Plan provides for the granting of options, ordinary shares, restricted stock units and performance stock units 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 equity grants to be made at the determination of our Board of Directors in accordance with applicable law. As of March 25, 2019, there were 10.9 million ordinary shares issuable upon the exercise of outstanding equity grants under the Plan.

In August 2013, our Board of Directors approved amendments to the Plan to take into account changes in laws and regulations that had occurred since its adoption and to extend the term of the plan until November 2023. In January 2016, our Board of Directors approved amendments to the Plan in order to permit the granting of restricted stock units, or RSUs, and performance stock units, or PSUs, to eligible grantees.

From time to time, our Board of Directors has approved an increase in the number of shares reserved for the purpose of equity grants pursuant to the Plan. As of March 25, 2019, the number of shares so reserved was 1.8 million.

Administration of Our Plan

Our Plan is administered by our Board of Directors for the purposes of making equity grants and approving the terms of those grants, including, in the case of options, exercise price, method of payment, vesting schedule, acceleration of vesting and the other matters necessary in the administration of these plans. Equity grants made under the Plan to eligible employees and office holders are made under Section 102 of the Israel Income Tax Ordinance pursuant to which the securities granted must be allocated or issued to a trustee and be held in trust for two years from the date upon which such grant was made, provided that securities granted prior to January 1, 2006, or the ordinary shares issued upon exercise of options, are subject to being held in trust for two years from the end of the year in which the securities are granted. Under Section 102, any tax payable by an employee from the grant of securities or the exercise of options is deferred until the transfer of the securities (or ordinary shares issued upon the exercise of options) by the trustee to the employee or upon the sale of the securities or ordinary shares, as the case may be, 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 the Plan generally vest over four years, and they expire 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 Compensation 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. The right to receive ordinary shares pursuant to PSUs granted under the Plan will vest upon the achievement by BioLineRx of certain performance goals to be established by the Board of Directors.

In the event of a merger, consolidation, reorganization or similar transaction or our voluntary liquidation or dissolution, all of our unexercised vested equity grants and any unvested equity grants 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 or transfer of all or substantially all of our outstanding shares assets, the equity grants 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) as were distributed to our shareholders in respect of the transaction. In addition to the foregoing, our Board of Directors has approved the inclusion in the option agreements of the Company's officers of a provision for accelerated vesting of options if both a change of control of the Company occurs and, following such change of control, the officer's employment is terminated or there is a significant demotion in the officer's new job or position.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth certain information regarding the beneficial ownership of our outstanding ordinary shares as of March 25, 2019 by each person who we know beneficially owns 5.0% or more of the outstanding ordinary shares. Each of our shareholders has identical voting rights with respect to its shares. All of the information with respect to beneficial ownership of the ordinary shares is given to the best of our knowledge. The beneficial ownership of ordinary shares is based on the 144,556,119 ordinary shares outstanding as of March 25, 2019 and 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 March 25, 2019, 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. To our knowledge, none of our shareholders of record are U.S. holders. Our principal shareholders do not have different or special voting rights.

	Number of Ordinary Shares Beneficially Held	Percent of Class
BVF Partners L.P. (1)	31,942,477	21.2
Senvest Management, LLC (2)	7,538,845	5.1

(1) Based upon information provided by the shareholder, or the BVF Group, in its Schedule 13D filed with the SEC on March 1, 2019. BVF Partners L.P., or Partners, as the general partner of Biotechnology Value Fund, L.P., or BVF, and Biotechnology Value Fund II, L.P., or BVF2, the sole member of BVF Partners OS Ltd., or Partners OS, and the investment manager of Biotechnology Value Trading Fund OS LP, or Trading Fund OS, and certain Partners-managed accounts, or the Partners Managed Accounts, may be deemed to beneficially own the 31,942,477 ordinary shares beneficially owned in the aggregate by BVF, BVF2, Trading Fund OS and the Partners Managed Accounts. BVF Inc., as the general partner of Partners, may be deemed to beneficially own the 31,942,477 ordinary shares beneficially owned by Partners. Mark N. Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the 31,942,477 ordinary shares beneficially owned by BVF Inc. In addition to ADSs, the BVF Group is the beneficial owner of Series A warrants and Series B warrants issued by us in July 2017. All the warrants held by the BVF Group are subject to a blocker provision that precludes the holders from exercising the warrants to the extent that the holder and its affiliates would beneficially own in excess of 24.99% of our ordinary shares outstanding immediately after giving effect to such exercise. As of the close of business on March 1, 2019, the blocker provision does not limit the exercise of the warrants by the BVF Group. The address of the principal business office of BVF Partners L.P. is 1 Sansome Street, 30th Floor, San Francisco, California 94104.

(2) Based upon information provided by the shareholder in its Schedule 13G filed with the SEC on February 8, 2019. Includes 2,725,000 ADSs issuable upon exercise of warrants issued by us in February 2019. The securities indicated above are held in the accounts of Senvest Master Fund, LP, Senvest Technology Partners Master Fund, LP and Senvest Global (KY), LP or collectively, the Investment Vehicles. Senvest Management, LLC may be deemed to beneficially own the securities held by the Investment Vehicles by virtue of Senvest Management, LLC's position as investment manager of the Investment Vehicles. Richard Mashaal may be deemed to beneficially own the securities held by the Investment Vehicles by virtue of Mr. Mashaal's status as the managing member of Senvest Management, LLC. None of the foregoing should be construed in and of itself as an admission by either Senvest Management, LLC or Mr. Mashaal as to beneficial ownership of the securities indicated above. The address of the principal business office of Senvest Management, LLC is 540 Madison Avenue, 32nd Floor, New York, New York 10022.

B. Related Party Transactions

Agreements with Directors and Officers

Employment Agreements

We have entered into employment agreements with each of our executive officers. See "Item 6. Directors, Senior Management and Employees — Compensation of Directors and Senior Management."

Indemnification Agreements

Our Articles of Association and Compensation Policy approved by our shareholders permit us to exculpate, indemnify and insure our directors and office holders to the fullest extent permitted by the 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' and officers' insurance for each of our officers and directors. See "Item 6. Directors, Senior Management and Employees — Board Practices — Exculpation, insurance and indemnification of office holders."

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and other Financial Information

See "Item 18. Financial Statements."

Legal Proceedings

We are not involved in any material legal proceedings.

Dividend Distributions

We have never declared or paid cash dividends to our shareholders. Currently we do not intend to pay cash dividends. We currently intend to reinvest any future 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.

B. Significant Changes

None.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our ADSs have been trading on Nasdaq under the symbol “BLRX” since July 2011. Our ordinary shares have been trading on the TASE under the symbol “BLRX” since February 2007.

B. Plan of Distribution

Not applicable.

C. Markets

Our ADSs trade on Nasdaq under the symbol “BLRX.” Our ordinary shares trade on the TASE under the symbol “BLRX.”

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Articles of Association

Our number with the Israeli Registrar of Companies is 513398750. Our purpose is set forth in Section 2 of our Articles of Association and includes every lawful purpose.

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.

Pursuant to the 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.

Our Articles of Association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the 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 (under certain circumstances), require a resolution of our Board of Directors and court approval. In May 2015, at an Extraordinary General Meeting of our shareholders, they approved a 1-for-10 reverse share split of our ordinary shares and a corresponding amendment to our Articles of Association, and further approved an increase to our share capital from NIS 7,500,000 divided into 75,000,000 ordinary shares of a nominal value of NIS 0.10 each to NIS 15,000,000 divided into 150,000,000 ordinary shares of nominal value NIS 0.10, and a corresponding amendment to our Articles of Association, effective immediately after the reverse share split became effective.

Dividends

We may declare a dividend to be paid to the holders of our ordinary shares in proportion to their respective shareholdings. Under the 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 Companies Law, we may only distribute dividends from our profits accrued over the previous two years, as defined in the 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.

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, other than with respect to the special approval requirements for the election of external directors (unless we qualify as an Eligible Company and opt to follow the exemption provided under the Relief Regulations regarding appointment of external directors and composition of the Audit and Compensation Committees) described under "Item 6. Directors, Senior Management and Employees — Board Practices — External Directors."

Pursuant to our Articles of Association, other than the external directors, for whom special election requirements apply under the Companies Law (unless we qualify as an Eligible Company and opt to follow the exemption provided under the Relief Regulations regarding appointment of external directors and composition of the Audit and Compensation Committees), 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 Companies Law and our Articles of Association. In addition, our Articles of Association allow our Board of Directors to appoint directors (other than external 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. Unless we qualify as an Eligible Company and opt to follow the exemption provided under the Amendment to the Relief Regulations regarding appointment of external directors and composition of the Audit and Compensation Committees, external directors are elected for an initial term of three years and may be removed from office pursuant to the terms of the Companies Law. See "Item 6. Directors, Senior Management and Employees — Board Practices — External Directors."

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 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 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 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 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 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, the approval of a compensation policy with respect to office holders or an approval of a merger, notice must be provided at least 35 days prior to the meeting.

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.

Quorum

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.

Resolutions

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;
- authorizing the chairman of the board of directors or his relative to act as the company's chief executive officer or act with such authority; or authorize the company's chief executive officer or his relative to act as the chairman of the board of directors or act with such authority; 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 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 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.

Unless otherwise stated under the Companies Law, or provided in a company's articles of association a 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 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.

Under the Companies Law, the board of directors of an Israeli publicly traded company is required to establish a compensation policy, to be approved by the shareholders of the company, pursuant to which the terms of office and compensation of the company's officer holders will be decided (unless the company qualifies as an Eligible Company and opts to follow the exemption provided under the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees). The final adoption of such compensation policy is subject to the approval of the shareholders, which approval is subject to certain special majority requirements, as set forth in the Companies Law, pursuant to which one of the following must be met:

- (i) the majority of the votes includes at least a majority of all the votes of shareholders who are not controlling shareholders of the company or who do not have a personal interest in the compensation policy and participating in the vote; abstentions shall not be included in the total of the votes of the aforesaid shareholders; or
- (ii) the total of opposing votes from among the shareholders described in subsection (i) above does not exceed 2% of all the voting rights in the company.

For this purpose, under the Companies Law "personal interest" is defined as: (1) a shareholder's personal interest in the approval of an act or a transaction of the company, including (i) the personal interest of his or her relative (which includes for these purposes any members of his/her (or his/her spouse's) immediate family or the spouses of any such members of his or her (or his/her spouse's) immediate family); and (ii) a personal interest of a body corporate in which a shareholder or any of his/her aforementioned relatives serves as a director or the chief executive officer, owns at least 5% of its issued share capital or its voting rights or has the right to appoint a director or chief executive officer, but (2) excluding a personal interest arising solely from the fact of holding shares in the company or in a body corporate.

In addition, pursuant to the Companies Law, terms of office and employment of office holders in a public company, and terms of employment and/or terms of office of a controlling shareholder in a public company, require the approval of the shareholders, which such approval is subject to the special majority required for approving the compensation policy (as detailed above). See "Item 6. Directors, Senior Management and Employees — Approval of Related Party Transactions under Israeli Law" for information regarding the shareholders' approval, and any additional approvals that might be required, with respect to the approval of terms of office and employment of office holders in a public company, pursuant to the Companies Law.

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 dividend or distribution rights that may be authorized in the future.

Access to Corporate Records

Under the 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 ISA. Furthermore, 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 Companies Law. However, we may deny such 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.

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 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 shares of the same class. If 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 (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved the tender offer except that if the total votes to reject the tender offer represent less than 2% of the company's issued and outstanding share capital, in the aggregate, approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer). However, a shareholder that had its shares so transferred may petition the court within six 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 unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights. 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, the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

Special Tender Offer

The 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 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 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, unless one of the exemptions in the 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 Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the 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.

Antitakeover Measures

The 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 annual report, 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. Shareholders voting in such meeting will be subject to the restrictions provided in the Companies Law as described above. In addition, the Israeli Securities Law and the rules and regulations of the TASE also limit the terms permitted with respect to a new class of shares created by a public company whose shares are traded on the TASE, and prohibit any such new class of shares from having voting rights.

C. Material Contracts

For a discussion of our out-licensing and in-licensing agreements, see "Item 4. Information on the Company." The following are summary descriptions of certain other material contracts to which we are a party. 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 this Annual Report on Form 20-F.

Clinical Trial Collaboration and Supply Agreement with MSD

In January 2016, we entered into a collaboration agreement with MSD, to support a Phase 2 study investigating our BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with metastatic pancreatic cancer. The Phase 2 study will evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T-cells into the tumor and their reactivity. According to the terms of the agreement, we are sponsoring and performing the study, which was initiated in September 2016, and MSD is supplying its compound for purposes of the study. The parties have agreed on the establishment of a joint development committee which has the responsibility of coordinating all regulatory and other activities under the agreement.

In July 2018, the collaboration agreement with MSD was amended in light of the parties' agreement to expand the study under the collaboration to include a triple combination arm investigating the safety, tolerability and efficacy of BL-8040, KEYTRUDA and chemotherapy. See "Item 4 — Information on the Company — Business Overview — Therapeutic Candidates — BL-8040." Upon completion of the study, or at any earlier point, both parties have the option to expand the collaboration to include a pivotal registration study.

Combination Study Agreement with Genentech

In September 2016, we entered into a collaboration with Genentech to support several Phase 1b studies investigating BL-8040 in combination with TECENTRIQ® (atezolizumab), Genentech's anti-PDL1 cancer immunotherapy, in multiple cancer indications. Under the collaboration agreement, Genentech is sponsoring and conducting trials in pancreatic and gastric cancer. In addition, we are sponsoring and conducting a study in AML patients. These Phase 1b studies are evaluating the clinical response, safety and tolerability of the combination of these therapies, as well as multiple pharmacodynamic parameters, in hematologic malignancies and solid tumors.

Upon completion of the studies, both parties have the option to expand the collaboration to include a pivotal registration study.

Loan Agreement with Kreos Capital

In October 2018, we entered into a loan agreement with Kreos Capital. The purpose of the loan was to finance the \$10 million payment made by the Company to Biokine as part of the consideration for amending the license agreement for BL-8040. See "Item 4. Information on the Company — Business Overview — In-Licensing Agreements — BL-8040." The loan has a 12-month, interest-only period followed by a 36-month repayment period. Borrowings under the loan will bear interest at a fixed rate of 9.5% per annum. As security for the loan, Kreos Capital received a first-priority, secured interest in all Company assets, including intellectual property. In connection with providing the loan, Kreos Capital received a warrant to purchase 957,549 ADSs at an exercise price of \$0.94 per ADS. The warrant is exercisable for a period of ten years from the date of issuance.

D. Exchange Controls

There are no Israeli government laws, decrees or regulations that restrict or that affect our export or import of capital or the remittance of dividends, interest or other payments to non-resident holders of our securities, including the availability of cash and cash equivalents for use by us and our wholly-owned subsidiaries, except or otherwise as set forth under "Item 10E. Additional Information — Taxation."

E. 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 or ADSs, both referred to in this Item 10E as the 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 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 corporate tax on their taxable income. The regular corporate tax rate in Israel was 25% for the year 2016, 24% for the year 2017, and 23% for the year 2018 and thereafter. Capital gains derived by an Israeli company are now generally subject to tax at the same rate as the corporate tax rate.

In May 2012, the Israeli Tax Authority, or ITA, approved our eligibility for tax benefits as a “Benefited Enterprise” under the Law for the Encouragement of Capital Investments, 5719-1959, as amended, or Investments Law, with respect to a portion of the consideration deriving from certain of our development programs, or Eligible Projects. Subject to compliance with the applicable requirements, the portion of our undistributed income derived from our Benefited Enterprise programs will be entitled to a seven-year period of tax benefits due to the Company’s location in Modi’in (a tax exemption for a period of two years, followed by five years at the Benefited Enterprise tax rate of 25%) commencing in the first year in which we generate taxable income after setting off our losses for Israeli tax purposes from prior years in the amount of approximately \$210 million. The seven-year period may not extend beyond 12 years from the beginning of the Benefited Enterprise’s election year. We received Benefited Enterprise status with respect to the Eligible Projects in 2009 and 2012 tax years, so depending on when the Benefited Enterprise programs begin to generate taxable income after offsetting tax losses, the benefit period could continue through 2023. However, any distribution of income derived from exempt income sourced in our Benefited Enterprise programs will result in such income being subject to a rate of corporate tax no greater than 25%.

We have the option to transition to a “Preferred Enterprise” regime under the Investments Law with respect to the year 2018 (through May 31, 2018), according to which all of our income which is eligible for benefits under the regime would be subject to flat corporate tax rates of 16% in 2018 and thereafter, whether or not distributed. A transition to a Preferred Enterprise regime may not be reversed.

In addition, the ITA approved certain of our operations as an “Industrial Enterprise” under the Investments Law, meaning that we are eligible for accelerated depreciation with respect to certain tangible assets belonging to our Benefited Enterprise.

Should we not meet the requirements for maintaining these benefits, they may be reduced or cancelled and, among other things, our income deriving from the Eligible Projects (assuming we are profitable for tax purposes after offsetting losses) would be subject to regular corporate tax rate in Israel at the standard rate. If these tax benefits are reduced or eliminated, the amount of taxes that we pay would likely increase, as all of our operations would consequently be subject to corporate tax at the standard rate, which could adversely affect our results of operations.

Taxation of Israeli Individual Shareholders on Receipt of Dividends. Israeli residents who are individuals are generally subject to Israeli income tax for dividends paid on our ordinary shares (other than bonus shares or share dividends) at a rate of either 25% or, if the recipient of such dividend is a substantial shareholder (as defined below) at the time of distribution or at any time during the preceding 12-month period 30%.

Taxation of Israeli Resident Corporations on Receipt of Dividends. Israeli resident corporations are generally exempt from Israeli corporate tax for dividends paid on our ordinary shares.

However, in the case of both Israeli individual shareholders and Israeli resident corporations, under the Investments Law, dividends distributed from taxable income accrued during the period of benefit of a Benefited Enterprise and which are attributable to a Benefited Enterprise are subject to tax at the rate of 20%, if the dividend is distributed during the tax benefit period under the Investment Law or within 12 years after that period. A weighted average rate may be set if the dividend is distributed from mixed types of income (regular and Benefited Enterprise income). Different tax rates might apply to dividends sourced from profits attributable to a Preferred Enterprise, but this matter is not currently relevant to the Company.

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 25% (or 30% if such person is a “substantial shareholder” at the time receiving the dividend or on any date in the 12 months preceding such date), which tax will be withheld at the source, unless a lower rate is provided in a tax treaty between Israel and the shareholder’s country of residence. If the income out of which the dividend is being paid is sourced from profits attributable to a Benefited Enterprise under the Investments Law, the rate is generally not more than 20%.

Under the U.S.-Israel Tax Treaty, Israeli withholding tax on dividends paid to a U.S. resident for treaty purposes may not, in general, exceed 25%, or 15% in the case of dividends paid out of the profits of a Benefited Enterprise, subject to certain conditions. Where the recipient is a U.S. corporation owning 10% or more of the voting stock of the paying corporation during the part of the paying corporation’s taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any) and the dividend is not paid from the profits of a Benefited Enterprise, the Israeli tax withheld may not exceed 12.5%, subject to certain conditions.

A “substantial shareholder” is generally a person who alone, or together with his relative or another person who collaborates with him on a regular 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 instruct someone who holds any of the aforesaid rights regarding the manner in which he or she is to exercise such right(s), and all regardless of the source of such right.

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.

Taxation of Capital Gains. Israeli law imposes a capital gains tax on the sale of any capital assets by residents of Israel, as defined for Israeli tax purposes, and on the sale of assets located in Israel, including shares in Israeli companies, by non-residents of Israel, unless a specific exemption is available or unless a tax treaty between Israel and the shareholder’s country of residence provides otherwise. The law distinguishes between real gain and inflationary surplus. The inflationary surplus is a portion of the total capital gain that is equivalent to the increase of the relevant asset’s purchase price which is attributable to the increase in the Israeli consumer price index or, in certain circumstances, a foreign currency exchange rate, between the date of purchase and the date of sale. The real gain is the excess of the total capital gain over the inflationary surplus.

Capital Gains Taxes Applicable to Israeli Resident Shareholders. An individual is subject to a tax at a rate of 25% on real capital gains derived from the sale of shares, as long as the individual is not a substantial shareholder at the time of sale or at any time during the 12-month period preceding the company’s issuance of the shares.

An individual who is a substantial shareholder at the time of sale or at any time during the preceding 12-month period is subject to tax at a rate of 30% in respect of real capital gains derived from the sale of shares issued by the company in which he or she is a substantial shareholder.

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 ordinary 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 one or more Israeli residents (a) have a controlling interest of 25% or more in such non-Israeli corporation or (b) are the beneficiaries of or are entitled to 25% or more of the revenues or profits of 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 (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; (2) the capital gains arising from such sale are attributable to a permanent establishment of the shareholder located in Israel; (3) a shareholder who is an individual is present in Israel for a period or periods aggregating 183 days or more during a taxable year. 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.

Excess Tax. Individuals who are subject to tax in Israel are also subject to an additional tax at a rate of 3% in 2017 and thereafter on annual income exceeding a certain threshold (NIS 641,800 for 2018 and thereafter, which amount is linked to the annual change in the Israeli consumer price index), including, but not limited to, dividends, interest and capital gains.

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 our ordinary shares and ADSs by U.S. Investors (as defined below) that are initial purchasers of such ordinary shares or ADSs and that hold such ordinary shares or ADSs as capital assets. This summary is based on the Internal Revenue Code of 1986, as amended, 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 our ordinary shares or ADSs as part of a straddle, hedge, conversion transaction or other integrated investment, persons that have a “functional currency” other than the Dollar, persons that own (or are deemed to own, indirectly or by attribution) 10% or more of our ordinary shares or ADSs, persons subject to special tax accounting rules under section 451(b), 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 our ordinary shares or ADSs that is, for U.S. federal income tax purposes, (i) an individual 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 a trust that has validly elected to be treated as a U.S. person for U.S. federal income tax purposes, whose status as a U.S. person is not overwritten by an applicable tax treaty.

If an entity treated as a partnership for U.S. federal income tax purposes holds our ordinary shares or ADSs, 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 advisor regarding the U.S. federal income tax considerations applicable to it and its partners of the purchase, ownership and disposition of its ordinary shares or ADSs.

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 advisors as to the particular tax considerations applicable to them relating to the purchase, ownership and disposition of their ordinary shares or ADSs, 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 or ADSs” below assumes that we will not be treated as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. However, we have not determined whether we will be a PFIC for the taxable year ending December 31, 2019, and it is possible that we will be a PFIC for the taxable year ending December 31, 2019 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 or ADSs, 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 or ADSs and to the extent they exceed that tax basis, will be treated as gain from the sale or exchange of those ordinary shares or ADSs. If we were to pay dividends to holders of our ordinary shares, we expect to pay such dividends in NIS; however, dividends paid to holders of our ADSs will be paid in dollars. 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 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 dollars. If the dividend is converted to 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 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 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 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. Investors should consult their own tax advisors 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 amounts paid to a U.S. Investor that year. Dividends paid on the ordinary shares or ADSs 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 credit purposes.

Since the rules governing foreign tax credits are complex, U.S. Investors should consult their own tax advisor regarding the availability of foreign tax credits in their particular circumstances.

Dividends paid on the ordinary shares and ADSs 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.

Distributions treated as dividends that are received by an individual U.S. Investor from "qualified foreign corporations" generally qualify for a 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 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. As mentioned above, we have not determined whether we are currently a PFIC or not.

Sale, Exchange or Other Disposition of Ordinary Shares and ADSs. 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 or ADSs 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 or ADSs. 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 or ADSs exceeds one year. Preferential tax rates for long-term capital gain 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 advisors regarding the U.S. federal income tax consequences of receiving currency other than Dollars upon the disposition of ordinary shares or ADSs.

Medicare Tax. In addition, certain U.S. persons, including individuals, estates and trusts, will be subject to an additional 3.8% Medicare tax on unearned income. For individuals, the additional Medicare tax applies to the lesser of (i) "net investment income" or (ii) the excess of "modified adjusted gross income" over \$200,000 (\$250,000 if married and filing jointly or \$125,000 if married and filing separately). "Net investment income" generally equals the taxpayer's gross investment income reduced by the deductions that are allocable to such income. Investment income generally includes passive income such as interest, dividends, annuities, royalties, rents, and capital gains. U.S. Investors are urged to consult their own tax advisors regarding the implications of the additional Medicare tax resulting from their ownership and disposition of ordinary shares or ADSs.

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 taxable years ended prior to December 31, 2009 and for taxable years ended December 31, 2011, 2012 and 2014 through 2018. We were not a PFIC for taxable years ended 2009, 2010 and 2013, and we have not determined whether we will be a PFIC for the taxable year ending December 31, 2018. 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 for taxable year ending December 31, 2019 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 or ADSs, which is referred to in this disclosure as a “timely QEF election,” makes a “mark-to-market” election with respect to the ordinary shares or ADSs (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 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 or ADSs 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 or ADSs).

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 or ADSs, any gain or loss recognized by such Electing U.S. Investor on the sale, exchange or other disposition of such ordinary shares or ADSs generally will be long-term capital gain or loss if such Electing U.S. Investor has held such ordinary shares or ADSs for more than one year at the time of such sale, exchange or other disposition. Preferential tax rates for long-term capital gain 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. A QEF election generally may not be revoked without the consent of the IRS. 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 advisor with respect to tax consequences of a QEF election with respect to us.

Mark-to-Market Election. Alternatively, if our ordinary shares or ADSs 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 or ADSs, 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 or ADSs at the end of the taxable year over such holder's adjusted tax basis in the ordinary shares or ADSs. Thus, the U.S. Investor may recognize taxable income without receiving any cash to pay its tax liability with respect to such income. 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 or ADSs 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 or ADSs would be adjusted to reflect any such income or loss amount. Gain realized on the sale, exchange or other disposition of the ordinary shares or ADSs would be treated as ordinary income, and any loss realized on the sale, exchange or other disposition of the ordinary shares or ADSs 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. A mark-to-market election will not apply to our ordinary shares or ADSs 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 unless our ordinary shares or ADSs cease to be marketable. A mark-to-market election generally may not be revoked without the consent of the IRS. Such election will not apply to any PFIC subsidiary that we own. Each U.S. Investor is encouraged to consult its own tax advisor with respect to the availability and tax consequences of a mark-to-market election with respect to our ordinary shares or ADSs.

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 or ADSs 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 the ordinary shares or ADSs), and (b) any gain realized on the sale or other disposition of such ordinary shares or ADSs. 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 or ADSs;
- 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 or ADSs, the Non-Electing U.S. Investor's successor would be ineligible to receive a step-up in tax basis of the ordinary shares or ADSs. Non-Electing U.S. Investors are encouraged to consult their tax advisors 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 ordinary shares or ADSs 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 advisors regarding the availability of a "purging election" as well as other available elections.

To the extent a distribution on our ordinary shares or ADSs 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. Investor is encouraged to consult its own tax advisor with respect to the appropriate U.S. federal income tax treatment of any distribution on our ordinary shares or ADSs.

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 advisor 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 advisors regarding the IRS information reporting and filing obligations that may arise as a result of the ownership of shares in a PFIC, including IRS Form 8621.

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 advisor 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 advisors with respect to the purchase, ownership and disposition of ordinary shares or ADSs, any elections available with respect to such ordinary shares or ADSs and the IRS information reporting obligations with respect to the purchase, ownership and disposition of ordinary shares or ADSs.

Certain Reporting Requirements

Certain U.S. Investors owning "specified foreign financial assets" with an aggregate value in excess of \$50,000 on the last day of the taxable year or \$75,000 at any time during the taxable year (or such higher dollar amount as may be prescribed by applicable IRS guidance) may be required to file IRS Form 8938, Statement of Specified Foreign Financial Assets, with respect to such assets with their tax returns. "Specified foreign financial assets" generally include any financial accounts maintained by foreign financial institutions, as well as any of the following, but only if they are not held in accounts maintained by financial institutions: (i) stocks and securities issued by non-U.S. persons, which may include the ordinary shares or ADSs, (ii) financial instruments and contracts held for investment that have non-U.S. issuers or counterparties and (iii) interests in foreign entities. The IRS has issued guidance exempting "specified foreign financial assets" held in a financial account from reporting under this provision (although the financial account itself, if maintained by a foreign financial institution, may remain subject to this reporting requirement). U.S. Investors are urged to consult their tax advisors regarding the application of these requirements to their ownership of the ordinary shares or ADSs.

If we are a PFIC, U.S. Investors may be required to file annual tax returns (including on IRS Form 8621) containing such information as the U.S. Treasury requires. A U.S. Investor that is not otherwise required to file a U.S. tax return must still file IRS Form 8621 in accordance with the instructions for the Form.

Backup Withholding Tax and Information Reporting Requirements

Generally, information reporting requirements will apply to distributions on our ordinary shares or ADSs or proceeds on the disposition of our ordinary shares or ADSs 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 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 timely 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 advisors concerning the tax consequences relating to the purchase, ownership and disposition of the ordinary shares or ADSs.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are currently subject to the information and periodic reporting requirements of the Exchange Act, and file periodic reports and other information with the SEC through its electronic data gathering, analysis and retrieval (EDGAR) system. As a foreign private issuer, all documents which were filed after September 24, 2010 on the SEC's EDGAR system are available for retrieval on the SEC's website at www.sec.gov.

As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not 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.

In addition, since our ordinary shares are traded on the TASE, we also file periodic and immediate reports with, and furnish information to, the TASE and the ISA, or the ISA, as required under Chapter Six of the Israel Securities Law, 1968 and the regulations enacted pursuant thereof, as applicable to a public company which also trades on Nasdaq. Copies of our filings with the ISA can be retrieved electronically through the MAGNA distribution site of the ISA (www.magna.isa.gov.il) and the TASE website (www.maya.tase.co.il).

We maintain a corporate website at www.bioginrx.com. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report on Form 20-F. We have included our website address in this Annual Report on Form 20-F solely as an inactive textual reference.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURE ON 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. We do not use derivative financial instruments for trading purposes. Accordingly, we have concluded that there is no material market risk exposure of the type contemplated by Item 11, and that no quantitative tabular disclosures are required. We are exposed to certain other types of market risks, as described below.

Risk of Interest Rate Fluctuation

Our investments consist primarily of cash, cash equivalents and short-term bank deposits. 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 reporting and functional currency is the dollar. However, we pay a significant portion of our expenses in NIS and in euro, and we expect this to continue. If the dollar weakens against the NIS or the euro in the future, there may be a negative impact on our results of operations. The revenues from our current out-licensing and co-development arrangements are payable in dollars and euros. Although we expect our revenues from future licensing arrangements to be denominated primarily in dollars, we are exposed to the currency fluctuation risks relating to the recording of our revenues in currencies other than dollars. For example, if the euro strengthens against the dollar, our reported revenues in dollars may be lower than anticipated. To date, fluctuations in the exchange rates have not materially affected our results of operations or financial condition for the periods under review.

From time to time, we have engaged in currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies, and we may continue to do so in the future. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Set forth below is a summary of some of the material terms of the deposit agreement among BioLineRx, The Bank of New York Mellon as depositary, or the Depositary, and the owners and holders from time to time of our ADSs.

Description of the ADSs

Each of our ADSs represents one of our ordinary shares deposited with the principal Tel Aviv office of either Bank Hapoalim B.M. or Bank Leumi Le-Israel, as Custodian for the Depositary. Our ADSs trade on Nasdaq.

The form of the deposit agreement for the ADS and the form of American Depositary Receipt (ADR) that represents an ADS have been incorporated by reference as exhibits to this Annual Report on Form 20-F. Copies of the deposit agreement are available for inspection at the principal office of The Bank of New York Mellon, located at 101 Barclay Street, New York, New York 10286.

Charges of Depositary

We will pay the fees, reasonable expenses and out-of-pocket charges of the Depositary and those of any registrar only in accordance with agreements in writing entered into between us and the Depositary from time to time. The following charges shall be incurred by any party depositing or withdrawing ordinary shares or by any party surrendering ADRs or to whom ADRs are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADRs or deposited ordinary shares or a distribution of ADRs pursuant to the terms of the deposit agreement):

- taxes and other governmental charges;
- any applicable transfer or registration fees;
- certain cable, telex and facsimile transmission charges as provided in the deposit agreement;
- any expenses incurred in the conversion of foreign currency;
- a fee of \$5.00 or less per 100 ADSs (or a portion thereof) for the execution and delivery of ADRs and the surrender of ADRs, including if the deposit agreement terminates;
- a fee of \$.05 or less per ADS (or portion thereof) for any cash distribution made pursuant to the deposit agreement;
- a fee for the distribution of securities pursuant to the deposit agreement;
- in addition to any fee charged for a cash distribution, a fee of \$.05 or less per ADS (or portion thereof) per annum for depositary services;
- a fee for the distribution of proceeds of rights that the Depositary sells pursuant to the deposit agreement; and
- any other charges payable by the Depositary, any of the Depositary's agents, or the agents of the Depositary's agents in connection with the servicing of ordinary shares or other Deposited Securities.

The Depositary may own and deal in our securities and in ADSs.

The Depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The Depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The Depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The Depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The Depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the Depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the Depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the Depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the Depositary and that may earn or share fees, spreads or commissions.

The Depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the Depositary or its affiliate receives when buying or selling foreign currency for its own account. The Depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the Depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Liability of Holders for Taxes, Duties or Other Charges

Any tax or other governmental charge with respect to ADSs or any deposited ordinary shares represented by any ADS shall be payable by the holder of such ADS to the Depositary. The Depositary may refuse to effect transfer of such ADS or any withdrawal of deposited ordinary shares represented by such ADS until such payment is made, and may withhold any dividends or other distributions or may sell for the account of the holder any part or all of the deposited ordinary shares represented by such ADS and may apply such dividends or distributions or the proceeds of any such sale in payment of any such tax or other governmental charge and the holder of such ADS shall remain liable for any deficiency.

ITEM 13. DEFAULTS, DIVIDENDS ARREARAGES AND DELINQUENCIES

Not applicable.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

We have performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that the material financial and non-financial information required to be disclosed to the SEC is recorded, processed, summarized and reported timely. Based on our evaluation, our management, including the Chief Executive Officer, or the CEO, and the Chief Financial Officer, or the CFO, has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this report are effective. Notwithstanding the foregoing, there can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within the Company to disclose material information otherwise required to be set forth in our reports.

(b) Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) promulgated under the Exchange Act. Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the reliability of financial reporting and the preparation and fair presentation of published financial statements for external purposes in accordance with generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate.

Our management, including the CEO and CFO, conducted an evaluation, pursuant to Rule 13a-15(c) promulgated under the Exchange Act, of the effectiveness, as of the end of the period covered by this Annual Report, of its internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013). Based on the results of this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2018.

(c) **Attestation Report of Registered Public Accounting Firm**

Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Ltd., our independent registered public accounting firm, has issued an attestation report on the effectiveness of our internal control over financial reporting, appearing under “Item 18. Financial Statements” on page F-2, and such report is incorporated herein by reference.

(d) **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERTS

Our Board of Directors has determined that Ms. Nurit Benjamini is the audit committee financial expert. Ms. Benjamini is one of our independent directors for the purposes of the Nasdaq Rules.

ITEM 16B. CODE OF ETHICS

In July 2011, our Board of Directors adopted a Code of Business Conduct and Ethics, or the Code of Conduct, that applies to all our employees, including without limitation our CEO, CFO and controller. Our Code of Conduct may be viewed on our website at www.biogenerx.com. A copy of our Code of Conduct may be obtained, without charge, upon a written request addressed to our investor relations department, 2 HaMa'ayan Street, Modi'in 7177871, Israel (Telephone no. +972-8-642-9100) (e-mail: info@BioLineRx.com).

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Registered Public Accounting Firm

The following table sets forth, for each of the years indicated, the fees billed by Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Ltd., our independent registered public accounting firm.

Services Rendered	Year Ended December 31,	
	2017	2018
	<i>(in thousands of U.S. dollars)</i>	
Audit Fees ⁽¹⁾	\$ 110	\$ 110
Audit-Related Fees ⁽²⁾	33	-
Tax Fees ⁽³⁾	27	14
All Other Fees	-	-
Total	\$ 170	\$ 126

(1) Audit fees consist of services that would normally be provided in connection with statutory and regulatory filings or engagements, including services that generally only the independent accountant can reasonably provide.

(2) Audit-related services relate to reports to the IIA and work regarding a public listing or offering.

(3) Tax fees relate to tax compliance, planning and advice.

Our Audit Committee, in accordance with its charter, reviews and pre-approves all audit services and permitted non-audit services (including the fees and other terms) to be provided by our independent auditors.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

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 Nasdaq Rules, we have elected to follow certain corporate governance practices permitted under the Companies Law and the rules of the TASE in lieu of compliance with certain corporate governance requirements otherwise required by the Nasdaq Rules.

In accordance with Israeli law and practice and subject to the exemption set forth in Rule 5615 of the Nasdaq Rules, we follow the provisions of the Companies Law, rather than the Nasdaq Rules, with respect to the following requirements:

- *Distribution of annual and quarterly reports to shareholders.* Under Israeli law, as a public company whose shares are traded on the TASE, we are not required to distribute annual and quarterly reports directly to shareholders and the generally accepted business practice in Israel is not to distribute such reports to shareholders but to make such reports publicly available through the website of the ISA and the TASE. In addition, we make our audited financial statements available to our shareholders at our offices. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules.

- *Quorum.* While the Nasdaq Rules require that the quorum for purposes of any meeting of the holders of a listed company's common voting stock, as specified in the company's bylaws, be no less than 33 1/3% of the company's outstanding common voting stock, 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 includes two external directors in accordance with the provisions contained in Sections 239-249 of the Companies Law and Rule 10A-3 of the general rules and regulations promulgated under the Securities Act, 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. We are required, however, to ensure that all members of our Audit Committee are "independent" under the applicable Nasdaq and SEC criteria for independence (as a foreign private issuer we are not exempt from the SEC independence requirement), and we must also ensure that a majority of the members of our Audit Committee are unaffiliated directors as defined in the Companies Law. Furthermore, Israeli law does not require, nor do our independent directors conduct, regularly scheduled meetings at which only they are present, which the Nasdaq Rules otherwise require. If we qualify as an Eligible Company and opt to follow the exemption provided under the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees, we will be required at all times to comply with the U.S. rules and regulations governing the appointment of independent directors and composition of the audit and compensation committees applicable to U.S. domestic issuers instead of complying with the Companies Law provisions relating to external directors and composition of the audit and compensation committees.
- *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 only one other director, who cannot be the chairman of our Board of Directors. Consistent with Israeli law, the independent auditors are elected at a meeting of shareholders instead of being appointed by the Audit Committee. If we qualify as an Eligible Company and opt to follow the exemption provided under the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees, we will be required at all times to comply with the U.S. rules and regulations governing the appointment of independent directors and composition of the Audit Committee applicable to U.S. domestic issuers instead of complying with the Companies Law provisions relating to external directors and composition of 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 "Item 6. Directors, Senior Management and Employees — Board Practices — 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 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 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 Committee and Compensation of Officers.* Israeli law, and our Articles of Association, do not require that a compensation committee composed solely of independent members of our Board of Directors determine (or recommend to the board of directors for determination) an executive officer's compensation, as required under Nasdaq's listing standards related to compensation committee independence and responsibilities; nor do they require that the Company adopt and file a compensation committee charter. Instead, our Compensation Committee has been established and conducts itself in accordance with provisions governing the composition of and the responsibilities of a compensation committee as set forth in the Companies Law, and is comprised of all of our external directors (who must comprise the majority of the members of the Compensation Committee), and at least one additional director who is entitled to the same compensation payable to our external directors, and who is not the chairman of our Board of Directors or otherwise employed by or a provider of services to, the Company. If we qualify as an Eligible Company and opt to follow the exemption provided under the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees, we will be required at all times to comply with the U.S. rules and regulations governing the appointment of independent directors and composition of the compensation committee applicable to U.S. domestic issuers instead of complying with the Companies Law provisions relating to external directors and composition of the compensation committee. Additionally, we comply with the requirements set forth under the Companies Law, pursuant to which transactions with office holders regarding their terms of office and employment, and a transaction with a controlling shareholder in a company regarding his or her employment and/or his or her terms of office with the company, may require the approval of the compensation committee, the board of directors and under certain circumstances the shareholders, either in accordance with our previously approved compensation policy or, in special circumstances in deviation therefrom, taking into account certain considerations set forth in the Companies Law. See "Item 6. Directors, Senior Management and Employees — Board Practices — Compensation Committee" for information regarding the Compensation Committee, and "Item 6. Directors, Senior Management and Employees — Approval of Related Party Transactions under Israeli Law" for information regarding the special approvals required with respect to approval of terms of office and employment of office holders, pursuant to the Companies Law. The requirements for shareholder approval of any office holder compensation, and the relevant majority or special majority for such approval, are all as set forth in the Companies Law. Thus, we will seek shareholder approval for all corporate actions with respect to office holder compensation requiring such approval under the requirements of the Companies Law, including seeking prior approval of the shareholders for the compensation policy and for certain office holder compensation, rather than seeking approval for such corporate actions in accordance with Nasdaq Listing Rules.
- *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 Companies Law, and the regulations promulgated thereunder, which require the approval of the audit committee, the compensation committee, the board of directors and shareholders, as may be applicable, for specified transactions, rather than approval by the audit committee or other independent body of our Board of Directors as required under the Nasdaq Rules.
- *Shareholder Approval.* We seek shareholder approval for all corporate actions requiring such approval in accordance with the requirements of the 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.
- *Equity Compensation Plans.* We do not necessarily seek shareholder approval for the establishment of, and amendments to, stock option or equity compensation plans (as set forth in Nasdaq Listing Rule 5635(c)), as such matters are not subject to shareholder approval under Israeli law. Our equity compensation plan is available to our employees, none of whom are currently U.S. employees, and provides features necessary to comply with applicable non-U.S. tax laws.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 17. FINANCIAL STATEMENTS

The Registrant has responded to Item 18 in lieu of responding to this Item.

ITEM 18. FINANCIAL STATEMENTS

See the financial statements beginning on page F-1. The following financial statements are filed as part of this Annual Report on Form 20-F together with the report of the independent registered public accounting firm.

ITEM 19. EXHIBITS

Exhibit Number	Exhibit Description
<u>2.1(3)</u>	<u>Articles of Association, as amended July 5, 2017</u>
<u>2.2(2)</u>	<u>Deposit Agreement dated as of July 21, 2011 among the Registrant, The Bank of New York Mellon, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder</u>
<u>2.3(2)</u>	<u>Form of American Depositary Receipt; the Form is Exhibit A of the deposit agreement which is Exhibit 2.2 above.</u>
<u>4.5(10)</u>	<u>Employment Agreement with Philip Serlin, dated May 24, 2009, as amended</u>
<u>4.16(1)</u>	<u>License Agreement entered into as of November 25, 2007 between BioLine Innovations Jerusalem L.P. and Innovative Pharmaceutical Concepts, Inc.</u>
<u>4.18(9)</u>	<u>BioLineRx Ltd. Amended and Restated 2003 Share Incentive Plan</u>
<u>4.33(4)</u>	<u>License Agreement entered into as of September 2, 2012 by and between the Registrant and Biokine Therapeutics Ltd.</u>
<u>4.34(5)†</u>	<u>Amendment Agreement entered into as of October 2, 2018 by and between the Registrant and Biokine Therapeutics Ltd.</u>
<u>4.35(5)</u>	<u>Loan Agreement entered into as of October 2, 2018, by and between the Registrant and Kreos Capital V (Expert Fund) L.P.</u>
<u>4.36(6)</u>	<u>Compensation Policy for Executives and Directors</u>
<u>4.37(7)</u>	<u>Lease Agreement entered into as of August 7, 2014 between S.M.L. Solomon Industrial Buildings Ltd. and Infrastructure Management and Development Established by C.P.M. Ltd. as Lessor and the Registrant as Lessee, as amended (English summary of the Hebrew original)</u>
<u>4.38(7)†</u>	<u>Investment and Collaboration Agreement entered into as of December 16, 2014 between the Registrant and Novartis Pharma AG</u>
<u>4.39(8)†</u>	<u>License Agreement entered into as of December 22, 2014 between the Registrant and Wartner Europe BV</u>
<u>4.40(4)†</u>	<u>Clinical Trial Collaboration and Supply Agreement entered into as of January 11, 2016 between the Registrant and Merck Sharp & Dohme B.V.</u>
<u>4.41†</u>	<u>Amendment No. 2 to Clinical Trial Collaboration and Supply Agreement entered into as of July 24, 2018 between the Registrant and Merck Sharp & Dohme B.V.</u>
<u>4.42(10)†</u>	<u>Combination Study Agreement entered into as of September 6, 2016 between the Registrant and Genentech, Inc.</u>
<u>4.43(10)</u>	<u>Employment Agreement with Mali Zeevi, dated September 16, 2009, as amended</u>
<u>4.44(10)</u>	<u>Employment Agreement with Abi Vainstein-Haras, dated April 2, 2014, as amended</u>

Exhibit Number	Exhibit Description
4.45⁽¹⁰⁾	Employment Agreement with Ella Sorani, dated January 11, 2017
4.46^{(10)†}	Amended and Restated Exclusive License Agreement entered into as of April 30, 2013 between the University of Massachusetts and Agalimmune Ltd.
4.47†	Patent and Know-how License Agreement entered into as of September 19, 2017 between Kode Biotech Limited and Agalimmune Ltd.
4.49†	Second Amendment Agreement entered into as of October 16, 2018 between the University of Massachusetts and Agalimmune Ltd.
4.50†	Amendment No. 1 to License Agreement entered into as of June 18, 2018 between the Registrant and Wartner Europe BV
12.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1	Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2	Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.5	Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Registrant
15.8⁽¹¹⁾	Subscription Agreement entered into as of July 26, 2017 among the Registrant and Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS, L.P., Investment 10, LLC and MSI BVF SPV, L.L.C. (the “BVF Investors”)
15.9⁽¹¹⁾	Form of Series A Warrant issued to the BVF Investors
15.10⁽¹¹⁾	Form of Series B Warrant issued to the BVF Investors
15.11⁽¹¹⁾	Voting and Standstill Agreement entered into as of July 26, 2017 among the Registrant and the BVF Investors
15.12⁽¹²⁾	At-the-market Sales Agreement entered into October 30, 2017, between the Registrant and BTIG, LLC
101	The following financial information from BioLineRx Ltd.’s Annual Report on Form 20-F for the fiscal year ended December 31, 2017 formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Statements of Financial Position at December 31, 2017 and 2016; (ii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2017, 2016 and 2015; (iii) Statements of Changes in Equity for the years ended December 31, 2017, 2016 and 2015; (iv) Consolidated Cash Flow Statements for the years ended December 31, 2017, 2016 and 2015; and (v) Notes to the Consolidated Financial Statements. Users of this data are advised, in accordance with Rule 406T of Regulation S-T promulgated by the SEC, that this Interactive Data File is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

† Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

(1) Incorporated by reference to the Registrant’s Registration Statement on Form 20-F (No. 001-35223) filed on July 1, 2011.

- (2) Incorporated by reference to Exhibit 1 of the Registration Statement on Form F-6EF (No. 333-218969) filed by the Bank of New York Mellon on June 26, 2017 with respect to the Registrant's American Depositary Shares.
- (3) Incorporated by reference to the Registrant's Registration Statement on Form F-3 (No. 333-222332) filed on December 28, 2017.
- (4) Incorporated by reference to the Registrant's Annual Report on Form 20-F/A filed on May 31, 2016.
- (5) Incorporated by reference to the Registrant's Form 6-K filed on October 3, 2018.
- (6) Incorporated by reference to the Registrant's Form 6-K filed on May 31, 2016.
- (7) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 23, 2015.
- (8) Incorporated by reference to the Registrant's Annual Report on Form 20-F/A filed on September 22, 2015.
- (9) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 10, 2016.
- (10) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 23, 2017.
- (11) Incorporated by reference to the Registrant's Form 6-K filed on July 31, 2017.
- (12) Incorporated by reference to the Registrant's Form 6-K filed on October 31, 2017.

SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

BIOLINERX LTD.

By: /s/ Philip A. Serlin

Philip A. Serlin
Chief Executive Officer

Date: March 28, 2019



REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the board of directors and shareholders of
BioLineRx Ltd.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of BioLineRx Ltd. and its subsidiaries (the "Company") as of December 31, 2018 and 2017, 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, 2018, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and their cash flows for each of the three years in the period ended December 31, 2018, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 15(b). Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Tel Aviv, Israel
March 25, 2019

Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Ltd.

We have served as the Company's auditor since 2003.

BioLineRx Ltd.
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	<u>Note</u>	<u>December 31,</u>	
		<u>2017</u>	<u>2018</u>
		<u>in USD thousands</u>	
Assets			
CURRENT ASSETS			
Cash and cash equivalents	5	5,110	3,404
Short-term bank deposits	6	44,373	26,747
Prepaid expenses		307	488
Other receivables	16a	586	1,339
Total current assets		<u>50,376</u>	<u>31,978</u>
NON-CURRENT ASSETS			
Long-term prepaid expenses	16b	61	56
Long-term investment	7	1,000	-
Property and equipment, net	8	2,505	2,227
Intangible assets, net	9	7,023	21,972
Total non-current assets		<u>10,589</u>	<u>24,255</u>
Total assets		<u><u>60,965</u></u>	<u><u>56,233</u></u>
Liabilities and equity			
CURRENT LIABILITIES			
Current maturities of long-term loans	10	93	895
Accounts payable and accruals:			
Trade	16c	5,516	4,493
Other	16c	1,113	1,363
Total current liabilities		<u>6,722</u>	<u>6,751</u>
NON-CURRENT LIABILITIES			
Long-term loans, net of current maturities	10	157	7,838
Warrants	11c, 18	1,205	323
Total non-current liabilities		<u>1,362</u>	<u>8,161</u>
COMMITMENTS AND CONTINGENT LIABILITIES			
Total liabilities	14	<u>8,084</u>	<u>14,912</u>
EQUITY			
Ordinary shares	11	2,836	3,110
Share premium		240,682	250,192
Capital reserve		10,337	11,955
Other comprehensive loss		(1,416)	(1,416)
Accumulated deficit		(199,558)	(222,520)
Total equity		<u>52,881</u>	<u>41,321</u>
Total liabilities and equity		<u><u>60,965</u></u>	<u><u>56,233</u></u>

The accompanying notes are an integral part of the consolidated financial statements.

BioLineRx Ltd.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	<u>Note</u>	<u>Year ended December 31,</u>		
		<u>2016</u>	<u>2017</u>	<u>2018</u>
		<u>in USD thousands</u>		
RESEARCH AND DEVELOPMENT EXPENSES	16d	(11,177)	(19,510)	(19,808)
SALES AND MARKETING EXPENSES	16e	(1,352)	(1,693)	(1,362)
GENERAL AND ADMINISTRATIVE EXPENSES	16f	(3,984)	(4,037)	(4,435)
OPERATING LOSS		(16,513)	(25,240)	(25,605)
NON-OPERATING INCOME (EXPENSES), NET	16g	214	(260)	2,397
FINANCIAL INCOME	16h	480	1,169	719
FINANCIAL EXPENSES	16i	(22)	(21)	(473)
NET LOSS AND COMPREHENSIVE LOSS		<u>(15,841)</u>	<u>(24,352)</u>	<u>(22,962)</u>
		in USD		
LOSS PER ORDINARY SHARE – BASIC AND DILUTED	13	<u>(0.28)</u>	<u>(0.27)</u>	<u>(0.21)</u>
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	13	<u>56,144,727</u>	<u>89,970,713</u>	<u>108,595,702</u>

The accompanying notes are an integral part of the consolidated financial statements.

BioLineRx Ltd.
STATEMENTS OF CHANGES IN EQUITY

	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Capital reserve</u>	<u>Other comprehensive loss</u>	<u>Accumulated deficit</u>	<u>Total</u>
	<u>in USD thousands</u>					
BALANCE AT JANUARY 1, 2016	1,455	196,201	10,735	(1,416)	(159,365)	47,610
CHANGES IN 2016:						
Issuance of share capital, net	57	2,126	-	-	-	2,183
Employee stock options exercised	1	171	(172)	-	-	-
Employee stock options expired	-	1,069	(1,069)	-	-	-
Share-based compensation	-	-	1,075	-	-	1,075
Comprehensive loss for the year	-	-	-	-	(15,841)	(15,841)
BALANCE AT DECEMBER 31, 2016	<u>1,513</u>	<u>199,567</u>	<u>10,569</u>	<u>(1,416)</u>	<u>(175,206)</u>	<u>35,027</u>
CHANGES IN 2017:						
Issuance of share capital, net	1,322	39,376	-	-	-	40,698
Employee stock options exercised	1	328	(329)	-	-	-
Employee stock options expired	-	1,411	(1,411)	-	-	-
Share-based compensation	-	-	1,508	-	-	1,508
Comprehensive loss for the year	-	-	-	-	(24,352)	(24,352)
BALANCE AT DECEMBER 31, 2017	<u>2,836</u>	<u>240,682</u>	<u>10,337</u>	<u>(1,416)</u>	<u>(199,558)</u>	<u>52,881</u>
CHANGES IN 2018:						
Issuance of share capital, net	263	8,567	-	-	-	8,830
Employee stock options exercised	11	415	(380)	-	-	46
Employee stock options expired	-	528	(528)	-	-	-
Share-based compensation	-	-	2,526	-	-	2,526
Comprehensive loss for the year	-	-	-	-	(22,962)	(22,962)
BALANCE AT DECEMBER 31, 2018	<u><u>3,110</u></u>	<u><u>250,192</u></u>	<u><u>11,955</u></u>	<u><u>(1,416)</u></u>	<u><u>(222,520)</u></u>	<u><u>41,321</u></u>

The accompanying notes are an integral part of the consolidated financial statements.

BioLineRx Ltd.
CONSOLIDATED CASH FLOW STATEMENTS

	Year ended December 31,		
	2016	2017	2018
	in USD thousands		
CASH FLOWS - OPERATING ACTIVITIES			
Net loss	(15,841)	(24,352)	(22,962)
Adjustments required to reflect net cash used in operating activities (see appendix below)	1,328	3,805	(1,230)
Net cash used in operating activities	<u>(14,513)</u>	<u>(20,547)</u>	<u>(24,192)</u>
CASH FLOWS - INVESTING ACTIVITIES			
Increase in long-term investment	-	(1,000)	-
Realization of long-term investment			1,500
Investments in short-term deposits	(32,982)	(44,016)	(26,500)
Maturities of short-term deposits	42,334	33,327	44,771
Purchase of property and equipment	(52)	(338)	(173)
Purchase of intangible assets	(3)	(3,900)	(10,043)
Net cash provided by (used in) investing activities	<u>9,297</u>	<u>(15,927)</u>	<u>9,555</u>
CASH FLOWS - FINANCING ACTIVITIES			
Issuance of share capital and warrants, net of issuance costs	2,183	38,773	3,830
Employee stock options exercised	-	-	46
Proceeds of long-term loan and warrants, net of issuance costs	-	-	9,632
Repayment of long-term loan	-	-	(318)
Repayments of bank loan	(93)	(93)	(93)
Net cash provided by financing activities	<u>2,090</u>	<u>38,680</u>	<u>13,097</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	<u>(3,126)</u>	<u>2,206</u>	<u>(1,540)</u>
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	<u>5,544</u>	<u>2,469</u>	<u>5,110</u>
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	<u>51</u>	<u>435</u>	<u>(166)</u>
CASH AND CASH EQUIVALENTS - END OF YEAR	<u><u>2,469</u></u>	<u><u>5,110</u></u>	<u><u>3,404</u></u>

The accompanying notes are an integral part of the consolidated financial statements.

BioLineRx Ltd.
CONSOLIDATED CASH FLOW STATEMENTS

	Year ended December 31,		
	2016	2017	2018
	in USD thousands		
APPENDIX			
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization	482	481	545
Long-term prepaid expenses	6	(9)	5
Exchange differences on cash and cash equivalents	(51)	(435)	166
Loss (gain) on adjustment of warrants to fair value	(207)	127	(1,743)
Share-based compensation	1,075	1,508	2,526
Interest and exchange differences on short-term deposits	(387)	(530)	(645)
Interest and linkage differences on loans	(1)	-	123
Gain on realization of long-term investment	-	-	(500)
Warrant issuance costs	-	17	-
	<u>917</u>	<u>1,159</u>	<u>477</u>
Changes in operating asset and liability items:			
Decrease (increase) in prepaid expenses and other receivables	42	(415)	(934)
Increase (decrease) in accounts payable and accruals	369	3,061	(773)
	<u>411</u>	<u>2,646</u>	<u>(1,707)</u>
	<u>1,328</u>	<u>3,805</u>	<u>(1,230)</u>
Supplemental information on interest received in cash	<u>453</u>	<u>494</u>	<u>834</u>
Supplemental information on non-cash transactions (see Notes 18 and 19)	<u>-</u>	<u>2,985</u>	<u>5,000</u>

The accompanying notes are an integral part of the consolidated financial statements.

NOTE 1 – GENERAL INFORMATION

a. General

BioLineRx Ltd. (“BioLineRx”), headquartered in Modi’in, Israel, was incorporated and commenced operations in April 2003.

BioLineRx and its subsidiaries (collectively, the “Company”) are engaged in the development of therapeutics, primarily in clinical stages, with a focus on the field of oncology.

In February 2007, BioLineRx listed its ordinary shares on the Tel Aviv Stock Exchange (“TASE”) and they have been traded on the TASE since that time. Since July 2011, BioLineRx’s American Depositary Shares (“ADSs”) have also been traded on the NASDAQ Capital Market.

In March 2017, the Company acquired Agalimmune Ltd. (“Agalimmune”), a privately held company incorporated in the United Kingdom, with a focus on the field of immuno-oncology. See Note 17.

Although the Company has generated revenues from out-licensing transactions in the past, the Company cannot determine with reasonable certainty when and if it will have sustainable profits.

b. Approval of consolidated financial statements

The consolidated financial statements of the Company for the year ended December 31, 2018 were approved by the Board of Directors on March 25, 2019, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer and the Chief Financial Officer.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation

The Company’s consolidated financial statements as of December 31, 2018 and 2017, and for each of the three years in the period ended December 31, 2018, have been prepared in accordance with International Financial Reporting Standards (“IFRS”), as issued by the International Accounting Standards Board (“IASB”). The significant accounting policies described below have been applied on a consistent basis for all years presented, unless noted otherwise.

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.

The Company classifies its expenses on the statement of comprehensive loss based on the operating characteristics of such expenses.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

a. Basis of presentation (cont.)

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 Company’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 Company’s management.

b. Principles of consolidation

Consolidated entities are all entities over which BioLineRx has control. BioLineRx controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Consolidated entities are fully consolidated from the date on which control of such entities is transferred to BioLineRx and they are de-consolidated from the date that control ceases.

c. Functional and reporting currency

The functional and reporting currency in these financial statements is the U.S. dollar (“dollar”, “USD” or “\$”), which is the primary currency of the economic environment in which the Company operates. Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are generally recognized in profit or loss.

Foreign exchange gains and losses that relate to borrowings are presented in the statement of comprehensive loss, within financial expenses. All other foreign exchange gains and losses are presented in the statement of comprehensive loss on a net basis within non-operating income or expenses.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

d. Cash equivalents and short-term bank deposits

Cash and cash equivalents include cash on hand and short-term bank deposits (up to three months from date of deposit) that are not restricted as to withdrawal or use, and are therefore considered to be cash equivalents. Bank deposits with original maturity dates of more than three months and with a current maturity date of less than one year from the balance sheet date are included in short-term bank deposits. The fair value of cash equivalents and short-term bank deposits approximate their carrying value, since they bear interest at rates close to the prevailing market rates. See also Note 6.

e. Property and equipment

Property and equipment are stated at historical cost less depreciation. 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 Company's management believes the residual values of the assets to be negligible, as follows:

	%
Computers and communications equipment	20-33
Office furniture and equipment	6-15
Laboratory equipment	15-20

The assets' residual values, methods of depreciation 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 shorter of the lease term or the estimated useful life of the improvements.

f. Intangible assets

The Company applies the cost method of accounting for initial and 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 Company recognizes in its financial statements intangible assets developed by the Company to the extent that the conditions stipulated in n. below are met. Intellectual property acquired by the Company is initially measured at cost. Intellectual property acquired by the Company for development purposes is not amortized and is tested annually for impairment. See g. 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 (3-5 years).

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

g. Impairment of non-financial assets

Impairment of intellectual property is required when the Company decides to terminate or suspend the development of a project based on such intellectual property. In addition, the Company performs impairment reviews on an annual basis, or more frequently if events or changes in circumstances indicate a potential impairment. 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 Company.

h. Financial assets

Effective January 1, 2018, the Company adopted IFRS 9 "Financial Instruments."

1) Classification

The financial assets of the Company are classified into the following two categories:

(i) financial assets at fair value through profit or loss, and (ii) financial assets at amortized cost. The classification is done on the basis of the Company's business model for managing the financial assets and the contractual cash flow characteristics of the financial assets.

a) Financial assets at amortized cost

Financial assets at amortized cost are assets held pursuant to a business model whose objective is to hold assets in order to collect contractual cash flows and the contractual terms of the financial assets give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Financial assets at amortized cost are included in current assets, except for those with maturities greater than 12 months after the balance sheet date (in which case they are classified as non-current assets).

The Company's financial assets at amortized cost are included in other receivables and bank deposits in the consolidated statements of financial position.

b) Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss are assets not measured at amortized cost in accordance with (1)(a) above. Assets in this category are classified as current assets if they are expected to be settled within 12 months; otherwise, they are classified as non-current assets.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

h. Financial assets (cont.)

2) Recognition and measurement

Regular purchases and sales of financial assets are recognized on the settlement date, which is the date on which the asset is delivered to the Company or delivered by the Company. Investments are initially recognized at fair value plus transaction costs for all financial assets not recorded at fair value through profit or loss, except for trade receivables, which are recognized initially at the amount of consideration that is unconditional unless they contain significant financing components.

Financial assets measured at fair value through profit or loss are initially recognized at fair value, and related transaction costs are expensed to profit or loss. Financial assets are derecognized when the rights to receive cash flow from the investments have expired or have been transferred and the Company has transferred substantially all risks and rewards of ownership. Financial assets at fair value through profit or loss are subsequently recorded at fair value. Financial assets at amortized cost are measured in subsequent periods at amortized cost using the effective interest method. Gains or losses arising from changes in the fair value of financial assets at fair value through profit or loss are presented in the Statement of Comprehensive Loss under financial income or expenses.

3) Impairment

The Company recognizes a loss allowance for expected credit losses on financial assets at amortized cost. At each reporting date, the Company assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. If the financial instrument is determined to have low credit risk at the reporting date, the Company assumes that the credit risk on a financial instrument has not increased significantly since initial recognition.

Prior to the effective date and adoption of IFRS 9, the financial assets of the Company were classified into the following categories: (i) financial assets at fair value through profit or loss, and (ii) loans and receivables. The classification depended on the purpose for which the financial assets were acquired. Also, prior to the adoption of IFRS 9, the Company assessed at December 31, 2017 whether there was any objective evidence that a financial asset or group of financial assets was impaired.

i. 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. In the event that the exercise price is not deemed to be fixed, the warrants are classified as a non-current derivative financial liability. This liability is initially recognized at its fair value on the date the contract is entered into and subsequently accounted for at fair value at each reporting date. The fair value changes are charged to non-operating income and expense on the statement of comprehensive loss. Issuance costs allocable to warrants are also recorded as non-operating expense on the statement of comprehensive loss.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

j. Share capital

The Company's 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.

k. Trade payables

Trade payables are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. These payables are classified as current liabilities if payment is due within one year or less. If not, they are presented as non-current liabilities. Trade payables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method.

l. 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 Company is currently engaged primarily 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.

m. Revenue from contract with customers

Effective January 1, 2018, the Company adopted IFRS 15, "Revenue from Contracts with Customers."

IFRS 15 introduces a five-step model for recognizing revenue from contracts with customers, as follows:

- identify the contract with a customer;
- identify the performance obligations in the contract;
- determine the transaction price;
- allocate the transaction price to the performance obligations in the contract; and
- recognize revenue when (or as) the entity satisfies a performance obligation.

During the reported years, the Company did not generate revenues, other than immaterial amounts received from an out-licensing agreement signed in 2014 with Perrigo Company plc., which have been included as non-operating income.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

n. Research and development expenses

Research expenses are charged to profit or loss 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:

- technological 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 profit or loss as incurred. Development costs previously expensed are not recognized as an asset in subsequent periods. As of December 31, 2018, the Company has not yet capitalized development expenses.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

o. Employee benefits

1) Pension and severance pay obligations

Israeli labor laws and the Company's employment agreements require the Company to pay retirement benefits to employees terminated or leaving their employment in certain other circumstances. Most of the Company's employees are covered by a defined contribution plan under Section 14 of the Israel Severance Pay Law.

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 each reporting date, net of the fair value of plan assets. 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.

The amounts recorded as an employee benefit expense in respect of pension and severance pay obligations for the years 2016, 2017 and 2018 were \$523,000, \$563,000 and \$618,000 respectively.

2) Vacation and recreation pay

Labor laws in Israel entitle every employee to vacation 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 Company 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 Company operates an equity-settled, share-based compensation plan, under which it grants equity instruments (options, restricted stock units and performance stock units) of the Company as additional consideration for services from employees. The fair value of the employee services received in exchange for grant of the equity instruments is recognized as an expense. The total amount to be expensed is determined by reference to the fair value of the equity instruments granted:

- including any market performance conditions (for example, the Company's share price); and
- 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).

Non-market performance and service conditions are included in assumptions about the number of equity instruments 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.

When the equity instruments 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 equity instruments are exercised.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

p. 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 ordinary shares outstanding 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 warrants issued to investors, as well as equity instruments granted to employees and service providers. The dilutive potential shares were not taken into account in computing loss per share in 2016, 2017 and 2018, as their effect would have been anti-dilutive.

q. Standards and interpretations to existing standards that are not yet in effect and have not been early adopted by the Company

International Financial Reporting Standard No. 16 “Leases” (“IFRS 16”)

IFRS 16 was issued in January 2016, sets out principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract, and replaces the previous lease standard, IAS 17, “Leases.” IFRS 16 eliminates the classification of leases for the lessee as either operating leases or finance leases as required by IAS 17, and instead introduces a single lessee accounting model whereby a lessee is required to recognize assets and liabilities for all leases with a term that is greater than 12 months, unless the underlying asset is of low value, and to recognize amortization of lease assets separately from interest on lease liabilities in the income statement. IFRS 16 is effective from January 1, 2019.

The Company intends to apply the new standard from its mandatory adoption date of January 1, 2019, using the simplified transition approach without restating comparative amounts for the year prior to first adoption.

The Company has reviewed all of its leasing arrangements outstanding as of December 31, 2018 in light of the new lease accounting rules in IFRS 16, and has determined that the standard will affect primarily the accounting for its operating leases.

The Company expects to recognize right-of-use assets and lease liabilities of approximately \$1.9 million on January 1, 2019. The Company does not expect adoption of the new standard to have a material effect on the consolidated statement of comprehensive income (loss) for 2019. The Company does expect certain changes in the consolidated cash flow statement for 2019, specifically an increase in operating cash flows of approximately \$0.3 million, along with a corresponding decrease in financing cash flows, as repayment of the principal portion of the lease liabilities will be classified as cash flows from financing activities.

NOTE 3 – FINANCIAL RISK MANAGEMENT

Based on assessments by Company management, the Company's exposure to credit risk as of December 31, 2018 is immaterial (see Note 3b). The activities of the Company expose it to market risk, primarily as a result of currency risk.

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 risk

1) Concentration of currency risk

The Company's activities are partly denominated in non-dollar currencies (primarily the New Israeli Shekel, or "NIS," and the Euro), which exposes the Company to risks resulting from changes in exchange rates.

The effect of fluctuations in various exchange rates on the Company's income and equity is as follows:

Sensitive instrument	December 31, 2018				
	Income (loss)		Value on balance sheet	Income (loss)	
	10% increase	5% increase		5% decrease	10% decrease
in USD thousands					
NIS-linked balances:					
Cash and cash equivalents	(64)	(33)	699	37	78
Other receivables	(45)	(23)	491	26	55
Trade payables	73	38	(807)	(42)	(90)
Other payables	57	30	(632)	(33)	(70)
Total NIS-linked balances	21	12	(249)	(12)	(27)
Euro-linked trade payables	(177)	(93)	(453)	102	216
Total	(156)	(81)	(702)	90	189

The Company also maintains cash and cash equivalent balances in other currencies in amounts that are not material.

Sensitive instrument	December 31, 2017				
	Income (loss)		Value on balance sheet	Income (loss)	
	10% increase	5% increase		5% decrease	10% decrease
in USD thousands					
NIS-linked balances:					
Cash and cash equivalents	(216)	(113)	2,376	125	264
Other receivables	(30)	(15)	325	17	36
Trade payables	69	36	(764)	(40)	(85)
Other payables	69	36	(756)	(40)	(84)
Total NIS-linked balances	(108)	(56)	1,181	62	131
Euro-linked trade payables	(94)	(49)	(1,031)	(54)	(115)
Total	(202)	(105)	150	8	16

NOTE 3 – FINANCIAL RISK MANAGEMENT (cont.)

a. Market risk (cont.)

1) Concentration of currency risk (cont.)

Set forth below is certain data regarding dollar exchange rates:

	Exchange rate of NIS per \$1	Exchange rate of Euro per \$1
As of December 31:		
2016	3.845	0.951
2017	3.467	0.835
2018	3.748	0.873
Percentage increase (decrease) in:		
2017	(9.8%)	(12.2%)
2018	8.1%	4.6%

Set forth below is information on the linkage of monetary items:

	December 31, 2017			December 31, 2018		
	Dollar	NIS	Other currencies	Dollar	NIS	GBP and other
	USD in thousands			USD in thousands		
Assets:						
Current assets:						
Cash and cash equivalents	2,623	2,376	111	2,274	699	431
Short term bank deposits	44,373	-	-	26,747	-	-
Other receivables	117	325	144	-	491	848
Total assets	47,113	2,701	255	29,021	1,190	1,279
Liabilities:						
Current liabilities:						
Current maturities of bank loan	93	-	-	895	-	-
Accounts payable and accruals:						
Trade	3,018	764	1,734	2,396	807	1,290
Other	99	756	258	708	632	23
Non-current liabilities						
Long-term bank loan, net of current maturities	157	-	-	7,838	-	-
	3,367	1,520	1,992	11,837	1,439	1,313
Net asset value	43,746	1,181	(1,737)	17,184	(249)	(34)

NOTE 3 – FINANCIAL RISK MANAGEMENT (cont.)

a. Market risk (cont.)

2) Fair value of financial instruments

As of December 31, 2018, the financial instruments of the Company consist of non-derivative assets and liabilities (primarily working capital items and deposits), as well as warrants classified as a liability.

With regard to non-derivative assets and liabilities, given their nature, the fair value of the financial instruments included in working capital is generally close or identical to their carrying amount.

With regard to the warrants classified as a liability, see Notes 11c(3) and 18. With regard to the long-term loan, see Note 18.

3) Exposure to market risk and management thereof

In the opinion of Company management, the market risk to which the Company is exposed is primarily related to currency risk exposure, as mentioned above. Additionally, Company management does not consider the interest rate risk mentioned in paragraph 4 below to be material.

4) Interest rate risk

Company 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 interest rates.

b. Credit risk

Credit risk is managed at the Company level. These risks relate to cash and cash equivalents, bank deposits and other receivables.

The Company's cash, cash equivalents and short-term bank deposits at December 31, 2017, and 2018 were mainly deposited with highly rated major Israeli and U.S. banks. In the Company's opinion, the credit risk associated with these balances is remote.

The Company considers its maximum exposure to credit risk to be as follows:

	December 31,	
	2017	2018
	in USD thousands	
Assets:		
Cash and cash equivalents	5,110	3,404
Short-term bank deposits	44,373	26,747
Other receivables	586	1,339
Total	50,069	31,490

NOTE 3 – FINANCIAL RISK MANAGEMENT (cont.)

c. Liquidity risk

Company management monitors rolling forecasts of the Company'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.

Although the Company has succeeded in generating significant revenues from a number of out-licensing transactions in the past, it cannot determine with reasonable certainty if and when it will become profitable on a current basis. Management believes that the Company's current cash (including the consideration from the offering as detailed in Note 19) and other resources will be sufficient to fund its projected cash requirements into 2021. Accordingly, in the event that the Company does not generate cash from its operating activities, the Company will need to raise additional capital in the future. Inability to raise additional capital would have a material adverse effect on the financial condition of the Company.

d. Fair value estimations

As described in Notes 11c(3) and 18, BioLineRx completed financing transactions in which it issued ADSs and warrants to purchase additional ADSs. The fair value of the warrants, which are not traded on an active market, is determined by using valuation techniques. These valuation techniques maximize the use of observable market data where it is available and rely as little as possible on entity specific estimates.

NOTE 4 – CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

As part of the financial reporting process, Company management is required to make estimates that affect the value of assets, liabilities, income, expenses and certain 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 used in the preparation of the financial statements are continually evaluated and adjusted 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 used in the preparation of the financial statements, the formulation of which required Company 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.

NOTE 4 – CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS (cont.)

Development expenses

Development expenses are capitalized in accordance with the accounting policy described in Note 2n. The capitalization of costs is based on management’s judgment of technological and economic feasibility, which is usually achieved when a 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, and the anticipated period of future benefits. Company management has concluded that, as of December 31, 2018, the foregoing conditions have not been met and therefore development expenses have not been capitalized for any project.

If management had determined that the aforementioned conditions had been met, the capitalization of development costs would have resulted in an increase in the Company’s profit or a decrease in its loss.

Impairment of intangible assets

The Company performs impairment reviews of intangible assets on an annual basis, or more frequently if events or changes in circumstances indicate a potential impairment. In light of the clinical progress and additional expenses incurred with regard to the clinical development of BL-8040 and AGI-134, the Company has concluded that the value of its intangible assets is higher than their carrying value.

NOTE 5 – CASH AND CASH EQUIVALENTS

	December 31,	
	2017	2018
	in USD thousands	
Cash on hand and in bank	3,960	2,329
Short-term bank deposits	1,150	1,075
	5,110	3,404

The short-term bank deposits included in cash and cash equivalents bear interest at annual rate of 0.15%. The carrying amount of cash and cash equivalents approximates their fair value, since they bear interest at rates similar to prevailing market interest rates.

NOTE 6 – SHORT-TERM BANK DEPOSITS

The short-term bank deposits are in US dollars and bear interest at annual rates of between 1.58% and 3.08%.

NOTE 7 – LONG-TERM INVESTMENT

In 2016, the Company established a joint venture with I-Bridge Capital, a Chinese venture capital fund focused on developing innovative therapies in China, with each party contributing initial seed capital to the venture of \$1.0 million. The joint venture, named iPharma, focused on the development of innovative clinical and pre-clinical therapeutic candidates to serve the Chinese and global healthcare markets. In April 2018, the Company sold its holdings in the joint venture to I-Bridge Capital for cash consideration of \$1.5 million. The gain of \$0.5 million is included in non-operating income on the statement of comprehensive loss.

NOTE 8 – PROPERTY AND EQUIPMENT

Set forth below are the composition of property and equipment and the related accumulated depreciation, grouped by major classifications, as well as the changes therein for the respective years:

	Cost			Accumulated depreciation				Net book value		
	Balance	Additions	Deletions	Balance	Balance	Additions	Deletions	Balance	December 31,	
	at			at					at	at
	beginning	during	during	end of	beginning	during	during	end of	In USD thousands	
	of year	year	year	year	of year	year	year	year		
		In USD thousands				In USD thousands				
Composition in 2016										
Office furniture and equipment	198	-	-	198	13	12	-	25	185	173
Computers and communications equipment	446	43	-	489	355	53	-	408	91	81
Laboratory equipment	1,194	104	-	1,298	482	188	-	670	712	628
Leasehold improvements	2,025	3	-	2,028	104	201	-	305	1,921	1,723
	<u>3,863</u>	<u>150</u>	<u>-</u>	<u>4,013</u>	<u>954</u>	<u>454</u>	<u>-</u>	<u>1,408</u>	<u>2,909</u>	<u>2,605</u>

	Cost			Accumulated depreciation				Net book value		
	Balance	Additions	Deletions	Balance	Balance	Additions	Deletions	Balance	December 31,	
	at			at					at	at
	beginning	during	during	end of	beginning	during	during	end of	In USD thousands	
	of year	year	year	year	of year	year	year	year		
		In USD thousands				In USD thousands				
Composition in 2017										
Office furniture and equipment	198	2	-	200	25	35	-	60	173	140
Computers and communications equipment	489	266	-	755	408	30	-	438	81	317
Laboratory equipment	1,298	70	-	1,368	670	159	-	829	628	539
Leasehold improvements	2,028	-	-	2,028	305	214	-	519	1,723	1,509
	<u>4,013</u>	<u>338</u>	<u>-</u>	<u>4,351</u>	<u>1,408</u>	<u>438</u>	<u>-</u>	<u>1,846</u>	<u>2,605</u>	<u>2,505</u>

BioLineRx Ltd.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 – PROPERTY AND EQUIPMENT (cont.)

	Cost			Accumulated depreciation				Net book value		
	Balance	Additions	Deletions	Balance	Balance	Additions	Deletions	Balance	December 31,	
	at			at				at	at	2017
	beginning	during	during	end of	beginning	during	during	end of	In USD thousands	
	of year	year	year	year	of year	year	year	year	In USD thousands	
	In USD thousands				In USD thousands					
Composition in 2018										
Office furniture and equipment	200	-	-	200	60	22	-	82	140	118
Computers and communications equipment	755	9	-	764	438	60	-	498	317	266
Laboratory equipment	1,368	164	-	1,532	829	153	-	982	539	550
Leasehold improvements	2,028	-	-	2,028	519	216	-	735	1,509	1,293
	<u>4,351</u>	<u>173</u>	<u>-</u>	<u>4,524</u>	<u>1,846</u>	<u>451</u>	<u>-</u>	<u>2,297</u>	<u>2,505</u>	<u>2,227</u>

NOTE 9 – INTANGIBLE ASSETS

	Cost			Accumulated depreciation and impairment				Net book value		
	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	December 31, 2015	December 31, 2016
	In USD thousands			In USD thousands				In USD thousands		
Composition in 2016										
Intellectual property	193	-	-	193	96	-	-	96	97	97
Computer software	328	57	-	385	273	28	-	301	55	84
	<u>521</u>	<u>57</u>	<u>-</u>	<u>578</u>	<u>369</u>	<u>28</u>	<u>-</u>	<u>397</u>	<u>152</u>	<u>181</u>
	Cost			Accumulated depreciation and impairment				Net book value		
	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	December 31, 2016	December 31, 2017
	In USD thousands			In USD thousands				In USD thousands		
Composition in 2017										
Intellectual property	193	6,703	-	6,896	96	-	-	96	97	6,800
Computer software	385	182	-	567	301	43	-	344	84	223
	<u>578</u>	<u>6,885</u>	<u>-</u>	<u>7,463</u>	<u>397</u>	<u>43</u>	<u>-</u>	<u>440</u>	<u>181</u>	<u>7,023</u>
	Cost			Accumulated depreciation and impairment				Net book value		
	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	December 31, 2017	December 31, 2018
	In USD thousands			In USD thousands				In USD thousands		
Composition in 2018										
Intellectual property	6,896	15,000	-	21,896	96	-	-	96	6,800	21,800
Computer software	567	43	-	610	344	94	-	438	223	172
	<u>7,463</u>	<u>15,043</u>	<u>-</u>	<u>22,506</u>	<u>440</u>	<u>94</u>	<u>-</u>	<u>534</u>	<u>7,023</u>	<u>21,972</u>

NOTE 10 – LONG-TERM LOANS

a. Composition

	December 31,	
	2017	2018
	In USD thousands	
Bank loan (1)	250	156
Loan from Kreos Capital (Note 18)	-	8,577
	250	8,733
Less current maturities:		
Bank loan	(93)	(93)
Loan from Kreos Capital	-	(802)
Total current maturities	(93)	(895)
Total long-term loans	157	7,838

- (1) The loan is denominated in dollars and bears interest at an annual rate of 3.75%. The book value of the loan approximates its fair value. The loan is repayable in 60 monthly installments and is collateralized by certain lab equipment.

b. Future repayments

Future repayments of the long-term loans indicated above (other than current maturities) in the years subsequent to the balance sheet date are as follows:

	Bank loan	Loan from Kreos Capital	Total
	In USD thousands		
	2020	63	2,402
2021	-	2,892	2,892
2022	-	2,481	2,481
	63	7,775	7,838

The loan from Kreos Capital is reflected net of amounts deducted from its carrying value relating to warrants and issuance costs associated with the initial loan transaction.

NOTE 11 – EQUITY

a. Share capital

As of December 31, 2017, and 2018 the Company's share capital is composed of ordinary shares, as follows:

	Number of Ordinary Shares	
	December 31,	
	2017	2018
Authorized share capital	250,000,000	250,000,000
Issued and paid-up share capital	105,063,437	114,933,144
	In USD and NIS	
	December 31,	
	2017	2018
Authorized share capital (in NIS)	25,000,000	25,000,000
Issued and paid-up share capital (in NIS)	10,506,344	11,493,314
Issued and paid-up share capital (in USD)	2,836,139	3,109,746

As of December 31, 2018, the market price on NASDAQ of BioLineRx's ADSs was \$0.44, and the market price on the Tel Aviv Stock Exchange of BioLineRx's ordinary shares was NIS 1.63.

b. Rights related to shares

The ordinary shares confer upon their holders voting and dividend rights and the right to receive assets of the Company upon its liquidation. As of December 31, 2017 and 2018, all outstanding share capital consisted of ordinary shares.

NOTE 11 – EQUITY (cont.)

c. Changes in the Company's equity

- 1) In March 2015, the Company completed an underwritten public offering of 14,375,000 ADSs at a public offering price of \$2.00 per ADS. The offering raised a total of \$28.8 million, with net proceeds of approximately \$26.4 million, after deducting fees and expenses.
- 2) In April 2017, the Company completed an underwritten public offering of 33,823,529 of its ADSs at a public offering price was \$0.85 per ADS. The offering raised a total of \$28.8 million, with net proceeds of approximately \$26.2 million, after deducting fees and expenses.
- 3) In July 2017, the Company completed a direct placement to BVF Partners L.P., its largest shareholder, for aggregate gross proceeds of \$9.6 million. The placement consisted of 8,495,575 ADSs, Series A warrants to purchase an additional 2,973,451 ADSs and Series B warrants to purchase an additional 2,973,451 ADSs. The Series A warrants have an exercise price of \$2.00 per ADS and are exercisable for a term of four years. The Series B warrants have an exercise price of \$4.00 per ADS and are also exercisable for a term of four years. Net proceeds from the transaction were approximately \$9.5 million, after deducting fees and expenses.

The warrants issued have been classified as a non-current financial liability due to a net settlement provision. This liability was initially recognized at its fair value on the date the contract was entered into and is subsequently accounted for at fair value at each balance sheet date. The fair value changes are charged to non-operating income and expense in the statement of comprehensive loss. The amount of the direct placement consideration initially allocated to the warrants was approximately \$1.1 million. Total issuance costs allocable to the warrants were not material.

The fair value of the warrants is computed using the Black and Scholes option pricing model. The fair value of the warrants upon issuance was computed based on the then-current price of an ADS, a risk-free interest rate of 1.66% and an average standard deviation of 57.8%.

The fair value of the warrants as of December 31, 2018 was based on the then-current price of an ADS, a risk-free interest rate of 2.47% (December 31, 2017 - 2.09%) and an average standard deviation of 55.3% (December 31, 2017 - 56.8%).

The changes in fair value for the years ended December 31, 2017 and 2018 of approximately \$100,000 and \$1,200,000 has been recorded as non-operating (expense) income, respectively, on the statement of comprehensive loss.

NOTE 11 – EQUITY (cont.)

d. Share purchase agreements

- 1) In May 2014, BioLineRx and Lincoln Park Capital Fund, LLC (“LPC”), entered into a \$20 million, 36-month purchase agreement, together with a registration rights agreement, whereby LPC agreed to purchase, from time to time, up to \$20 million of BioLineRx’s ADSs, subject to certain limitations, during the 36-month term of the purchase agreement.

In consideration for entering into the agreement, BioLineRx paid to LPC an initial commitment fee of \$300,000, paid via the issuance of 150,000 ADSs, and agreed to pay a further commitment fee of up to \$500,000, pro rata, as the facility was used over time, to be paid in ADSs valued based on the prevailing market prices of BioLineRx’s ADSs at such time.

In connection with the purchase agreement, BioLineRx paid an initial cash finder’s fee to Oberon Securities of \$50,000, plus an additional cash finder’s fee equal to 2.0% of the dollar amount of ADSs sold under the new agreement, up to an aggregate additional finder’s fee of \$200,000.

The purchase agreement with LPC expired in accordance with its terms in July 2017. On a cumulative basis, from the effective date of the purchase agreement through the date of its expiration, BioLineRx sold a total of 5,550,603 ADSs to LPC for aggregate gross proceeds of \$7,000,000. In connection with these issuances, a total of 138,766 ADSs were issued to LPC as a commitment fee and a total of \$140,000 was paid to Oberon Securities as a finder’s fee.

- 2) In October 2017, the Company entered into an at-the-market (“ATM”) sales agreement with BTIG, LLC (“BTIG”), pursuant to which the Company may, at its sole discretion, offer and sell through BTIG, acting as sales agent, ADSs having an aggregate offering price of up to \$30.0 million throughout the period during which the ATM facility remains in effect. The Company will pay BTIG a commission of 3.0% of the gross proceeds from the sale of ADSs under the facility. From the effective date of the agreement through December 31, 2018, 5,439,203 ADSs were sold under the program for total net proceeds of approximately \$5.1 million, leaving an available balance under the facility of approximately \$24.9 million as of December 31, 2018.

NOTE 11 – EQUITY (cont.)

e. Share-based payments

1) Share Incentive plan – general

In 2003, BioLineRx adopted the 2003 Share Incentive Plan (the “Plan”). The Plan provides for the granting of stock options and ordinary shares to the Company’s employees, directors, consultants and other service providers. Options are issued at the determination of the Board of Directors in accordance with applicable law. The options are generally exercisable for a ten-year period and the grants generally vest over a four-year period. In 2013, the Company’s Board of Directors approved amendments to the Plan to take into account changes in laws and regulations that had occurred since its adoption and to extend the term of the plan until November 2023. In 2016, the Board of Directors approved amendments to the Plan to allow the grant of restricted stock units (“RSUs”) and performance stock units (“PSUs”).

PSUs are RSUs that are linked to any one or more performance goals (in addition to, or in lieu of, time-based vesting terms) determined appropriate by the Board of Directors. Once vested, each PSU granted is equivalent to one ordinary share. The specific performance goals, as well as the time period associated with achieving such goals, are approved by the Board and are set forth in the grantee’s grant agreement. To date, each PSU grant has had between three to five performance goals on which vesting is based, each such goal being either a specified Company milestone and or the success of a specific project, with vesting of 20%-33% on the achievement of each goal. The tranche of PSUs associated with a given milestone expires 12 months after the target date established for that milestone. During 2018, 285,410 PSUs vested in accordance with their original terms.

As of December 31, 2018, there were 11,759,697 ordinary shares issuable upon the exercise of outstanding equity instruments under the Plan.

Ordinary shares resulting from grants under the Plan confer the same rights as all other ordinary shares of BioLineRx.

Company employees and directors are granted options under Section 102 of the Israeli Income Tax Ordinance (the “Ordinance”), primarily under the “capital gains” track. Non-employees of the Company (consultants and other service providers), as well as controlling shareholders in BioLineRx (as this term is defined in Section 32(9) of the Ordinance), are granted options under Section 3(i) of the Ordinance.

In November 2014, December 2015 and December 2017 the Company’s Board of Directors approved increases of 1.6 million, 5.0 million and 5.2 million shares, respectively, to the total pool of authorized ordinary shares reserved for purposes of the Plan and any other present or future share incentive plans of the Company, bringing the pool to an aggregate of 14.8 million shares. As of December 31, 2018, there were 1.8 million remaining authorized but unissued ordinary shares in the pool reserved for future share-based incentive grants. In March 2019, the Board approved an increase of 9.0 million shares to the pool.

NOTE 11 – EQUITY (cont.)

e. Share-based payments (cont.)

2) Employee share incentive plan:

The following table contains additional information concerning equity instruments granted to employees and directors under the existing share incentive plans.

	Year ended December 31,					
	2016		2017		2018	
	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 year	3,500,262	8.7	4,557,927	6.5	10,651,097	4.4
Granted	2,505,684	3.8	7,292,560	3.5	2,853,080	2.8
Forfeited and expired	(1,435,990)	7.2	(1,164,961)	6.5	(1,649,090)	4.0
Exercised	(12,029)	0.4	(34,429)	0.2	(395,390)	0.4
Outstanding at end of year*	<u>4,557,927</u>	<u>6.5</u>	<u>10,651,097</u>	<u>4.4</u>	<u>11,459,697</u>	<u>4.2</u>
Exercisable at end of year	<u>1,786,209</u>	<u>9.4</u>	<u>2,356,948</u>	<u>7.6</u>	<u>4,489,816</u>	<u>5.9</u>

* As of the December 31, 2016, 2017 and 2018, includes 222,428, 1,178,128 and 1,163,018 PSUs at an exercise price of 0.10 NIS (par value of ordinary shares), for which performance obligations have not been met.

NOTE 11 – EQUITY (cont.)

e. Share-based payments (cont.)

The total consideration received from the exercise of equity instruments during 2016, 2017 and 2018 was not material.

Set forth below is data regarding the range of exercise prices and weighted-average remaining contractual life (in years) for the equity instruments outstanding at the end of each of the years indicated.

Range of exercise prices (in NIS)	Year ended December 31,					
	2016		2017		2018	
	Number of options outstanding	Weighted average remaining contractual life (in yrs.)	Number of options outstanding	Weighted average remaining contractual life (in yrs.)	Number of options outstanding	Weighted average remaining contractual life (in yrs.)
Up to 5.00	1,979,244	8.2	8,642,472	8.2	9,631,342	8.2
5.01-10.00	1,522,800	4.3	1,213,225	5.9	1,089,875	4.3
10.01-20.00	1,037,436	2.7	795,400	4.7	738,480	3.3
20.01-55.00	18,448	0.5	-	-	-	-
	<u>4,557,927</u>	<u>5.5</u>	<u>10,651,097</u>	<u>7.8</u>	<u>11,459,697</u>	<u>7.5</u>

The fair value of equity instruments granted to employees through December 31, 2018 has been determined using the Black-Scholes option-pricing model. These values are based on the following assumptions as of the applicable grant dates:

	2016	2017	2018
Expected dividend yield	0%	0%	0%
Expected volatility	66%	63%	61%
Risk-free interest rate	2%	2%	3%
Expected life of options (in years)	6	6	6

NOTE 11 – EQUITY (cont.)

e. Share-based payments (cont.)

3) Stock options to consultants

From inception through December 31, 2015, the Company issued to consultants options for the purchase of 81,523 ordinary shares at a weighted average exercise price of NIS 20.69 per share.

In 2016, the Company issued additional options to consultants for the purchase of 150,000 ordinary shares at a weighted average price of NIS 4.55 per share

In 2017, the Company issued additional options to consultants for the purchase of 105,000 ordinary shares at a weighted average price of NIS 4.056 per share

In 2018, the Company issued additional options to consultants for the purchase of 35,000 ordinary shares at a weighted average price of NIS 3.48 per share

The options to consultants generally vest over four years and may be exercised for periods of between five and ten years. As of December 31, 2018, 300,000 options to consultants were outstanding with a weighted average exercise price of NIS 4.42 per share and a weighted average contractual life of 7.80 years.

Company 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 each of the years 2016, 2017 and 2018 was not material.

NOTE 12 – TAXES ON INCOME

a. Corporate taxation in Israel

The income of BioLineRx is taxed at the standard Israeli corporate tax rate, which was 25% in 2016, 24% in 2017 and 23% for 2018 and thereafter.

As the Company has not created any deferred tax assets or liabilities (see Note 2, paragraph 1), these differences have no effect on the Company's financial statements.

b. Approved enterprise benefits

In May 2012, the Israeli Tax Authority ("ITA") approved BioLineRx's eligibility for tax benefits as a "Benefited Enterprise" under the Law for the Encouragement of Capital Investments, 5719-1959, as amended (the "Investments Law"), with respect to certain development programs (the "Eligible Projects").

Subject to compliance with the applicable requirements, the portion of income eligible for benefits under the Benefited Enterprise regime will be entitled to a tax exemption for a period of two years, followed by five years at the Benefited Enterprise tax rate of 25%, commencing in the first year in which BioLineRx generates taxable income after setting off losses for Israeli tax purposes from prior years (see c. below). The seven-year period may not extend beyond 12 years from the beginning of the Benefited Enterprise's election year. BioLineRx received Benefited Enterprise status with respect to Eligible Projects in the 2009 and 2012 tax years, so depending on when the Benefited Enterprise programs begin to generate taxable income, the benefits period could continue through 2023. However, any distribution of dividends derived from exempt income sourced in the Benefited Enterprise programs will be subject to a "claw back" of corporate tax at a rate no greater than 25%. In addition, dividends distributed by a publicly traded Israeli company to non-Israeli residents or Israeli individuals are generally subject to withholding tax of 25%. Under an applicable tax treaty, the withholding tax might be lower.

BioLineRx has the option to transition to a "Preferred Enterprise" regime under the Investments Law. Upon an irrevocable election made by a company, a uniform corporate tax rate will apply to all qualifying industrial income of such company, as opposed to the previous incentives under the Investments Law, which were limited to income from Benefited Enterprises during the benefits period. Under the Investments Law, when the election is made, the uniform tax rate for 2018 would be 16% for BioLineRx's location in Israel. Preferred Enterprise profits are freely distributable as dividends, subject to a 20% withholding tax, or lower under an applicable tax treaty.

In addition, the ITA approved BioLineRx's operations as an "Industrial Enterprise" under the Investments Law in 2012, meaning that BioLineRx is eligible for accelerated depreciation with respect to certain tangible assets belonging to its Benefited Enterprise. Should BioLineRx not meet the requirements for maintaining these benefits, they may be reduced or cancelled and, among other things, income deriving from the Eligible Projects would be subject to Israeli corporate tax at the standard rates.

NOTE 12 – TAXES ON INCOME (cont.)

c. Tax loss carryforwards

As of December 31, 2018, the tax loss carryforwards of BioLineRx were approximately \$210 million. The tax loss carryforwards have no expiration date.

The Company has not created deferred tax assets in respect of these tax loss carryforwards. See Note 2, paragraph 1.

d. Tax assessments

In accordance with Israeli tax regulations, the tax returns filed by BioLineRx through the 2013 tax year are considered final.

e. Theoretical taxes

As described in Note 2, paragraph 1, the Company has not recognized any deferred tax assets in the financial statements, as it does not expect to generate taxable income in the foreseeable future. The reported tax on the Company's income before taxes differs from the theoretical amount that would arise using the weighted average tax rate applicable to income of the consolidated entities as follows:

	Year ended December 31,					
	2016		2017		2018	
	25.0%	USD in thousands	24.0%	USD in thousands	23.0%	USD in thousands
Loss before taxes		(15,841)		(24,352)		(22,962)
Theoretical tax benefit		(3,960)		(5,962)		(5,281)
Disallowed deductions (tax exempt income):						
Loss (gain) on adjustment of warrants to fair value		(52)		30		(401)
Share-based compensation		269		369		581
Other		15		21		10
Increase in taxes for tax losses and timing differences incurred in the reporting year for which deferred taxes were not created		3,728		5,542		5,091
Taxes on income for the reported year		-		-		-

NOTE 13 – LOSS PER SHARE

The following table contains the data used in the computation of the basic loss per share:

	Year ended December 31,		
	2016	2017	2018
	In USD thousands		
Loss attributed to ordinary shares	(15,841)	(24,352)	(22,962)
Number of shares used in basic calculation (in thousands)	56,145	89,971	108,596
	in USD		
Basic and diluted loss per ordinary share	(0.28)	(0.27)	(0.21)

NOTE 14 – COMMITMENTS AND CONTINGENT LIABILITIES

a. Commitments

1) Obligation to pay royalties to the State of Israel

The Company is required to pay royalties to the State of Israel (represented by the Israel Innovation Authority, or IIA), computed on the basis of proceeds from the sale or license of products whose development was supported by grants from the predecessor of the IIA, the Office of the Chief Scientist. This obligation relates solely to financial participation in the development of products by the Company.

In accordance with the terms of grants provided by the IIA, the State is entitled to royalties on the sale or license of any product whose development was supported with State participation. These royalties are generally 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 dollar) received by the Company, plus annual interest at the LIBOR rate. Under certain circumstances, the royalty rate is calculated according to a formula based on the ratio of participation by the IIA in the project to the total project costs incurred by the Company

In connection with the in-licensing of BL-8040 from Biokine Therapeutics Ltd. (“Biokine”), and as a condition to IIA consent to the transaction, the Company agreed to abide by any obligations resulting from funds previously received by Biokine from the IIA. The contingent liability to the IIA assumed by the Company relating to this transaction amounts to approximately \$3.2 million as of December 31, 2018. The Company has a full right of offset for amounts payable to the IIA from payments due to Biokine in the future. Therefore, in the opinion of management, the likelihood of any future Company payment obligation to the IIA with regard to this matter is remote.

NOTE 14 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

2) Licensing agreements

From time to time, the Company enters into in-licensing agreements with academic institutions, research institutions and companies (the “licensors”) in connection with the development of therapeutic compounds. Pursuant to these licensing agreements, the Company generally obtains the rights for one or more therapeutic compounds in pre-clinical and early-clinical stages of development, in order to continue development of the compounds through more advanced stages of development and, subsequently, to manufacture, distribute and market the drugs or to out-license the development, manufacturing and commercialization rights to third parties. Such development activities are carried out by either the Company and/or by companies or institutions to which the Company has entered into an out-license agreement, subject to certain restrictions stipulated in the various agreements.

The licenses that have been granted to the Company 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 Company to perform all development activities on its own, or by outsourcing under Company 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, through the date the applicable license agreement is effective, remain with the licensor, while the rights in products and/or other deliverables developed by the Company after the license is granted belong to the Company. In cases where the licensor has a claim to an invention that was jointly developed with the Company, the licensor also co-owns the related intellectual property. In any event, the scope of the license also covers these intellectual property rights.

In addition, the Company generally undertakes in the licensing agreements to protect registered patents resulting from developments under the various licenses, to promote the registration of patents covering new developments in cooperation with the licensor, and to bear responsibility for all related costs. Pursuant to the various agreements, the Company generally works to register the various patents on a broad basis worldwide, and if the Company decides not to initiate or continue a patent registration proceeding in a given country, the Company is required to notify the applicable licensor to this effect and the licensor is entitled to take action for registration of the patent in such country.

NOTE 14 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

2) Licensing agreements (cont.)

The consideration paid pursuant to the licensing agreements generally includes several components that may be 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, up-front payment and/or periodic payments; (b) payments through the early stages of development (i.e., through the end of phase 2); (c) payments upon the achievement of milestones necessary for advancing to phase 3; (d) payments from the end of a successful phase 3 trial through approval of the therapeutic compound; and e) royalties on sales of the final product resulting from development under the license or including any component thereof, ranging between 3%-5% of the Company's net sales of the product, although in specific instances the royalty rate has been higher or lower than this range. In instances where the Company has out-licensed the product for further development, the Company pays a percentage of the net consideration received from the licensee ("Sublicense Receipts") to the upstream licensor that generally range from 20% to 29.5% of such consideration, although in specific instances the percentage paid has been higher or lower than this range. These Sublicense Receipts generally take the place of most or all of the milestone and royalty payments set forth in (b) through (e) above.

The license agreements may be cancelled by the licensor only in specific circumstances, generally upon the occurrence of one of the following events: (a) the Company's failure to meet certain milestones stipulated in the applicable license agreement and appended timetables; (b) default, insolvency, receivership, liquidation, etc. of the Company 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. The Company may generally cancel a license agreement with prior notice of 30 to 90 days, due to unsuccessful development or any other cause.

The Company has undertaken to indemnify certain 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 Company'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 Company is committed to pay the various licensors a fixed monthly amount over the period stipulated in the agreement for their assistance in the continued research and development under the license.

3) Purchase orders

The Company's outstanding open purchase order commitments as of December 31, 2018 amounted to \$13.3 million.

NOTE 14 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

4) Lease agreements

- a) The Company's leases its premises under an operating lease agreement entered into in August 2014. Payments under the lease commenced in June 2015 and will expire in June 2020. The monthly lease fee is approximately \$28,000 (including maintenance fees and parking). The Company has the option to extend the lease for 3 additional lease periods totaling up to an additional 10 years, each option at a 5% increase to the preceding lease payment amount. As of December 31, 2018, minimum future rental payments (without considering the aforementioned extension periods) under the lease were \$340,000 and \$177,000 for 2019 and 2020, respectively.

See Note 14b regarding a guarantee provided to secure the Company's liability under the lease agreement.

- 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 CPI, are approximately \$241,000. To secure the terms of the lease agreements, the Company has made certain prepayments to the leasing companies, representing approximately two months of lease payments. These amounts have been recorded as prepaid expenses. See also Note 16b.

b. Contingent liabilities

To secure the Company's lease obligation on its premises, the Company has provided a bank guarantee in the amount of approximately \$100,000 for the benefit of the lessor, which remains outstanding as of December 31, 2018. See also Note 10a regarding equipment pledged as collateral to secure a bank loan.

NOTE 15 – TRANSACTIONS AND BALANCES WITH RELATED PARTIES

Transactions with related parties

Expenses:

	Year ended December 31,		
	2016	2017	2018
	In USD thousands		
Benefits to related parties:			
Compensation and benefits to senior management, including benefit component of equity instrument grants	1,912	2,183	2,680
Number of individuals to which this benefit related	6	6	6
Compensation and benefits to directors, including benefit component of equity instrument grants	316	356	307
Number of individuals to which this benefit related	7	7	7

NOTE 15 – TRANSACTIONS AND BALANCES WITH RELATED PARTIES (cont.)

Transactions with related parties (cont.)

Key management compensation

Key management includes directors and executive officers. The compensation paid or payable to key management for services during each of the years indicated is presented below.

	Year ended December 31,		
	2016	2017	2018
	In USD thousands		
Salaries and other short-term employee benefits	1,609	1,808	1,669
Post-employment benefits	129	136	137
Other long-term benefits	30	34	35
Share-based compensation	460	561	1,146
	<u>2,228</u>	<u>2,539</u>	<u>2,987</u>

NOTE 16 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

a. Other receivables

	December 31,	
	2017	2018
	In USD thousands	
Government institutions	446	1,337
Other	140	2
	<u>586</u>	<u>1,339</u>

b. Long-term prepaid expenses

The prepaid expenses relate to operating lease agreements in respect of the vehicles leased by the Company.

NOTE 16 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (cont.)

c. Accounts payable and accruals

	December 31,	
	2017	2018
	In USD thousands	
1) Trade:		
Accounts payable:		
Overseas	4,350	3,273
In Israel	1,166	1,220
	<u>5,516</u>	<u>4,493</u>
2) Other:		
Accrued expenses	620	792
Accrual for vacation and recreation pay	215	287
Payroll and related expenses	259	270
Other	19	14
	<u>1,113</u>	<u>1,363</u>

The carrying amounts of accounts payable and accruals approximate their fair value, as the effect of discounting is not material.

d. Research and development expenses

	Year ended December 31,		
	2016	2017	2018
	In USD thousands		
Research and development services	5,501	12,123	11,609
Payroll and related expenses	3,475	5,097	5,704
Lab, occupancy and telephone	769	920	993
Professional fees	678	662	688
Depreciation and amortization	452	452	424
Other	302	256	390
	<u>11,177</u>	<u>19,510</u>	<u>19,808</u>

e. Sales and marketing expenses

	Year ended December 31,		
	2016	2017	2018
	In USD thousands		
Payroll and related expenses	659	817	973
Marketing	600	797	291
Overseas travel	93	79	98
	<u>1,352</u>	<u>1,693</u>	<u>1,362</u>

NOTE 16 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (cont.)

f. General and administrative expenses

	Year ended December 31,		
	2016	2017	2018
	In USD thousands		
Payroll and related expenses	2,172	2,060	2,510
Professional fees	1,144	1,298	1,142
Insurance	154	210	221
Depreciation	30	29	27
Other	484	440	535
	<u>3,984</u>	<u>4,037</u>	<u>4,435</u>

g. Non-operating income (expenses), net

	Year ended December 31,		
	2016	2017	2018
	In USD thousands		
Issuance costs	-	(133)	(90)
Changes in fair value of warrants	207	(127)	1,743
Gain from realization of long-term investment	-	-	500
Other	7	-	244
	<u>214</u>	<u>(260)</u>	<u>2,397</u>

h. Financial income

	Year ended December 31,		
	2016	2017	2018
	In USD thousands		
Interest income and exchange differences	469	824	719
Gain on foreign currency hedging	11	345	-
	<u>480</u>	<u>1,169</u>	<u>719</u>

i. Financial expenses

	Year ended December 31,		
	2016	2017	2018
	In USD thousands		
Interest expense and exchange differences	8	-	452
Bank commissions	14	21	21
	<u>22</u>	<u>21</u>	<u>473</u>

NOTE 17 – AGALIMMUNE ACQUISITION

In March 2017, the Company acquired substantially all the outstanding shares of Agalimmune Ltd. for initial consideration of approximately \$6.0 million, of which \$3.0 million was in cash and the remainder in the Company's ADSs. The acquisition expanded the Company's pipeline to include Agalimmune's primary asset, AGI-134, a novel immuno-oncology agent for various cancer indications at the near-clinical stage of development. Due in part to the early stage of development of AGI-134 and other elements evaluated by the Company's management as required by IFRS, the acquisition has been accounted for in the Company's financial statements as an asset transaction. Total costs associated with bringing the asset into the Company's pipeline include additional expenses of approximately \$0.7 million, resulting in a total increase in intangibles reflected in the Company's financial statements of approximately \$6.7 million as of December 31, 2017.

Additional consideration may be due to Agalimmune shareholders based on certain development and commercial milestones, including future sales of Agalimmune products. In addition, the selling shareholders of Agalimmune have certain reversionary rights in the event of a breach of the transaction agreement and certain other limited triggering events.

NOTE 18 – AMENDMENT TO BL-8040 LICENSE AND LONG-TERM LOAN

In October 2018, the Company amended its license agreement with Biokine Therapeutics Ltd. ("Biokine"), originally entered into in September 2012, relating to the in-licensing rights to BL-8040. The amendment reduces the payment owed by the Company to Biokine on sublicense receipts (as defined in the license agreement) from 40% to 20% of sublicense receipts in exchange for: (i) a cash payment from the Company to Biokine of \$10 million; (ii) the issuance of 4,980,080 ADSs with a value of \$5 million and (iii) the payment of certain future milestone payments, up to an aggregate of \$5 million in total, as specified in the amendment. Additionally, in certain limited instances, if the Company enters into a sublicense (as defined in the license agreement) within a defined period, the Company will pay Biokine an additional 10% of any upfront sublicense receipts received by the Company as a result of such sublicense.

The \$10 million payment referred to above was financed in full via the receipt of a \$10 million loan from Kreos Capital V (Expert Fund) L.P. ("Kreos Capital"). As security for the loan, Kreos Capital received a first-priority, secured interest in all Company assets, including intellectual property. The loan has a 12-month, interest-only period, followed by a 36-month repayment period. Borrowings under the loan will bear interest at a fixed rate of 9.5% per annum. In connection with providing the loan, Kreos Capital received a warrant to purchase 957,549 ADSs at an exercise price of \$0.94 per ADS. The warrant is exercisable for a period of ten years from the date of issuance.

The fair value of the warrant at the date of issuance, computed using the Black and Scholes option pricing model, amounted to \$861,000. The fair value was computed based on the then current price of an ADS, a risk-free interest rate of 3.05% and an average standard deviation of 69.1%. The fair value of the warrants as of December 31, 2018 was based on the then current price of an ADS, a risk-free interest rate of 2.69% and an average standard deviation of 68.7%. The change in fair value for the year ended December 31, 2018 of \$593,000 has been recorded as non-operating income (expense).

NOTE 18 – AMENDMENT TO BL-8040 LICENSE AND LONG-TERM LOAN (cont.)

The warrant issued has been classified as a non-current financial liability due to a net settlement provision. This liability was initially recognized at its fair value on the date the contract was entered into and is subsequently accounted for at fair value at each balance sheet date. The total net proceeds from Kreos Capital were initially allocated to the warrant based on its fair value, with the remainder of the net proceeds allocated to the loan. The loan is treated as a liability at amortized cost

NOTE 19 – EVENT SUBSEQUENT TO THE BALANCE SHEET DATE

In February 2019, BioLineRx completed an underwritten public offering of 28,000,000 of its ADSs and warrants to purchase 28,000,000 ADSs, at a public offering price of \$0.55 per ADS and accompanying warrant. The warrants are exercisable immediately, expire five years from the date of issuance and have an exercise price of \$0.75 per ADS. The offering raised a total of \$15.4 million, with net proceeds of approximately \$14.1 million, after deducting fees and expenses.

[*] Represents material that has been omitted and will be filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended.

AMENDMENT NO. 1 TO LICENSE AGREEMENT

THIS AMENDMENT NO. 1 (“**Amendment**”) is entered into effective as of June 18th, 2018 (the “**Amendment Effective Date**”) by and between **BioLineRx Ltd.** (“**BioLine**”) and **Wartner Europe BV** (“**Perrigo**”).

PREFACE:

- A. BioLine and Perrigo entered into a License Agreement dated as of December 22, 2014 (the “**Agreement**”).
- B. The Parties now wish to amend certain provisions of the Agreement.

Now **THEREFORE**, the Parties hereby agree as follows:

- 1. Section 3.1 of the Agreement is hereby deleted in its entirety and replaced with the following:
 - 3.1 a. With respect to the Licensed Products referred to in Section 7.2, in consideration for the exclusive license granted to Licensee under Section 2.1, for each Licensed Product unit sold by Licensee and its Sublicensees in a given calendar quarter, Licensee will pay Licensor an amount equal to [*].
 - b. For the purpose of this Agreement, [*].
 - 2. Subsections (a) and (b) of Section 3.2 are hereby deleted in their entirety and replaced with the following: [*]
 - 3. Section 3.3 is hereby deleted in its entirety and not replaced.
 - 4. (a) In Section 4.1, the sentence “Licensor has the right to examine Records that were created within five (5) years of the date of Licensor’s request” is hereby amended to read “Licensor has the right to examine Records that were created within seven (7) years of the date of Licensor’s request.”
 - (b) In Section 4.2, the reference to “five (5) years” in the second line is hereby amended to “seven (7) years.”
 - 5. In Section 7.2(a), [*]
 - 6. Following the Amendment Effective Date, if Perrigo desires to add one or more countries to the Territory, it shall notify BioLine of such desire, and the Parties shall negotiate in good faith as to whether and on what terms such country(ies) will be added to the Territory.
 - 7. Capitalized terms used but not defined herein shall have the meanings set out in the Agreement. Except as otherwise specifically agreed in this Amendment, the existing terms of the Agreement shall remain in full force and effect.
 - 8. This Amendment shall be binding upon the parties once executed by all parties and shall enter into force and become effective as of the Amendment Effective Date first written above.
-

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their duly authorized representatives as of the Amendment Effective Date.

BioLineRx Ltd.

By: /s/ Philip Serlin

Name: Philip Serlin

Title: Chief Executive Officer

Wartner Europe BV

By: /s/ Christophe Van Damme

Name: Christophe Van Damme

Title: Director

[*] REPRESENTS MATERIAL THAT HAS BEEN OMITTED AND WILL BE FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT UNDER RULE 24b-2 OF THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

CONFIDENTIAL

AMENDMENT NO. 2 TO
CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT
(FOR PANCREATIC CANCER STUDY)

This Amendment No. 2 to the CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT (this “**Amendment No. 2**”), made as of the date of last signature hereunder (the “**Amendment No. 2 Effective Date**”), is by and between Merck Sharp & Dohme B.V. (“**Merck**”) and BioLineRx Ltd. (“**BioLineRx**”). Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Agreement.

WHEREAS, the Parties entered into a Clinical Trial Collaboration and Supply Agreement effective January 11, 2016 and amended it as of the same date (such agreement, as amended, will be referred to hereunder as the “**Agreement**”); and

WHEREAS, the Parties wish to amend certain provisions of the Agreement, including with respect to the supply of the Compounds.

NOW, THEREFORE, the Parties hereby agree as follows:

1 Section 1.65 of the Agreement is hereby deleted in its entirety and replaced with the following

“1.65. “**Protocol**” means the written documentation that describes the Study and sets forth specific activities to be performed as part of the Study conduct, a copy of which in its approved final form is attached hereto as Appendix A.”

2 Section 4.1 of the Agreement is hereby deleted in its entirety and replaced with the following.

“4.1. Protocol. The approved final Protocol is attached hereto as Appendix A. BioLineRx shall provide any subsequent proposed revisions to the approved final Protocol to Merck for Merck’s review and comment, consistent with the remaining provisions of this Section 4.1.

4.1.1. Notwithstanding the provisions of Section 4.1, each Party shall have the following decision rights:

a) Any further, material changes to the approved final Protocol (other than relating solely to the BioLineRx Compound) and [*] shall require Merck’s prior written consent. Any such proposed changes will be sent in writing to Merck’s Project Manager and Merck’s Alliance Manager. Merck will provide such consent, or a written explanation for why such consent is

being withheld, within [*] Business Days of receiving a copy of BioLineRx’s requested changes.

b) [*]

c) [*]

3 Section 8.1 of the Agreement is hereby deleted in its entirety and replaced with the following.

“8.1. Supply of the Compounds. Subject to the terms and conditions of this Agreement, BioLineRx and Merck will each use commercially reasonable efforts to supply, or cause to be supplied, such quantities of its Compound in accordance with the delivery schedule set forth on Appendix B. In the event that BioLineRx determines that the quantities of Compounds as set forth on Appendix B are not sufficient to complete the Study, BioLineRx shall so notify Merck in writing, and the Parties shall discuss in good faith regarding whether additional quantities of Compounds may be provided and the schedule on which such additional quantities may be provided. Each Party shall also provide to the Party a contact person for the supply of its Compound under this Agreement. [*].”

4 Appendix A of the Agreement is hereby deleted in its entirety and replaced with the new Appendix A, which is attached to this Amendment No. 2 as Exhibit 1.

5 Appendix B of the Agreement is hereby deleted in its entirety and replaced with the new Appendix B, which is attached to this Amendment No. 2 as Exhibit 2.

6 Schedule I of the Agreement is hereby deleted in its entirety and replaced with the new Schedule I, which is attached to this Amendment No. 2 as Exhibit 3.

7 The remaining provisions of the Agreement shall remain in full force and effect Upon execution of this Amendment No. 2 by both Parties, all references in the Agreement to the “Agreement” shall mean the Agreement as modified by this Amendment No. 2.

8 This Amendment No. 2 may be executed in two (2) or more counterparts as set forth in the Agreement.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the respective authorized representatives of the Parties have executed this Amendment No. 2 on the date set forth under the signatures below.

BioLineRx Ltd.

By: /s/ Philip Serlin

Philip Serlin
Name

Chief Executive officer
Title

24-July-2018
Date

Merck Sharp & Dohme B.V.

By: /s/ P. R. Koopman

P. R. Koopman
Name

Proxy Holder
Title

July 17, 2018
Date

Exhibit 1

Appendix A PROTOCOL

[*]



Exhibit 2

Appendix B DELIVERY SCHEDULE

[*]

Exhibit 3

Schedule I

DATA SHARING AND SAMPLE TESTING SCHEDULE

[*]



[*] REPRESENTS MATERIAL THAT HAS BEEN OMITTED AND WILL BE FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT UNDER RULE 24b-2 OF THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

CONFIDENTIAL

Execution Copy

PATENT & KNOW-HOW

LICENSE AGREEMENT

THIS AGREEMENT dated September 19, 2017 is between the following Parties:

- (1) **KODE BIOTECH LIMITED**, a New Zealand limited company (company no. 713905) having its registered office at 19 Mount Street, Scott Laboratory Building, Auckland University of Technology, Auckland (the “**Licensor**”); and
- (2) **AGALIMMUNE LTD.**, a private limited company incorporated in England and Wales (company no. 08504603) having its registered office at 1st Floor, Thavies Inn House, 3-4 Holborn Circus, London EC1N 2HA (the “**Licensee**”).

Background

- A. The Licensor has developed a range of water dispersible glycan-lipid conjugates and is the owner of Exclusionary Rights in respect of the KODE™ Constructs and associated KODE™ Know how.
- B. The Licensee undertakes research into tumour anticancer therapy in humans and is developing a method of promoting tumour regression and destruction by the administration of glycolipids comprising the α -gal epitope.
- C. On March 31, 2015 the Licensee was granted by the Licensor the right to require the Licensor to enter into a license to pursue clinical development and commercialisation of the use of the KODE™ Technology as part of its method (“**Option**”).
- D. The Licensee has exercised its Option by delivery of an “**Option Exercise Notice**” as referred to in the Option, and this Agreement accordingly sets out the terms and conditions of the license granted by the Licensor.

IT IS AGREED as follows:

1 Definitions and Interpretation

- 1.1 Definitions. In this Agreement (including the Background), the following words shall have the following meanings:

Affiliate: means an entity that controls, is controlled by, or is under common control with a Party to this Agreement. The term “control” as used in the preceding sentence means possession of the power to direct or call for the direction of the management and policies of an entity, whether through ownership of a majority of the outstanding voting securities, by contract, or otherwise.

Agalimmune Patent: means the patent application by the Licensee listed in Part 2 of Schedule 1 together with any and all granted patents, continuations, continuations-in-part, divisionals, extensions, reissues, supplementary protection certificates and similar rights that are based on or derive priority from the foregoing.

Confidential Information: means any confidential or proprietary information (including without limitation any trade secrets, Exclusionary Rights, and any inventions, designs, information, know-how, specifications, formulae, data, processes, methods, techniques and other technology) in any form belonging or relating to one Party (the “**Disclosing Party**”), its Affiliates, its or their business or affairs and directly or indirectly furnished to the other Party (the “**Receiving Party**”) in connection with this Agreement.

Control: in relation to a body corporate, the power of a person to secure that the affairs of the body corporate are conducted in accordance with the wishes of that person (or persons):

(a) by means of the holding of shares, or the possession of voting power, in or in relation to, that or any other body corporate; or

(b) by virtue of any powers conferred by the constitutional or corporate documents, or any other document, regulating that or any other body corporate,

and a **Change of Control** occurs if a person who controls any body corporate ceases to do so or if another person acquires control of it.

Exclusionary Rights: Intellectual property or other proprietary rights (such as registered designs, patents and registered trademarks) that provide the right to exclude others from using the claimed subject matter.

Dollar or \$: US Dollar.

Effective Date: The date of delivery of the Option Exercise Notice.

Field: Treatment of cancer in humans whether by way of intramural injection or direct application to tumours.

KODE™ Constructs: [*]

KODE™ Know-How: all know-how owned by the Licensor relating to KODE™ Technology that is not generally known and is useful or necessary for the Licensee to enjoy the benefits of the right and licence granted by the Licensor under Clause 2 including Regulatory Documentation, and all pre-clinical and clinical data owned by the Licensor that is relevant to the Licensed Product. Examples of the KODE™ Know-How include, without limitation, all technical, scientific and other know-how, information and data, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including pre-clinical and clinical trial results (including Regulatory Documentation), manufacturing procedures, test procedures and purification and isolation techniques, whether or not confidential, proprietary, patented or patentable.

KODE™ Technology: The KODE™ Constructs, their preparation, and biological entities (including cells and virions) incorporating or prepared using KODE™ Constructs.

LCIA: The London Court of International Arbitration.

Licensed Patents: All KODE Technology granted patents and applications owned by the Licensor including those listed in Part 1 of Schedule 1 together with any improvements, continuations, continuations-in-part, divisionals, extensions, reissues, supplementary protection certificates and similar rights that are based on or derive priority from the foregoing. The Licensed Patents also include any granted patents and applications forming part of the New Rights created or acquired by the Licensor during the Term.

Licensed Product: A product in the Field that cannot be developed, manufactured, used, or sold without infringing one or more Valid Claims.

Net Sales: means the actual invoiced amount on sales of Licensed Products in arm's length transactions by the Licensee (and/or its Affiliates or a Sublicensee as applicable), less the following:

- (a) customary trade, quantity, or cash discounts to non-affiliated brokers or agents to the extent actually allowed and taken;
- (b) amounts repaid or credited by reason of rejection or return;
- (c) to the extent identified on the invoice, any costs of packing, insurance, transport, delivery; and
- (d) 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, delivery, or use of a Licensed Product which is paid by or on behalf of the Licensee (or the applicable Affiliates or Sublicensee).

In any transfers of Licensed Products between any of the Licensee and its Affiliates (or a Sublicensee and its Affiliates as applicable), Net Sales are subject to and calculated based on the final sale of the Licensed Product to an independent Third Party. If non-monetary consideration is received for any Licensed Products, Net Sales are calculated based on the fair market value of that consideration. If a Licensed Product is used or disposed of by the Licensee (or its Affiliate or the Sublicensee as applicable) in the provision of a commercial service, the Licensed Product is sold and the Net Sales are calculated based on the sales price of the Licensed Product to an independent Third Party during the same Royalty Period or, in the absence of sales, on the fair market value of the Licensed Product as determined by the Parties in good faith.

New Rights has the meaning given in Clause 6.2(a).

Parties: The Licensor and the Licensee and their respective permitted successors and assigns, and 'Party' shall mean each of them.

Regulatory Approval: Means any and all approvals (including pricing and reimbursement approvals), licenses, registrations or authorizations of any Regulatory Authority, necessary for the marketing and sale of a Licensed Product in a country.

Regulatory Authority: Means any applicable government entities regulating or otherwise exercising authority with respect to the manufacturing, marketing, sale, reimbursement and/or pricing of the Licensed Products in the Territory, including, without limitation, in the United States, the United States Food and Drug Administration, and in the European Union, the European Medicines Agency, and any successor governmental authority having substantially the same function.

Regulatory Documentation: Means (a) all applications, registrations, licenses, authorizations and approvals submitted to or received from Regulatory Authorities by Licensor, (b) all correspondence submitted to or received from Regulatory Authorities by Licensor, (c) minutes and official contact reports relating to any communications by Licensor with any Regulatory Authority, (d) all supporting documents and all clinical studies and tests by Licensor, relating to any Licensed Product, and (e) all data contained in any of the foregoing, including all advertising and promotion documents, adverse event files and complaint files, but excluding any and all Regulatory Approvals with respect to such Licensed Product.

Royalty Period: means the partial calendar quarter commencing on the date on which the first sale of a Licensed Product is entered into (including for clarity by a Sublicensee) and every complete or partial calendar quarter thereafter during which either:

- (a) this Agreement remains in effect; or
- (b) the Licensee has the right to complete and sell work-in-progress and inventory of Licensed Products.

Sublicensee: means any sublicensee of the rights granted the Licensee under this Agreement, and “**Sublicense**” shall be construed accordingly.

Sublicense Net Sales: means Net Sales by a Sublicensee.

Sublicense Royalties: means royalties due to and received by the Licensee under a Sublicense in respect of sales of Licensed Products.

Term: The period defined in Clause 8.1.

Third Party: Any person other than a Party.

Valid Claim: means:

- (a) a claim of an issued and unexpired patent covering the Licensed Patents which has not been permanently revoked or held unenforceable or invalid by an unappealable or unappealed decision of a court or government agency of competent jurisdiction; or
- (b) a claim of a pending patent application within the Licensed Patents that has not been abandoned or finally disallowed within [*] years of the first filing date without the possibility of appeal or refiling.

For the purposes of Clause 8.1 (Commencement and termination by expiry) Valid Claims shall be construed with regard to the Agalimmune Patent mutatis mutandis.

- 1.2 Interpretation. Except where otherwise stated, any reference in this Agreement to a Clause or a Schedule is to a Clause of or a Schedule to this Agreement. The provisions of the Schedules shall form part of this Agreement as if set out here. The headings and sub-headings in this document are inserted for convenience only and shall not affect the construction or interpretation of this Agreement.

2 License

- 2.1 Grant of License. For the Term, and subject to the provisions of this Agreement, the Licensor hereby grants to the Licensee a worldwide, exclusive, royalty-bearing, transferable license in the Exclusionary Rights under the Licensed Patents to:

- (a) use the KODE™ Technology and KODE™ Know-how in the Field; and
- (b) develop, have developed, make, have made, use, have used, import, have imported, sell and have sold Licensed Products.

The Licensor undertakes not to grant others the right to exploit the Exclusionary Rights under the Licensed Patents in the Field during the Term.

- 2.2 Additional Know-how. The Licensor shall promptly make available to the Licensee such further KODE™ Know-how as the Licensor acquires after the date of this Agreement and is at liberty to disclose to the Licensee for commercial use. Such further KODE™ Know-how so supplied by the Licensor under this Clause shall, where it has been identified by describing and recording it when provided to the Licensee, be deemed to be part of the KODE™ Know-how. Nothing in this Agreement shall constitute any representation or warranty that any such further KODE™ Know-how supplied to the Licensee pursuant to this Clause is accurate, up to date, complete, or relevant to the KODE™ Technology or the manufacture of the Licensed Products.
- 2.3 Sublicenses. The Licensee may grant Sublicenses of its rights licensed under this Agreement. All Sublicenses executed by the Licensee pursuant to this Clause shall expressly bind the Sublicensee to the relevant terms of this Agreement. The Licensee shall promptly furnish the Licensor with a fully executed copy of any Sublicense.
- 2.4 Retained Rights. For the avoidance of doubt the Licensor retains the right to use and exploit the Exclusionary Rights under the Licensed Patents outside of the Field.
- 2.5 Supply and Use of KODE™ Constructs. To enable the Licensee to enjoy the benefits of the right and licence granted by the Licensor hereunder the Licensee will from time to time require a reliable, good quality supply of KODE™ Constructs. The Licensor shall take commercially reasonable steps during the term of this licence to ensure that at all material times one or more suppliers (each an “**Authorised KODE™ Construct Manufacturer & Supplier**”) is granted a license to enable the manufacture and supply of KODE™ Constructs to the Licensee. Each such licence shall:
- (a) require the Authorised KODE™ Construct Manufacturer & Supplier to ensure that all KODE™ Constructs supplied to the Licensee are, as a minimum, manufactured in accordance with [*] as certified by the Licensor (or an appropriate independent third party certifier approved by the Licensor); and
 - (b) provide that the Licensor’s royalties for such licence shall not exceed a margin of [*] over the Authorised KODE™ Construct Manufacturer & Supplier’s costs of goods manufactured.

The Licensor shall give reasonable consideration to (if applicable) a proposal or proposals from time to time by the Licensee for:

- (c) the Licensee itself to become an Authorised KODE™ Construct Manufacturer & Supplier; and/or
- (d) for a Third Party to become an Authorised KODE™ Construct Manufacturer & Supplier,

subject always to agreeing commercially reasonable quality and supply terms for the manufacture and supply KODE™ Constructs for the Licensee. Such a license is required to be separately negotiated with the Licensor.

The terms set forth in clause 1 of the Letter Agreement dated 18 March 2017, as amended, between the Licensor and the Licensee are incorporated in this Agreement as though fully set forth herein, thereby granting the Licensee a license to be an Authorised KODE™ Construct Manufacturer & Supplier as contemplated by this clause 2.5.

3 Diligence and Commercialisation Requirements

3.1 Diligence Requirements. The Licensee shall use reasonable diligent efforts or require its Affiliates and Sublicensees to use reasonable diligent efforts to develop at least one Licensed Product and to introduce such Licensed Product into the commercial market.

3.2 Development Plans & Reports. The Licensee shall furnish the Licensor with plans and reports as follows:

Plans & Report	Due Date
A written business plan under which the Licensee intends as of the Effective Date to develop and commercialize Licensed Products	Within [*] days of the Effective Date
A written update of the business plan including without limitation: <ul style="list-style-type: none"> · research and development progress during the prior year; · efforts to obtain regulatory approval during the prior year; · marketing, and sales figures during the prior year; · a discussion of its intended development and commercialisation efforts; and · sales projections for the current year. 	Within [*] days after the start of each calendar year, beginning on 1 January 2016

3.3 Compliance.

- (a) KODE™ Constructs. The Licensee shall comply with all applicable laws, regulations and guidelines relevant to the use of KODE™ Constructs.
- (b) Licensed Products Compliance. The Licensee shall take all reasonable steps to comply with, and shall require that its Affiliates and Sublicensees comply with, all local, state, federal, and international laws and regulations relating to the development, testing, manufacture, use, and sale of Licensed Products. The Licensee expressly agrees to comply with the following:
 - (i) The Licensee or its Affiliates or Sublicensees shall obtain all necessary approvals from the United States Food & Drug Administration and any similar foreign governmental authorities in countries or regions in which the Licensee or Affiliate or Sublicensee intends to make, use, or sell Licensed Products.
 - (ii) The Licensee and its Affiliates and Sublicensees shall comply with all United States laws and regulations controlling the export of commodities and technical data, including without limitation all Export Administration Regulations of the United States Department of Commerce. Among other things, these laws and regulations prohibit or require a license for the export of certain types of commodities and technical data to specified countries and foreign nationals. The Licensee hereby gives written assurance that it will comply with and will cause its Affiliates and Sublicensees to comply with all United States export control laws and regulations, that it bears sole responsibility for any violation of those laws and regulations by itself or its Affiliates or Sublicensees.

- 3.4 Use of Licensor Name. In accordance with Clause 7.2, but subject to Clause 3.5, the Licensee and its Affiliates and Sublicensees may not use the name “KODE Biotech Ltd” or any variation of that name in connection with the marketing or sale of any Licensed Products without prior consent.
- 3.5 Use of Trademarks. The Licensee shall be entitled to use (and to grant the right to Sublicensees to use) the KODE™ trademark and other relevant trademarks of Licensor in the form and manner approved by the Licensor (acting reasonably) on or in relation to Licensed Products manufactured and sold, including without limitation use in brochures and marketing materials, provided always that such use is legally permissible. The Licensee will submit sample copies of the proposed use (including the details of proposed package inserts, packaging or promotional or advertising materials) to the Licensor for approval, such approval not to be unreasonably withheld or delayed. The Licensor hereby grants to the Licensee the non-exclusive right to use the KODE™ trademark and other relevant Licensor trademark(s) as contemplated in accordance with the terms of and for the duration of this agreement.
- 3.6 Marking of Licensed Products. To the extent commercially feasible and consistent with prevailing business practices, the Licensee shall mark and shall cause its Affiliates and Sublicensees to mark all Licensed Products that are manufactured or sold under this Agreement with the number of each issued patent under the Licensed Patents that applies to a Licensed Product.
- 3.7 Indemnity.
- (a) Indemnitees. The Licensee shall indemnify the Licensor, its agents and employees (“**Indemnitees**”) against all Claims and Losses arising from the Licensee’s receipt, use, or keeping of KODE™ Constructs, provided that the Licensee shall have no liability to the extent any Claim or Loss is directly attributable to the negligence or intentional misconduct of the Licensor or its officers, employees, and agents, or for any special incidental, consequential or punitive damages. ‘**Claims**’ shall mean all demands, claims, proceedings, penalties, fines, and liability (whether criminal or civil, in contract, tort, or otherwise), and ‘**Losses**’ shall mean all losses including without limitation financial losses, damages, reasonable legal costs, and other reasonable expenses of any nature.
- (b) Procedures. The Indemnitees agree to provide the Licensee with prompt written notice of any claim, suit, action, demand, or judgment for which indemnification is sought under this Agreement. The Indemnitees shall cooperate fully with the Licensee in the defence and will permit the Licensee to conduct and control the defence and the disposition of the claim, suit, or action (including all decisions relative to litigation, appeal, and settlement). However, any Indemnitee may (acting reasonably) retain its own counsel, at the expense of the Licensee, if representation of the Indemnitee by the counsel retained by the Licensee would be inappropriate because of actual or potential conflicts in the interests of the Indemnitee and any other party represented by that counsel. The Licensee agrees to keep the Licensor reasonably informed of the progress in the defence and disposition of the Claim and to consult with the Licensor regarding any proposed settlement.
- (c) Insurance. The Licensee shall maintain insurance that is reasonably sufficient to fulfil its obligations under this Agreement, including the following:

Effective Date	Insurance	Coverage
Commencing on the Effective Date	Employers’ liability insurance	Statutory limits as required by law
Commencing as of 1 October 2017	Commercial general liability insurance	[*]
Upon commencing testing or sales	Clinical trials insurance (upon commencing testing) / product liability insurance (upon sale)	[*]
In connection with the conduct of any clinical testing	Professional liability insurance (errors and omissions)	[*]

- (i) Upon commencement of coverage (as required above) and thereafter annually upon renewal, the Licensee shall provide the Licensor with written evidence of insurance.
- (ii) Such insurance shall list the Licensor as an additional insured. All policies shall be endorsed to indicate that they provide primary coverage without right of contribution by any insurance carrier or self-insured by the Licensor. A waiver of subrogation in favour of the indemnitees shall also be endorsed to the policies. If such coverage is not written on an “occurrence” basis (i.e., it is written on a “claims made” basis), the Licensee shall maintain such insurance coverage during the term of this Agreement and for five (5) years thereafter.
- (iii) For purposes of this Clause, references to the “Licensee” shall include any Affiliate of the Licensee to which the Licensee grants a sublicense hereunder or to which it otherwise delegates any of the Licensee’s obligations hereunder, and the Licensee shall ensure that the foregoing insurance obligations shall apply to any such Affiliate.

4 Consideration

4.1 Licence Fee. In partial consideration of the rights granted under this Agreement, the Licensee shall pay to the Licensor the following licence issue fee

Event	Payment
Within [*] days after the first anniversary of the Effective Date	[*]

This licence issue fee payment is non-refundable and is not creditable against any other payments due to the Licensor under this Agreement.

4.2 Maintenance Fees. The Licensee shall pay to the Licensor the following licence maintenance fees:

Event	Payment
Within [*] days after each anniversary of the Effective Date	[*]

These licence maintenance fee payments are non-refundable and are not creditable against any other payments due to the Licensor under this Agreement.

4.3 Milestone Payments. The Licensee shall pay to the Licensor the following milestone payments:

Event	Payment
Within [*] days after initiation of first Phase III Clinical Trial of a Licensed Product (initiation being first dose of first patient)	[*]
Within [*] days after approval of first Licensed Product for a first indication	[*]
Within [*] days after first commercial sale of a first Licensed Product following approval for use in humans	[*]
Within [*] days after the financial year end of the first financial year in which net sales of Licensed Products for use in humans achieve not less than [*]	[*]

These milestone payments are non-refundable and are not creditable against any other payments due to the Licensor under this Agreement.

4.4 Net Sales Royalties. The Licensee shall pay to the Licensor royalties in respect of its sales of Licensed Products as follows:

Net Sales	Payment
Net Sales in [*]	[*]
Net Sales in [*]	[*]

4.5 Sublicense Royalties. The Licensee shall pay to the Licensor royalties in respect of sales of Licensed Products by each Sublicensee as follows:

(a) The greater of:

(i) [*]

(ii) [*]

(b) The greater of:

(i) [*]

(ii) [*]

4.6 Change of Control. In order that the royalty rates in Clause 4.5 in respect of sales of Licensed Products by each Sublicensee shall not be circumvented, if a Sublicensee or affiliated party acquires Control of the Licensee, and within [*] months the Sublicense previously held by such Sublicensee is terminated, then with effect from the date of termination of the Sublicense the royalty rates payable by the Licensee to the Licensor pursuant to Clause 4.4 in respect of those sales of Licensed Products which would otherwise have been sold pursuant to the applicable Sublicense shall be adjusted to such rate as preserves the effective royalty rate to which the Licensor was entitled immediately prior to termination of the Sublicense.

- 4.7 No Multiple Royalties. No multiple royalties shall be payable because any Licensed Product is covered by more than one Licensed Patent.
- 4.8 Buy Out. The Licensor shall give reasonable consideration to any proposal by the Licensee (or its assignee or successor) for a one-time lump sum payment in full consideration of all future payment obligations to the Licensor under this Agreement, including, without limitation, royalties, milestone payments, license maintenance fees and manufacturing royalties; provided, however that the Licensor shall have the right in its sole discretion to reject any and all proposals for any reason whatsoever or for no reason at all.

5 Royalty Reports; Payments; Records

- 5.1 First Sale. The Licensee shall report to the Licensor the date of:

- (a) First manufacture and supply of KODE™ Constructs within [*] days after occurrence by the Licensee and by each Authorised Manufacturer & Supplier; and
- (b) First commercial sale (whether by the Licensee, or its Affiliate or any Sublicensee) of each Licensed Product within [*] days after occurrence in each country.

- 5.2 Reports and Payments.

- (a) Within [*] days after the conclusion of each Royalty Period, the Licensee shall deliver to the Licensor a report containing the following information:
 - (i) With regard to KODE™ Constructs acquired, the identity of the Authorised KODE™ Construct Manufacturer & Supplier(s) and the volumes of KODE™ Construct purchased, and the Licensor will promptly thereafter provide such information as reasonably required to verify its margin royalty in respect of such supplies;
 - (ii) With regard to the royalties payable in respect of Licensed Products:
 - A the number of Licensed Products sold to independent third parties in each country;
 - B the gross sales price for each Licensed Product by the Licensee and its Affiliates during the applicable Royalty Period in each country;
 - C the calculation of Net Sales for the applicable Royalty Period in each country, including a listing of applicable deductions with specific identification of the Russian Federation; and
 - D total royalties payable on Net Sales in United States dollars, together with the exchange rates used for conversion; and
 - (iii) With regard to royalties due to the Licensor in respect of Sublicenses for the applicable Royalty Period:
 - A details of the identity of the Sublicensees;
 - B the gross Sublicense Net Sales during the applicable Royalty Period;

- C the gross Sublicense Royalties during the applicable Royalty Period; and
- D the calculation of the and total, amount due to the Licensor in respect of the Sublicense for the applicable Royalty Period in United States dollars, together with the exchange rates used for conversion.

Concurrent with this report, the Licensee shall remit to the Licensor any payment due for the applicable Royalty Period. If no amounts are due to the Licensor for any Royalty Period, the report shall so state.

- 5.3 Payments in United States Dollars. The Licensee shall make all payments in United States dollars. The Licensee shall convert foreign currency to United States dollars at the conversion rate existing in the United States (as reported in the Wall Street Journal) on the last working day of the calendar quarter preceding the applicable Royalty Period. The Licensee may not deduct exchange, collection, or other charges.
- 5.4 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, the Licensee shall give the Licensor prompt written notice of the restriction within the [*] reporting and payment deadline for each Royalty Period. The Licensee shall pay any amounts due the Licensor through whatever lawful methods the Licensor reasonably designates. However, if the Licensor fails to designate a payment method within [*] days after the Licensor is notified of the restriction, the Licensee may deposit payment in local currency to the credit of the Licensor in a recognized banking institution selected by the Licensee and identified by written notice to the Licensor, and that deposit fulfils all obligations of the Licensee to the Licensor with respect to that payment.
- 5.5 Records. The Licensee shall maintain and shall cause its Affiliates and require its Sublicensees to maintain complete and accurate records of Licensed Products that are made, used, or sold under this Agreement and any amounts payable to the Licensor in relation to Licensed Products with sufficient information to permit the Licensor to confirm the accuracy of any reports delivered to the Licensor under Clause 5.2.
- (a) The relevant party shall retain records relating to a given Royalty Period for at least [*] years after the conclusion of that Royalty Period, during which time the Licensor may, at its expense, cause its internal accountants or an independent, certified public accountant to inspect records during normal business hours for the sole purpose of verifying any reports and payments delivered under this Agreement.
 - (b) The accountant may not disclose to the Licensor any information other than information relating to accuracy of reports and payments delivered under this Agreement.
 - (c) The Parties shall reconcile any underpayment or overpayment within [*] days after the accountant delivers the results of the audit.
 - (d) If any audit performed under this Clause 5.5 reveals an underpayment in excess of [*] percent [*] in any Royalty Period, the Licensee shall bear the full cost of the audit; if less than [*] percent [*] the Licensor shall bear its own costs.
 - (e) The Licensor may exercise its rights under this Clause 5.5 only once every year and only with reasonable prior notice to the Licensee (or other relevant party).

- 5.6 Late Payments. Any payments due to the Licensor by the Licensee that are not paid on or before the date payments are due under this Agreement bear interest at [*] per month, calculated on the number of days that payment is delinquent.
- 5.7 Method of Payment. All payments under this Agreement should be made to “KODE Biotech Limited” and sent to the address identified below. Each payment should reference this Agreement and identify the obligation under this Agreement that the payment satisfies.
- 5.8 Withholding and Similar Taxes. Royalty payments and other payments due to the Licensor under this Agreement may not be reduced by reason of any withholding or similar taxes applicable to payments to the Licensor. Therefore all amounts owed to the Licensor under this Agreement are net amounts and shall be grossed-up to account for any withholding taxes, value-added taxes or other taxes, levies or charges. In the event that the Licensor shall receive any repayment of any such tax or of any credit obtained by reference to any such deduction that is attributable to such tax, the Licensor shall pay, or shall procure that there is paid, to the Licensee an amount equivalent to the amount overpaid.

6 Intellectual Property and Exclusionary Rights

- 6.1 Existing Exclusionary Rights. It is expressly agreed that all Exclusionary Rights are and shall [*]. It is further expressly agreed that the license granted by the Licensor hereunder is for the Term and no further rights to use KODE™ Technology and KODE™ Know-How are granted under this Agreement.
- 6.2 New Exclusionary Rights.
- (a) The ownership of any Exclusionary Rights in respect of any discoveries, innovations or inventions made jointly by the Parties during the Term, and capable of being protected under patent law, shall be allocated according to the flowchart appended to this Agreement as Schedule 2 (“**New Rights**”).
 - (b) The Licensor acknowledges that the Licensee will be solely responsible for prosecuting, maintaining and defending any New Rights assigned to the Licensee, in addition to any other patent rights owned solely by the Licensee.
 - (i) Where in accordance with the flowchart at Schedule 2 the subject matter defined in a New Rights claim provided in the specification does not consist of KODE™ Technology, and the New Rights claim is not in respect of KODE™ Technology, and the Licensee is allocated the rights in respect of the claimed subject matter, the Licensor shall at the Licensee’s reasonable request do all such acts and execute all such documents reasonably required by the Licensee to confirm that title in all such New Rights are assigned, or will be assigned to the Licensee, or at the Licensee’s option that the Licensor grants or will grant to the Licensee a worldwide, exclusive, royalty-free, transferable license in such New Rights, or one or more specific use, with the right to sublicense. The Licensee shall promptly reimburse all reasonable costs and expenses incurred by the Licensor in connection with providing such assistance. The Licensor acknowledges that no further remuneration or compensation other than that provided for in this Clause is or may become due to the Licensor in respect of the performance of its obligations under this Clause.
 - (c) The Licensor shall promptly notify the Licensee on becoming aware of any improvement of the KODE™ Technology, or any new KODE™ Technology, that the Licensor believes may have relevance to the Field. The Licensor shall use reasonable endeavours to monitor developments by other KODE™ Technology licensees.

6.3 Responsibility for Licensed Patents.

- (a) The Licensor has primary responsibility at its expense and under its own control for the preparation, filing, prosecution, and maintenance of all Licensed Patents. The Licensor shall advise the Licensee as to the preparation, filing, prosecution, and maintenance of all Licensed Patents reasonably prior to any deadline or action with the United States Patent & Trademark Office or any foreign patent office and shall furnish the Licensee with copies of relevant documents reasonably in advance of consultation. The Licensor shall consider in good faith any comments of the Licensee on any patent filings for the Licensed Patents.
- (b) If the Licensor desires to abandon any patent or patent application within the Licensed Patents, the Licensor shall provide the Licensee with reasonable prior notice of the intended abandonment, and the Licensee may, at its expense, prepare, file, prosecute, and maintain the relevant Licensed Patents. If the Licensor elects to abandon any patent or patent application or cease payment of any patent expenses, the Licensor loses all rights under this Agreement with respect to the particular Licensed Patents in those one or more countries.

6.4 Cooperation. Each Party shall provide reasonable cooperation in the preparation, filing, prosecution, and maintenance of all Licensed Patents. Cooperation includes, without limitation, promptly informing the other Party of matters that may affect the preparation, filing, prosecution, or maintenance of Licensed Patents (such as, becoming aware of an additional inventor who is not listed as an inventor in a patent application).

6.5 Licensed Patents Infringement.

- (a) Notification of Infringement. Each Party agrees to provide written notice to the other Party promptly after becoming aware of any infringement of the Licensed Patents.
- (b) Licensor Responsibility for Prosecution in the Field. The Licensor has primary responsibility at its expense for initiating the prosecuting of any third party infringement of the Licensed Patents in the Field and defending the Licensed Patents in any declaratory judgment action brought by a third party which alleges invalidity, unenforceability, or infringement of the Licensed Patents in the Field.
 - (i) Prior to commencing any action, the Licensor shall consult with the Licensee and shall in good faith consider the views of the Licensee regarding the advisability and conduct of the proposed action and its effect on this Agreement.
 - (ii) The Licensor shall keep the Licensee reasonably informed of material actions taken by the Licensor pursuant to the infringement or declaratory action.
 - (iii) The Licensor may not enter into any settlement, consent judgment, or other voluntary final disposition of any infringement action under this Clause without the prior written consent of the Licensee, which consent may not be unreasonably withheld or delayed.
 - (iv) Any recovery obtained in an action under this Clause shall be distributed as follows: [*].
- (c) Licensee as Indispensable Party. If and to the extent required by law, the Licensee shall permit any action under Clause 6.5(b) to be brought in its name, provided that the [*].

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- (d) Licensee Right to Prosecute. If the Licensor declines or fails to initiate an infringement action within a reasonable time after it first becomes aware of the basis for the action, or to answer a declaratory judgment action within a reasonable time after the action is filed, the Licensee may prosecute the infringement or answer the declaratory judgment action under its [*]. If and to the extent required by law, the Licensor shall permit any such action to be brought in its name, [*]. If the Licensee takes action under this Clause, the Licensee shall keep the Licensor reasonably informed of material actions taken by the Licensee pursuant to the infringement or declaratory action.
- (e) Prosecution in Other Fields. If the Licensor or any licensee of the Licensed Patents in a field other than the Field initiates an infringement action the Licensor shall keep the Licensee reasonably informed of material actions taken pursuant to the infringement or declaratory action and shall consider the views of the Licensee regarding the advisability and conduct of the proposed action and its effect on this Agreement.
- (f) Cooperation. Both Parties shall cooperate fully in any action under this Clause which is controlled by the other 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 assistance. Unless it would be unlawful to do so in a particular jurisdiction, the controlling Party may from time to time request the cooperating Party to provide reasonable financial support towards the conduct of an action under this Clause 6.5, and the cooperating Party will give reasonable consideration to such request, having regard (amongst other things) to the advisability and conduct of such action and its effect on this Agreement, the likelihood of the action's prospects of success, and the impact on the cooperating Party if action is not taken or (as the case may be) is discontinued. For clarity any such financial support shall be in the discretion of the cooperating Party and may be subject to such terms and for such duration, or impose such limits or conditions as the cooperating Party may determine.

7 Confidentiality & Publicity

7.1 Confidentiality

- (a) Obligations. For [*] years after disclosure of any Confidential Information, the Receiving Party shall:
 - (i) maintain Confidential Information in confidence, except that the Receiving Party may disclose or permit the disclosure of any Confidential Information to its officers or directors, officers, employees, consultants, and advisors, and those of its Affiliates and Sublicensees who are obligated to maintain the confidential nature of Confidential Information and who need to know Confidential Information for the purposes of this Agreement;
 - (ii) use Confidential Information solely for the purposes of this Agreement; and
 - (iii) allow its officers or directors, officers, employees, consultants, and advisors to reproduce the Confidential Information only to the extent necessary for the purposes of this Agreement, with all reproductions being Confidential Information.

The rights of use and reproduction under (ii) and (iii) above shall extend to the Licensee's Affiliates with a need for such use and reproduction as well as to Sublicensees.

- (b) Exceptions. The confidentiality obligations of the Receiving Party above do not apply to the extent that the Receiving Party can demonstrate that Confidential Information:
- (i) was in the public domain prior to the time of its disclosure under this Agreement;
 - (ii) entered the public domain after the time of its disclosure under this Agreement through means other than an unauthorized disclosure resulting from an act or omission by the Receiving Party;
 - (iii) was already known or independently developed or discovered by the Receiving Party without use of the Confidential Information;
 - (iv) is or was disclosed to the Receiving Party at any time, whether prior to or after the time of its disclosure under this Agreement, by a third party having no fiduciary relationship with the Disclosing Party and having no obligation of confidentiality with respect to the Confidential Information; or
 - (v) is required to be disclosed to comply with applicable laws or regulations or with a court or administrative order, provided that (to the extent permitted by law) the Disclosing Party receives reasonable prior written notice of the disclosure.
- (c) Ownership and Return. The Receiving Party acknowledges that the Disclosing Party (or a Third Party entrusting its own information to the Disclosing Party) owns the Confidential Information in the possession of the Receiving Party. Upon expiration or termination of this Agreement, or at the request of the Disclosing Party, the Receiving Party shall return to the Disclosing Party all originals, copies, and summaries of documents, materials, and other tangible manifestations of Confidential Information in the possession or control of the Receiving Party, except that the Receiving Party may retain one copy of the Confidential Information in the possession of its legal counsel solely for the purpose of monitoring its obligations under this Agreement.

7.2 Publicity Restrictions. The Licensee may not use the name of the Licensor or any of its officers, employees, or agents, or any adaptation of their names, or any terms of this Agreement in any promotional material or other public announcement or disclosure without the prior written consent of the Licensor. The foregoing notwithstanding, the Licensee may disclose that information without the consent of the Licensor in any prospectus, offering memorandum, or other document or filing required by applicable securities laws or other applicable law or regulation, provided that the Licensee provides the Licensor at least [*] days (or a shorter period in order to enable the Licensee to make a timely announcement to fulfil applicable securities laws or other applicable law or regulation, while affording the Licensor the maximum feasible time to review the announcement) prior written notice of the proposed text for the purpose of giving the Licensor the opportunity to comment on the text.

7.3 No information warranty. No warranty or representation is given by either Party as to the accuracy or completeness of information provided under this Agreement. Each Party must make its own independent assessment of the information provided and rely on its own judgment in reaching any conclusion.

8 Term and Termination

8.1 Commencement and termination by expiry. This Agreement, and the licence granted under Clause 2.1 shall come into effect on the Effective Date and, unless terminated earlier in accordance with this Clause 8, shall continue in force and remains in effect until the later of expiration or abandonment of all Valid Claims.

8.2 Voluntary termination. The Licensee may terminate this Agreement:

- (a) at any time on [*] days' notice in writing to the Licensor; or
- (b) on [*] days' notice if there is a Change of Control of the Licensor, or the Licensor sells all or substantially all of the KODE™ Technology assets to an entity that is a competitor of the Licensee being an entity engaged, directly or indirectly, in any one or more of the development, production, marketing, distribution and/or exploitation of a competing product in the Field.

8.3 Termination by Default. Either Party may terminate this Agreement at any time by notice in writing to the other Party (the '**Other Party**'), such notice to take effect as specified in the notice:

- (a) if the Other Party is in persistent breach of this Agreement other than a failure by the Licensee to pay any amount due to the Licensor under this Agreement, and, in the case of a breach capable of remedy within [*] days, the breach is not remedied within [*] days of the Other Party's receiving notice specifying the breach and requiring its remedy; or
- (b) If the alleged breach consists of non-payment of any uncontested amounts due to the Licensor under this Agreement, and the Licensee fails to cure that breach within [*] days after receiving notice of the breach, the Licensor may terminate this Agreement immediately upon written notice to the Licensee;
- (c) if (A) the Other Party becomes insolvent or unable to pay its debts as and when they become due, or (B) an order is made or a resolution is passed for the winding up of the Other Party (other than voluntarily for the purpose of solvent amalgamation or reconstruction), or (C) a liquidator, administrator, administrative receiver, receiver, or trustee is appointed in respect of the whole or any part of the Other Party's assets or business, or (D) the Other Party makes any composition with its creditors, or (E) the other Party ceases to continue its business, or (F) as a result of debt and/or maladministration the other Party takes or suffers any similar or analogous action in any jurisdiction.

8.4 Force Majeure. Neither Party is responsible for delays resulting from causes beyond its reasonable control, including without limitation fire, explosion, flood, war, strike, act of terrorism or riot, provided that the nonperforming Party uses commercially reasonable efforts to avoid or remove those causes of non-performance and continues performance under this Agreement with reasonable dispatch whenever the causes are removed.

8.5 Consequences of Termination.

- (a) Upon the early termination of this Agreement, the Licensee and its Affiliates and Sublicensees may complete and sell any work-in-progress and inventory of Licensed Products that exist as of the effective date of termination, provided that:
 - (i) the Licensee is current in payment of all amounts due the Licensor under this Agreement,
 - (ii) the Licensee pays the Licensor the applicable royalty on sales of Licensed Products in accordance with the terms of this Agreement; and
 - (iii) the Licensee and its Affiliates and Sublicensees complete and sell all work-in-progress and inventory of Licensed Products within nine (9) months after the effective date of termination.

- (b) Upon the expiration or termination of this Agreement, for each Sublicensee, upon termination of the Sublicense with such Sublicensee, if the Sublicensee is not then in breach of such Sublicense with the Licensee such that the Licensee would have the right to terminate such Sublicense, the 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; *provided, however*, 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 the Licensor which are not included in this Agreement. The Licensor's consent to such Sublicensee request shall not be unreasonably withheld. Save as expressly provided, upon termination of this Agreement for any reason the Licensee and each Sublicensee shall no longer be licensed to use or otherwise exploit in any way, either directly or indirectly, KODE™ Technology or KODE™ Know-How, in so far and for as long as any of the Licensed Patents remain in force, and except in respect of any accrued rights and those provisions expressed to survive termination, neither Party shall be under any further obligation to the other.
- (c) All rights and obligations of the Parties shall cease to have effect immediately upon termination of this Agreement provided that termination shall not affect the continued existence and validity of the rights and obligations of the parties under those Clauses of this Agreement which are expressed to survive termination and any provision of this Agreement necessary for the interpretation or enforcement of this Agreement. A Party's right of termination under this Agreement, and the exercise of any such right, shall be without prejudice to any other right or remedy (including any right to claim damages) that such Party may have in the event of a breach of contract or other default by the other Party.

9 Dispute Resolution.

9.1 Procedures Mandatory. The parties shall resolve any dispute arising out of or relating to this Agreement solely by means of the procedures set forth in this Clause. These procedures constitute legally binding obligations that are an essential provision of this Agreement. If either Party fails to observe the procedures of this Clause, as modified by their written agreement, the other Party may bring an action for specific performance in any court of competent jurisdiction.

9.2 Dispute Resolution Procedures.

- (a) Negotiation. In the event of any dispute arising out of or relating to this Agreement, the affected Party shall notify the other Party, and the parties shall attempt in good faith to resolve the matter within [*] days after the date of notice (the "**Notice Date**"). Any disputes not resolved by good faith discussions shall be referred to senior executives of each Party, who shall meet and attempt to negotiate a settlement within [*] days after the Notice Date. Subject as provided the representatives of the Parties may participate in meetings, adjourn and otherwise regulate their meetings as they think fit, and in determining whether such representatives are participating in a meeting, it is irrelevant where any representative is or how they communicate with each other.
- (b) Mediation. If the matter remains unresolved within [*] days after the Notice Date, or if the senior executives fail to meet within [*] days after the Notice Date, the Parties shall first seek settlement of that dispute by mediation in accordance with the then current LCIA Mediation Rules, which Rules are deemed to be incorporated by reference into this Clause.

- (c) Arbitration. If the Parties fail to resolve the dispute through mediation, or if neither Party elects to initiate mediation, each Party may serve notice on the other Party that it wishes to refer the matters in dispute to be finally resolved by arbitration under the then current LCIA Arbitration Rules, which Rules are deemed to be incorporated by reference into this Clause.
 - (i) The number of arbitrators shall be one.
 - (ii) The seat, or legal place, of arbitration shall be London.
 - (iii) The language to be used in the arbitral proceedings shall be English.
 - (iv) The governing law of the contract shall be the substantive law of England.

9.3 Preservation of Rights Pending Resolution.

- (a) Performance to Continue. Each Party shall continue to perform its obligations under this Agreement pending final resolution of any dispute arising out of or relating to this Agreement. However, a Party may suspend performance of its obligations during any period in which the other Party fails or refuses to perform its obligations.
- (b) Provisional Remedies. Although the procedures specified in this Clause are the exclusive procedures for resolution of disputes arising out of or relating to this Agreement, either Party may seek a preliminary injunction or other provisional equitable relief if, in its reasonable judgment, that action is necessary to avoid irreparable harm to itself or to preserve its rights under this Agreement.
- (c) Statute of Limitations. The Parties agree that all applicable statutes of limitation and time-based defences (such as, estoppel and laches) are tolled while the negotiation, mediation and/or arbitration procedures set forth in Clause 9.2.(a), 9.2(b) or 9.2(c) are pending. The Parties shall take any actions necessary to effectuate this result.

10 General

10.1 Representations and Warranties. The Licensor warrants that its employees and contractors have assigned to the Licensor their entire right, title, and interest in and to the Licensed Patents, the KODE™ Technology and KODE™ Know-how, and that it has authority to grant the rights and licenses set forth in this Agreement, and that it has not granted any rights in or to the Licensed Patents and/or the KODE™ Technology and/or the KODE™ Know-how to any Third Party that is inconsistent with the grant of rights in this Agreement. Save as expressly provided in this agreement, neither Party makes any other warranty or accepts any liability in connection with the supply and use of KODE™ Constructs hereunder and specifically does not give any warranty that:

- (a) [*]
- (b) [*]
- (c) [*]

10.2 Limitation of liability. Neither Party shall be entitled to recover from the other any special incidental, consequential or punitive damages.

10.3 No Partnership. Nothing in this Agreement is intended to, or shall be deemed to, establish any partnership or joint venture between the Parties, constitute either Party the agent of the other Party, nor authorise either Party to make or enter into any commitments for or on behalf of the other Party.

10.4 Binding Effect. This Agreement is binding upon and inures to the benefit of the Parties and their respective permitted successors and assigns.

10.5 Notices.

Any notices required or permitted under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be (a) delivered personally, or (b) sent by recognized national overnight courier; or (c) sent by registered or certified mail, postage prepaid, return receipt requested, to the following addresses:

If to the Licensor:

KODE Biotech Limited
19 Mount Street
Scott Laboratory Building
Auckland University of Technology
Auckland, New Zealand
Attention: CEO

If to the Licensee:

Agalimmune Limited
c/o Wilson Wright LLP
1st Floor Thavies Inn House
London
United Kingdom EC1N 2HA
Attention: CEO/Director
With a copy to:
BioLineRx Ltd.
2 HaMa'ayan Street
Modi'in 7177871
Israel

Attention: Chief Financial Officer

All notices under this Agreement are effective and deemed received (a) if delivered personally, at the time of delivery; (b) if sent by recognized national overnight courier, two business days from the date of dispatch; (c) in the case of pre-paid registered or certified mail, four business days from the date of posting. If deemed receipt under the previous paragraphs of this Clause is not within business hours (meaning 9.00 am to 5.30 pm Monday to Friday on a day that is not a public holiday in the place of receipt), when business next starts in the place of receipt. To prove service in the case of post, it is sufficient to prove that the envelope containing the notice was properly addressed and posted. A Party may change its contact information immediately upon written notice to the other Party in the manner provided in this Clause.

10.6 Entire agreement. This Agreement sets out the entire agreement between the Parties relating to its subject matter and supersedes all prior oral or written agreements, arrangements or understandings between them relating to such subject matter, including

- (a) the Mutual Confidentiality Undertakings dated 29 July 2014.
- (b) Evaluation License & Option Agreement dated 31 March 2015.

The Parties acknowledge that they are not relying on any representation, agreement, term, or condition that is not set out in this Agreement. Nothing in this Agreement excludes liability for fraud.

- 10.7 Variation & Waiver. This Agreement, including this Clause, may be amended, varied or renewed only by a document in writing signed by a duly authorized representative of each Party. The waiver of any rights or failure to act in a specific instance relates only to that instance and is not an agreement to waive any rights or fail to act in any other instance.
- 10.8 No assignment. Neither Party shall assign, transfer, charge, encumber, or otherwise deal with the whole or any part of this Agreement, or its rights or obligations under this Agreement without the prior written consent of the other Party which consent may not be unreasonably withheld or delayed. Notwithstanding the foregoing, this Agreement may be assigned by either Party in connection with a merger, consolidation, sale of all of the equity interests of the Party, or a sale of all or substantially all of the assets of the Party to which this Agreement relates save that the prior written consent of Licensee shall be required for an assignment, transfer, or other disposal by Licensor of the whole or any part of this Agreement to a competitor of Licensee being a person engaged, directly or indirectly, in any one or more of the development, production, marketing, distribution and/or exploitation of a competing product in the Field.
- 10.9 Severability. If any provision of this Agreement is held invalid or unenforceable for any reason, the invalidity or unenforceability does not affect any other provision of this Agreement, and the Parties shall negotiate in good faith to modify the Agreement to preserve (to the extent possible) their original intent. While the dispute is pending resolution, this Agreement shall be construed as if the provision were deleted by agreement of the Parties.
- 10.10 Counterparts. This Agreement may be executed in one or more counterparts, each of which is an original, and all of which together are one instrument. Transmission by electronic means of and electronic form of a duly executed counterpart shall be deemed to constitute due and sufficient delivery of such counterpart and will be accepted and will be binding on the Parties whether or not subsequently replaced by originally signed duplicates.
- 10.11 Law and jurisdiction. This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) is governed by and construed in accordance with the laws of England irrespective of any conflicts of law principles. The Parties submit to the exclusive jurisdiction of the English courts in respect of any dispute arising out of or relating to this Agreement (including non-contractual disputes or claims) except that a Party may bring urgent or interim proceedings in any court of competent jurisdiction.

THIS AGREEMENT has been entered into and executed by the Parties as of the Effective Date.

Agreed by the Parties through their authorized signatories:

For and on behalf of **KODE Biotech Limited:**

/s/ Stephen Henry

Signed
Stephen Henry
Print name
CEO
Job title
28 March 2018
Date

For and on behalf of **Agalimmune Ltd.:**

/s/ Philip Serlin

Signed
Philip Serlin
Print name
Chairman of the Board
Job title
28 March 2018
Date

Signed
Print name
Job title
Date

Schedule 1

PART 1

Licensed Patents

KBL ref	Title	Filing date	CC	Application no. (patent no.)	Priority document(s)	Status
[*]	[*]	[*]	[*]	[*]	[*] [*] [*] [*]	[*]
[*]	[*]	[*]	[*]	[*]	[*] [*] [*] [*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*] [*]	[*]

Schedule 1

PART 2

Agalimmune Patent

KBL ref	Title	Filing date	CC	Application no. (Patent no.)	Priority document(s)	Status
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]

[*]

[*] Represents material that has been omitted and will be filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended.

SECOND AMENDMENT AGREEMENT

This Amendment Agreement (“**Amendment Agreement**”), dated as of **October 16, 2018** (the “**Execution Date**”), is between the University of Massachusetts (“**University**”), a not-for-profit, public institution of higher education of the Commonwealth of Massachusetts, established by Chapter 75 of the Massachusetts General Laws, as represented by its Medical School (Worcester campus), and Agalimmune Ltd (“**Company**”), a private limited company incorporated in England & Wales (company registration number 08504603) with registered address at 1st Floor Thavies Inn House, 3-4 Holborn Road, London, EC1N 2HA, United Kingdom.

WHEREAS University and Company entered into an Exclusive License Agreement effective as of **April 30, 2013** and thereafter amended such agreement in a document dated **February 6, 2017** (the License Agreement as amended shall be referred to as the “**Agreement**”).

AND WHEREAS University and Company wish to further amend the License Agreement, with effect from the Effective Date (as defined below).

THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, University and Company agree as follows:

1 Definitions

1.1 “Effective Date” shall mean March 20, 2017.

1.2 Terms defined in the Agreement (including by way of cross-reference), unless otherwise defined herein, have the same meaning herein as if set out in this Amendment Agreement.

2 Amendments to the Agreement.

2.1 Amendment of Section 3.1. Section 3.1(b) of the Agreement shall be and is hereby replaced as of the Effective Date in its entirety by the following:

3.1(b) Development of Licensed Products.

(i) Within [*] days of the Commencement Date, Company shall furnish University with a written business plan under which Company intends as of the Commencement Date to develop Licensed Products.

(ii) Within [*] days after the start of each calendar year, beginning on January 1, 2014 Company shall furnish University with a written report on progress during the prior year to develop and commercialize Licensed Products, including without limitation research and development, efforts to obtain regulatory approval, marketing, and sales figures. Company shall also include in the report a discussion of its intended development and commercialization efforts and sales projections for the current year.

(iii) During [*], Company, its Affiliate or Sublicensee shall commence a Phase I clinical trial or its equivalent covering at least one (1) Licensed Product.

(iv) During [*], Company, its Affiliate or Sublicensee shall commence a Phase II clinical trial or its equivalent covering at least one (1) Licensed Product, should such a trial be required by the FDA.

(v) During [*], Company, its Affiliate or Sublicensee shall commence a Phase III clinical trial or its equivalent covering at least one (1) Licensed Product.

(vi) No later than [*], Company, its Affiliate or Sublicensee shall be ready to file a New Drug Application (“NDA”) or Biologics License Application (“BLA”) with the FDA covering at least one (1) Licensed Product.

(vii) Within [*] months after receiving FDA approval of the NDA or BLA for any Licensed Product, Company, its Affiliate or Sublicensee shall market the approved Licensed Product in the United States.

3 Miscellaneous

3.1 Binding Effect. This Amendment Agreement is binding upon and inures to the benefit of the parties and their respective permitted successors and assigns and are not intended to benefit, or be enforceable by, anyone else.

3.2 Assignment. This Amendment Agreement may not be assigned by either party without the prior written consent of the other party, which consent may not be unreasonably withheld or delayed. Notwithstanding the foregoing, this Amendment Agreement may be assigned by either party in connection with a merger, consolidation, sale of all of the equity interests of the party, or a sale of all or substantially all of the assets of the party to which this Amendment Agreement relates.

3.3 Amendment and Waiver. The parties may only amend, supplement, or otherwise modify this Amendment Agreement through a written instrument signed by both parties. The waiver of any rights or failure to act in a specific instance relates only to that instance and is not an agreement to waive any rights or fail to act in any other instance.

3.4 Governing Law. This Amendment Agreement is governed by and construed in accordance with the laws of the Commonwealth of Massachusetts irrespective of any conflicts of law principles. The parties may only bring legal action that arises out of or in connection with this Amendment Agreement in the Massachusetts Superior Court in Suffolk County.

3.5 Severability. If any provision of this Amendment Agreement is held invalid or unenforceable for any reason, the invalidity or unenforceability does not affect any other provision of this Amendment Agreement, and the parties shall negotiate in good faith to modify the Agreement to preserve (to the extent possible) their original intent. If the parties fail to reach a modified agreement within sixty (60) days after the relevant provision is held invalid or unenforceable, then the dispute shall be resolved in accordance with the procedures set forth in Article 9 of the Agreement. While the dispute is pending resolution, this Amendment Agreement shall be construed as if the provision were deleted by agreement of the parties.

3.6 Counterparts. This Amendment Agreement may be executed in one or more counterparts, each of which is an original, and all of which together are one instrument. A copy of an executed counterpart may be delivered by facsimile or other electronic means and such counterpart so delivered shall be equally effective for all purposes.

3.7 Entire Agreement. This Amendment Agreement constitutes the entire agreement between the parties with respect to its subject matter and supersedes all prior agreements or understandings between the parties relating to its subject matter.

THE PARTIES have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

UNIVERSITY OF MASSACHUSETTS

AGALIMMUNE LTD.

By: /s/ James P. McNamara

By: /s/ Mali Zeevi

Name: James P. McNamara, Ph.D.,

Name: Mali Zeevi

Title: Executive Director

Title: Chief Financial Officer

Office of Technology Management



[*] Represents material that has been omitted and will be filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended.

AMENDMENT NO. 1 TO LICENSE AGREEMENT

THIS AMENDMENT NO. 1 (“**Amendment**”) is entered into effective as of June 18th, 2018 (the “**Amendment Effective Date**”) by and between **BioLineRx Ltd.** (“**BioLine**”) and **Wartner Europe BV** (“**Perrigo**”).

PREFACE:

- A. BioLine and Perrigo entered into a License Agreement dated as of December 22, 2014 (the “**Agreement**”).
- B. The Parties now wish to amend certain provisions of the Agreement.

Now **THEREFORE**, the Parties hereby agree as follows:

1. Section 3.1 of the Agreement is hereby deleted in its entirety and replaced with the following:
 - 3.1 a. With respect to the Licensed Products referred to in Section 7.2, in consideration for the exclusive license granted to Licensee under Section 2.1, for each Licensed Product unit sold by Licensee and its Sublicensees in a given calendar quarter, Licensee will pay Licensor an amount equal to [*].
 - b. For the purpose of this Agreement, [*].
2. Subsections (a) and (b) of Section 3.2 are hereby deleted in their entirety and replaced with the following: [*]
3. Section 3.3 is hereby deleted in its entirety and not replaced.
4. (a) In Section 4.1, the sentence “Licensor has the right to examine Records that were created within five (5) years of the date of Licensor’s request” is hereby amended to read “Licensor has the right to examine Records that were created within seven (7) years of the date of Licensor’s request.”

(b) In Section 4.2, the reference to “five (5) years” in the second line is hereby amended to “seven (7) years.”
5. In Section 7.2(a), [*]
6. Following the Amendment Effective Date, if Perrigo desires to add one or more countries to the Territory, it shall notify BioLine of such desire, and the Parties shall negotiate in good faith as to whether and on what terms such country(ies) will be added to the Territory.
7. Capitalized terms used but not defined herein shall have the meanings set out in the Agreement. Except as otherwise specifically agreed in this Amendment, the existing terms of the Agreement shall remain in full force and effect.
8. This Amendment shall be binding upon the parties once executed by all parties and shall enter into force and become effective as of the Amendment Effective Date first written above.

[signature page follows]

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their duly authorized representatives as of the Amendment Effective Date.

BioLineRx Ltd.

Wartner Europe BV

By: /s/ Philip Serlin

By: /s/ Christophe Van Damme

Name: Philip Serlin

Name: Christophe Van Damme

Title: Chief Executive Officer

Title: Director

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER UNDER SECTION 302 OF THE
SARBANES-OXLEY ACT**

I, Philip A. Serlin, certify that:

1. I have reviewed this annual report on Form 20-F of BioLineRx Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 28, 2019

/s/ Philip A. Serlin
Philip A. Serlin
Chief Executive Officer

**CERTIFICATION OF THE CHIEF FINANCIAL OFFICER UNDER SECTION 302 OF THE
SARBANES-OXLEY ACT**

I, Mali Zeevi, certify that:

1. I have reviewed this annual report on Form 20-F of BioLineRx Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 28, 2019

/s/ Mali Zeevi

Mali Zeevi
Chief Financial Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER UNDER SECTION 906 OF THE
SARBANES-OXLEY ACT**

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of BioLineRx Ltd. (the “Company”) hereby certifies to such officer’s knowledge that:

(i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2018 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 28, 2019

/s/ Philip A. Serlin

Philip A. Serlin

Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**CERTIFICATION OF CHIEF FINANCIAL OFFICER UNDER SECTION 906 OF THE
SARBANES-OXLEY ACT**

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of BioLineRx Ltd. (the “Company”) hereby certifies to such officer’s knowledge that:

(i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2018 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 28, 2019

/s/ Mali Zeevi

Mali Zeevi
Chief Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.



CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-176419, 333-183976, 333-201326 and 333-208865) and on Form F-3 (333-222332 and 333-229021) of BioLineRx Ltd., of our report dated March 25, 2019, relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 20-F.

Tel-Aviv, Israel
March 28, 2019

Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

*Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel,
P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax: +972 -3- 7954556, www.pwc.com/il*
