## **UNITED STATES**

#### SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

## FORM 20-F/A

Amendment No. 2

(Mark One)

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

OR

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

For the fiscal year ended December 31, 2014

OR

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

OR

0 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)

Modi'in Technology Park 2 HaMa'ayan Street Modi'in 7177871, Israel (Address of principal executive offices)

Philip Serlin +972 (2) 548-9100 +972 (2) 548-9101 (facsimile) phils@biolinerx.com Modi'in Technology Park 2 HaMa'ayan Street Modi'in 7177871, Israel (Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person) Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class American Depositary Shares, each representing 10 ordinary shares, par value NIS 0.01 per share

Ordinary shares, par value NIS 0.01 per share

\*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.

<u>None</u> (Title of Class)

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

<u>None</u> (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. 391,150,507

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

Yes o No x

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 o No x

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.

Name of each exchange on which registered Nasdaq Capital Market

Nasdaq Capital Market\*

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 x No o

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). N/A

#### Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o	Non-accelerated filer x
Indicate by check mark which basis of accounting the	registrant has used to prepare the fin	ancial statements included in this filing:

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

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

o Item 17 o Item 18

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 o No x

#### (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 o No o

#### EXPLANATORY NOTE

This Amendment No. 2 (the "Amendment") amends our Annual Report on Form 20-F for the year ended December 31, 2014 (the "Annual Report"), as filed with the U.S. Securities and Exchange Commission (the "Commission") on March 23, 2015 (the "Original Filing Date"). This Amendment No. 2 is being filed solely to amend Exhibit 4.39 (the "Exhibit") originally filed with the Annual Report. The Registrant had previously submitted a request for confidential treatment to the Commission concerning this exhibit, and the final redacted agreement has been included in this Amendment.

The Exhibit filed herewith supersedes in its entirety the Exhibit originally filed with the Annual Report. Other than as expressly set forth above, this amendment does not, and does not purport to amend, restate, or update the information contained in the Annual Report, or reflect any events that have occurred after the Annual Report was filed. As a result, our Annual Report, as amended hereby, continues to speak as of the Original Filing Date of our Annual Report. Additionally, in connection with the filing of this Amendment No. 2, the Company is including new certifications of the Company's chief executive officer and chief financial officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act. The Company is not including certifications pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C.1350) as no financial statements are being filed with this Amendment No. 2.

### **ITEM 19. EXHIBITS**

Exhibit	Description

Exhibit Number	Exhibit Description
2.1 <sup>(5)</sup>	Articles of Association of the Registrant, as amended May 15, 2012.
2.2 <sup>(2)</sup>	Form of Deposit Agreement dated as of July 21, 2011 among BioLineRx, Ltd., The Bank of New York Mellon, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder.
2.3(2)	Form of American Depositary Receipt; the Form is Exhibit A of the Form of Depositary Agreement.
4.3 <sup>(1)</sup>	Employment Agreement with Kinneret Savitsky, Ph.D., dated October 13, 2004.
4.5 <sup>(1)</sup>	Employment Agreement with Philip Serlin, dated May 24, 2009.
4.6†(1)	License Agreement entered into as of January 10, 2005, by and between BioLine Innovations Jerusalem L.P. and B.G. Negev Technologies and Applications Ltd.
4.7 <sup>(1)</sup>	Assignment Agreement dated as of January 1, 2009 entered into by and between BioLine Innovations Jerusalem L.P. and BioLineRx Ltd.
4.16† <sup>(1)</sup>	License Agreement between Innovative Pharmaceutical Concepts, Inc. and BioLineRx Ltd. dated November 25, 2007.
4.17†(11)	Amended and Restated License and Commercialization Agreement by and among Ikaria Development Subsidiary One LLC and BioLineRx Ltd. and BioLine Innovations Jerusalem L.P. dated August 26, 2009, as amended and supplemented.
4.18 <sup>(10)</sup>	BioLineRx Ltd. Amended and Restated 2003 Share Incentive Plan.
4.19 <sup>(1)</sup>	Lease Agreement between Kaps-Pharma Ltd. and BioLine Innovations Jerusalem L.P., dated July 10, 2005, and Extension to Lease Agreement, dated December 4, 2008.
4.20 <sup>(1)</sup>	Amendment to Employment Agreement with Kinneret Savitsky, Ph.D., dated January 2, 2004.
<b>1</b> .21 <sup>(1)</sup>	Employment Agreement with Leah Klapper, Ph.D., dated January 27, 2005.
<b>4.28</b> <sup>(1)</sup>	Sponsored Research Agreement entered into as of June 23, 2011 by and between Yissum Research Development Company of the H University of Jerusalem Ltd. and BioLineRx Ltd.
4.29 <sup>(1)</sup>	License Agreement entered into as of June 23, 2011 by and between Yissum Research Development Company of the Hebrew Univ Jerusalem Ltd. and BioLineRx Ltd.
4.30 <sup>(4)</sup>	Employment Agreement with David Malek, dated August 8, 2011
4.31 <sup>(3)</sup>	Form of Warrant to purchase American Depositary Shares
.32 <sup>(7)</sup>	Form of Warrant to purchase American Depositary Shares
4.33† <sup>(8)</sup>	License Agreement entered into as of September 2, 2012 by and between BioLineRx Ltd. and Biokine Therapeutics Ltd.
4.34 <sup>(10)</sup>	Consulting Agreement with Arnon Aharon, M.D., dated January 1, 2014

Exhibit Number	Exhibit Description	
4.35 <sup>(10)</sup> †	License Agreement entered into as of February 15, 2011 by Valorisation-Recherche, Limited Partnership, and BioLineRx Ltd.	
4.36 <sup>(9)</sup>	Executive Compensation Plan	
4.37 <sup>(11)</sup>	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 December 9, 2014 (English summary of the Hebrew original)	
4.38†(11)	Investment and Collaboration Agreement entered into as of December 16, 2014 between Novartis Pharma AG and the Registrant	
4.39†	License Agreement by and between the Registrant and Wartner Europe BV dated as of December 22, 2014	
8.1(1)	List of subsidiaries of the Registrant.	
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 <sup>(11)</sup>	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 <sup>(11)</sup>	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	
15.1 <sup>(3)</sup>	Form of Purchase Agreement between BioLineRx Ltd. and the Purchasers named therein, dated February 15, 2012	
15.4 <sup>(7)</sup>	Subscription Agreement between BioLineRx Ltd. and OrbiMed Israel Partners Limited Partnership, dated February 6, 2013	
15.5 <sup>(11)</sup>	Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Registrant.	
15.6 <sup>(6)</sup>	Purchase Agreement between BioLineRx Ltd. and Lincoln Park, LLC, dated May 28, 2014	
15.7(6)	Registration Rights Agreement between BioLineRx Ltd. and Lincoln Park, LLC, dated May 28, 2014	

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

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

<sup>(2)</sup> Incorporated by reference to Exhibit 1 of the Registration Statement on Form F-6 (No. 333-175360) filed by the Bank of New York Mellon with respect to the Registrant's American Depositary Receipts.

<sup>3</sup> 

- (3) Incorporated by reference to the Registrant's Form 6-K filed on February 15, 2012.
- (4) Incorporated by reference to the Registrant's Registration Statement on Form F-1 (No. 333-179792) filed on February 29, 2012.
- (5) Incorporated by reference to the Registrant's Registration Statement on Form S-8 (No. 333-183976) filed on September 19, 2012.
- (6) Incorporated by reference to the Registrant's Form 6-K filed on May 30, 2014.
- (7) Incorporated by reference to the Registrant's Form 6-K filed on February 6, 2013.
- (8) Incorporated by reference to the Registrant's Form 6-K filed on October 16, 2012.
- (9) Incorporated by reference to the Registrant's Form 6-K filed on November 13, 2013.
- (10) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 17, 2014.
- (11) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 23, 2015.

## 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/ Kinneret Savitsky

Kinneret Savitsky, Ph.D. Chief Executive Officer

Date: September 22, 2015

# [\*] 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.

#### LICENSE AGREEMENT

This license agreement ("**Agreement**") is entered into as of December 22<sup>nd</sup>, 2014 ("**Effective Date**") by and between **BIOLINERX LTD.**, having its principal place of business at 19 Hartum Street, Jerusalem 9777518, Israel ("**Licensor**"), and **WARTNER EUROPE BV**, on behalf of itself and its Affiliates, having its principal place of business at Kralingseweg 201, 3062 CE Rotterdam, the Netherlands (all such entities to be referred to collectively as "**Licensee**"). Licensor and Licensee may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

#### **Recitals**

Licensor Controls rights in certain intellectual property which is the subject of this Agreement;

Licensee desires to obtain a license from Licensor related to such intellectual property Controlled by Licensor, as set forth in this Agreement; and

Licensor is willing to grant such a license under the terms and conditions of this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants herein contained, the Parties agree as follows:

#### 1. Definitions

- 1.1 "Affiliate" means, with respect to a Party, any person, corporation, partnership or other entity that directly or indirectly controls, is controlled by, or is under common control with such Party. As used in this definition, the term "control" (and, with correlative meaning, the terms "controlled by" and "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity (or such lesser maximum ownership interest percentage permitted by applicable law and considered a control percentage in a particular jurisdiction), or by contract or otherwise.
- 1.2 **"Change of Control**" means, in respect of a Party, the consummation of a single transaction, or of a transaction that is part of a series of transactions, (a) in which a Third Party acquires, merges or consolidates with such Party, or possesses (directly or indirectly) the power to direct or cause the direction of management or policies of such Party through ownership of a majority of securities, partnership, or other ownership rights or agreements; or (b) in which such Party transfers or sells all or substantially all of its assets or business to which this Agreement relates; provided, however, that a transaction in which the stockholders of such Party immediately prior to the transaction own, directly or indirectly, fifty percent (50%) or more of the voting power of the surviving corporation following the transaction shall not be considered a Change of Control.

1.3 **"Confidential Information**" means any and all inventions, ideas, discoveries, data, instructions, designs, information, components, methods, tools, developments, innovations, techniques, materials, technology, protocols, procedures, results, formulae, trade secrets, know-how and other non-public and proprietary materials, products, processes or information, including research, product plans, manufacturing processes, manufacturing or operating costs, services, software, hardware, customer lists, price lists, business plans, marketing plans or financial information, that is or was disclosed or supplied by a Party (the "**Disclosing Party**") to the other Party (the "**Receiving Party**") after the Effective Date in connection with this Agreement.

Notwithstanding the foregoing, Confidential Information shall not include any part of the foregoing that the Receiving Party can demonstrate through competent, contemporaneous written records:

- a. was already known to the Receiving Party, other than any portion of such information that was under an obligation of confidentiality at the time of its disclosure;
- b. Became generally available to the public or otherwise becomes part of the public domain after disclosure of such information to the Receiving Party, other than by breach of this Agreement by the Receiving Party or by anyone to whom the Receiving Party disclosed such information;
- c. was subsequently lawfully, and without any restriction on disclosure, disclosed to the Receiving Party by a Third Party; or
- d. was independently developed or discovered by employees of the Receiving Party who had no access to the Confidential Information of the Disclosing Party and did not make use of the Confidential Information of the Disclosing Party, as demonstrated by competent, contemporaneous written records.
- 1.4 **"Control"** or **"Controlled by"** means, in the context of a license to or ownership of intellectual property, the ability on the part of a Party to grant access to or a license or sublicense of such intellectual property as provided for herein without violating the terms of any agreement or other arrangement between such Party and any Third Party existing at the time such Party would be required hereunder to grant such access or license or sublicense.
- 1.5 **"Field of Use"** means all over-the-counter (**"OTC**") therapeutic applications in any diseases in humans and animals.
- 1.6 "First Sale" means the first commercial sale of a Licensed Product unit by Licensee or one of its Sublicensees.

- 1.6 **"Inventions**" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by Licensee or its Sublicensees, or any of their respective personnel, in the course of use, practice and/or exploitation of the license rights granted to Licensee under this Agreement.
- 1.7 **"Licensed Patents**" means the issued patents ("**Issued Patents**") and pending patent applications ("**Pending Patent Applications**") in the Territory (a) Controlled by Licensor; (b) that are filed prior to the Effective Date; and (c) that are necessary or useful for Licensee's research, development, manufacturing, or commercialization activities relating to Licensed Products in the Field of Use. The Licensed Patents existing in the Territory as of the Effective Date are set forth in **Schedule A**, attached hereto and incorporated herein by reference. The term "Licensed Patents" will include any and all related domestic and foreign counterparts, divisions, continuations, continuations-in-part, reissues, reexaminations, substitutes and extensions thereof in the Territory that are Controlled by Licensor and rely on the priority date of an Issued Patent or a Pending Patent Application.
- 1.8 **"Licensed Product**" means a BL-5010 applicator or formulation or their combination (a) wherein the use or practice of such product would, but for the license granted herein, infringe a Valid Claim within the Licensed Patents, or (b) that uses, comprises, contains or incorporates Licensed Technology.
- 1.9 **"Licensed Technology**" means data, results, technology, and information of any type whatsoever, in any tangible or intangible form, that is disclosed by Licensor and is necessary or useful for research, development, regulatory or clinical activities, manufacture, commercialization or other use or exploitation of Licensed Product in the Field of Use in accordance with the terms of this Agreement, including (but not limited to) know-how, trade secrets, practices, techniques, methods, devices, instruments, designs, systems, materials, strategies and expertise, test data and other technical data. The term "Licensed Technology" expressly excludes Licensed Patents.
- 1.10 "**New IP**" means any and all new intellectual property rights (a) arising in the course of use, practice and/or exploitation of the license rights granted to Licensee under this Agreement (including but not limited to information, know-how, data, designs, methods, processes, techniques, materials, formulae, trade secrets, trademarks, copyrights, patents and patent applications and other proprietary information), (b) identified, developed, generated or obtained by Licensee or its Sublicensees, and (c) related to Licensed Patents, Licensed Technology or Licensed Products. For the avoidance of doubt, it is hereby clarified that "New IP" does not include Trademarks as defined in Section 1.14 and that the Trademarks and trade dress of Licensee, related copyrightable material, domain names, used on and/or in connection with any of the Licensed Products whether used on Products, packaging, labeling, advertising, sales promotion materials, or otherwise are and shall remain the ownership of Licensee.
- 1.11 **"Sublicense**" means any right granted, license given, or agreement entered into, by Licensee to or with any other person or entity, under or with respect to or permitting any use or exploitation of any Licensed Patent or any of the Licensed Technology (or any part thereof) or otherwise permitting the development, manufacture, marketing, distribution and/or sale of Licensed Products.

- 1.12 "Sublicensee" means a person or entity granted a Sublicense in accordance with Section 2.2. For the avoidance of doubt, an Affiliate of Licensee is not considered to be a Sublicensee.
- 1.13 "Territory" means the countries listed in Schedule B, attached hereto and incorporated herein by reference.
- 1.14 "Trademark" means any trademark or brand created by Licensee and used in connection with the Licensed Product.
- 1.15 **"Third Party**" shall mean any person or entity other than the Parties or their Affiliates.
- 1.16 **"Upstream License Agreement**" shall mean that certain License Agreement dated November 25, 2007 between the Upstream Licensor and BioLine, including its amendments/addendums thereto (if any), as it may be amended from time to time.
- 1.17 "**Upstream Licensor**" shall mean Innovative Pharmaceutical Concepts (IPC) Inc., having a place of business at Geneva Place, 2<sup>nd</sup> Floor, Waterfront Drive, PO Box 3339, Road Town, Tortola, British Virgin Islands.
- 1.18 **"Valid Claim**" means (a) a claim of an Issued Patent that is not expired, which has not been held unpatentable, invalid or unenforceable by a court or other government agency of competent jurisdiction and has not been disclaimed or admitted to be invalid or unenforceable through reissue, reexamination or otherwise, or (b) a claim of a Pending Patent Application that has not been abandoned, finally rejected, or expired.

#### 2. Grant

- 2.1 During the Term, and subject to the terms of this Agreement, Licensor hereby grants to Licensee an exclusive license, with the right to Sublicense (subject to the conditions in Section 2.2), under the Licensed Patents and Licensed Technology to make, use, sell, offer to sell, import and otherwise exploit Licensed Products within the Field of Use in the Territory.
- 2.2 Sublicenses.
  - a. Subject to the terms and conditions of this Section 2.2, Licensee shall be entitled to grant Sublicenses to third parties under the license granted to Licensee pursuant to Section 2.1. All such Sublicenses shall be made for consideration and in arm's length transactions.
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b. Sublicenses to Sublicensees shall only be granted pursuant to written agreements. Licensee shall provide Licensor with a copy of each Sublicense agreement within twenty (20) days of receipt of an executed agreement from the Sublicensee. Each such Sublicense agreement shall contain, *inter alia*, provisions to the following effect:

(i) All provisions necessary to ensure Licensee's compliance with its obligations under this Agreement, including reporting and audit requirements;

(ii) In the event of termination of the license granted to Licensee under this Agreement and if no new agreement is entered into between Licensee and the Upstream Licensor, any existing Sublicense agreements that contain a Sublicense of Licensed Patents or Licensed Technology shall terminate to the extent of such Sublicense; and

(iii) Licensee must obtain Licensor's prior written approval for any proposed further sublicensing by the Sublicensee of the Sublicense granted to such Sublicensee (not to be unreasonably withheld). If Licensor approves any such further Sublicense grant, the corresponding Sublicense agreement shall be subject to execution of a written agreement consistent with the terms of this Section 2.2, and shall be made for consideration and in arm's length transactions. For clarity, if a Sublicensee has been granted commercialization rights in a Core Country (as defined in subsection (c) below) with Licensor's approval, such Sublicensee may not further sublicense any of those commercialization rights in a Core Country without Licensor's prior written approval.

- c. The Parties will mutually agree upon countries within the Territory where Licensee is required to commercialize Licensed Products itself or through its Affiliates (and only through a Sublicensee with the prior written approval of Licensor). Such countries are or will be listed in Schedule C, attached hereto and incorporated herein by reference (each a "Core Country"), which schedule may be amended from time to time by written mutual agreement of the Parties. For the grant of a Sublicense by Licensee that does not involve the right to commercialize Licensed Product(s) in a Core Country, or that involves a Sublicense grant in a country in the Territory that is not a Core Country, Licensee is not required to obtain Licensor's prior written approval for Licensee's grant of this type of Sublicense; however, in each case of a granted Sublicense agreement within twenty (20) days after execution; provided that, if the granted Sublicense is a portion of a broader license or sublicense agreement. Licensee may redact the portions of the broader agreement that do not pertain to a Sublicense under this Agreement. Licensee may not redact the effective date of the Sublicense agreement or the name and address of the Sublicensee.
- d. Any permitted Sublicense granted by Licensee (or granted by a Sublicensee in accordance with this Section 2.2) will:

(i) incorporate terms and conditions into the corresponding Sublicense agreement sufficient to enable Licensee and each Sublicensee to comply with this Agreement;

(ii) be consistent with the terms, conditions and limitations of this Agreement that are applicable to such Sublicensee (including, without limitation, diligence obligations with respect to Licensed Products),

- (iii) contain a prohibition against Sublicensee commercializing [\*] that could be competitive with Licensed Products; and
- (iv) terminate on termination of this Agreement.
- 2.3 Notwithstanding anything to the contrary in this Agreement, if a Sublicense granted by Licensee is terminated due to termination of this Agreement and a Sublicensee of Licensee is in compliance in all material respects with the terms of its Sublicense from Licensee in effect on the date of termination of this Agreement, Licensor will negotiate in good faith a grant directly to the Sublicensee of a substantially similar Sublicense under the Licensed Patents and Licensed Technology as compared to the Sublicense agreement executed by Licensee and such Sublicensee.
- 2.4 Licensor reserves all rights not expressly licensed or granted to Licensee hereunder, and nothing in this Agreement entitles Licensee to use any intellectual property of Licensor other than the Licensed Patents and Licensed Technology to exploit Licensed Products (for clarity, Licensed Products include filled BL-5010 applicators; BL-5010 formulations alone (without BL-5010 applicators); and the combination of BL-5010 applicators and BL-5010 formulations, (but expressly exclude unfilled BL-5010 applicators) in the Field of Use in the Territory. Without Licensor's written approval, Licensee is not permitted to use or reference the name or trade names of Licensor in connection with Licensee's promotion, practice or use of the Licensed Products, Licensed Patents or Licensed Technology.
- 2.5 During the first two months following the Effective Date, Licensor shall transfer to Licensee the information comprising Licensed Technology at no charge to Licensee. Thereafter, Licensor will provide technical support to Licensee in connection with the Licensed Patents and/or Licensed Technology, including but not limited to assistance in clinical development and regulatory matters, under terms and conditions to be separately negotiated by the Parties in writing.
- 2.6 A copy of the Upstream License Agreement (with financial terms redacted) has been provided to Licensee prior to the Effective Date. In the event that the Upstream License Agreement is terminated, then pursuant to Section 2.2.2.2 of the Upstream License Agreement, Licensee (as a sublicensee of the Upstream Licensor) has the right to request from the Upstream Licensor a new license agreement between Licensee and the Upstream Licensor. In such case, Licensor shall, at Licensee's request, provide all reasonable assistance to Licensee in Licensee's efforts to enter into a license agreement with the Upstream Licensor on substantially the same terms as those contained in this Agreement, including through enforcement of the provisions of Section 2.2.2.2 of the Upstream License Agreement.

#### 2A. Joint Steering Committee

- 2A.1 Within 30 days after the Effective Date, the Parties will establish a joint steering committee (the "Joint Steering Committee" or "JSC") to oversee and coordinate the Parties' activities under this Agreement with respect to development, pre-commercialization, commercialization and manufacture activities with respect to the Licensed Products in the Field of Use in the Territory. The JSC shall also be a forum for the exchange of information regarding the Parties' performance of their respective obligations under the applicable development and commercialization plans. The JSC shall facilitate, coordinate, support and oversee the Parties' cooperative efforts in order to achieve the mutually desired objective of speed, efficiency and coordination regarding the Parties' research, development, manufacturing and commercialization activities hereunder. Each Party's JSC members shall disclose to the other Party's JSC members all significant issues and decisions related to the research, development, manufacturing and commercialization of the Licensed Product in or for the Territory. To avoid doubt, the Parties acknowledge that the JSC is intended to be an advisory body only.
- 2A.2 Without limiting the foregoing, Licensee's JSC members shall (i) provide Licensor's JSC members with periodic reports concerning all material activities undertaken in respect of Licensee's exercise of the manufacturing rights granted to Licensee under this Agreement, (ii) at Licensor's request, from time to time, provide Licensor's JSC members with further information relating to Licensee's activities in exercise of the manufacturing rights granted to Licensee's activities in exercise of the manufacturing rights granted to Licensee's activities in exercise of the manufacturing rights granted to Licensee under this Agreement and (iii) provide Licensor's JSC members with periodic reports concerning all material activities undertaken in respect of Licensee's development, pre-commercialization and commercialization activities of Licensed Product. During the period between the Effective Date and the date of the First Sale, Licensee's JSC members shall provide the reports specified in (i) and (iii) above not less than once every three months; thereafter, the reports shall be provided not less than once every six months.
- 2A.3 Each Party shall initially appoint two representatives to the JSC, each of whom will have sufficient seniority and expertise within the applicable Party to make decisions arising with the scope of the JSC's responsibilities. The JSC may change its size from time to time by mutual consent of the Parties. Each Party may replace its JSC representatives at any time upon written notice to the other Party. The JSC may invite non-members to participate in the discussions and meetings of the JSC where appropriate (and subject to such individuals being subject to mutually acceptable binders of confidentiality), provided that such participants shall have no voting authority at the JSC. The JSC shall have a chairperson who shall be selected by Licensor. The role of the chairperson shall be to convene and preside at meetings of the JSC and to ensure the preparation of minutes, but the chairperson shall otherwise have no additional powers or rights beyond those held by the other JSC representatives.
- 2A.4 The JSC shall meet at least quarterly during the Term unless the Parties mutually agree in writing to a different frequency for such meetings; provided that during the period between the Effective Date and the date of the First Sale, there should be face-to-face in-person meetings at least twice per year at a location and time agreed by the Parties and thereafter, there should be such a meeting at least once per year. No later than 15 days prior to any regularly scheduled meeting of the JSC, the chairperson of the JSC shall prepare and circulate an agenda for such meeting and, as soon as practicable, materials for the meeting; provided, however, that either Party may propose additional topics to be included on such agenda prior to such meeting. The JSC may meet in person, by videoconference or by teleconference. Each Party will bear the expense of its respective JSC members' participation in JSC meetings. Meetings of the JSC shall be effective only if at least one representative of each Party is present or participating in such meeting. The chairperson of the JSC will be responsible for preparing reasonably detailed written minutes in English of all JSC meetings that reflect, without limitation, material decisions made at such meetings. The JSC chairperson shall send draft meeting minutes to each member of the JSC for review within 15 days after each JSC meeting. The members of the Committee shall have 15 days to provide comments. The JSC chairperson shall incorporate timely received comments and distribute revised minutes to all members of the JSC.



#### 3. Consideration for Licensed Products [\*]

- 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 [\*].
  - 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 [\*].
  - c. For the purpose of this Agreement:
    - (i) "Licensed Product unit sold" means each Licensed Product that is invoiced by Licensee and its Sublicensees for a value higher than zero and that has not been returned to and credited by Licensee and/or its Sublicensees.
    - (ii) [\*]
    - (iii) [\*]
- 3.2 [\*]
- 3.3 [\*]
- 3.4 Within twenty-five (25) days of the end of each calendar quarter, Licensee shall deliver to Licensor a report summarizing the previous calendar quarter's Licensed Product units sold together with a calculation of the payments due pursuant to Section 3.1 (the "**Report**"). Upon the basis of the Report, Licensor shall issue an invoice to Licensee for the payments due for the previous calendar quarter. Such invoice will be in EUR and will be paid by Licensee no later than the end of the calendar month following the month in which such invoice is issued. [\*] Licensor reserves the right to inspect Licensee's written records supporting such Reports or payments delivered as part of an examination performed in accordance with Section 4.1 below.

#### 3.5 [\*]

- 3.6 Licensee will pay to Licensor interest on late payments computed at the rate of one percent (1%) per month, or the maximum interest rate permitted by applicable law, whichever is less, on each overdue, unpaid amount, in each calendar month that such payment is overdue.
- 3.7 For purposes of this Agreement, the word "Tax(es)" means any tax (other than income tax), duty, tariff or other governmental charge levied on the sale of a Licensed Product, including consumption tax. If any payment required to be made by Licensee to Licensor hereunder is subject to a deduction of Tax or withholding Tax, then, subject to the second paragraph of this Section 3.7, the sum payable by Licensee (in respect of which such deduction or withholding is required to be made) shall be made to Licensor after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted in accordance with applicable laws. In all events, it is acknowledged that Licensee may deduct and withhold the required Taxes from payments due to Licensor in the event of any changes in Tax law, administrative interpretations or treaties that may change current rules as applicable to such payments or as a consequence of a tax audit imposing such deduction of Tax or withholding Tax on Licensee, subject to providing Licensor with at least sixty (60) days' advance notification of the intention to withhold such Taxes and giving Licensor an opportunity to provide a written Tax opinion or other form of evidence that such Taxes should not be withheld, which will be given reasonable consideration by Licensee; and subject further, in the case of an audit, to providing Licensor with reasonably sufficient notice of the intention of a taxing authority to carry out an audit in order that Licensor may participate in any negotiations with such authority and otherwise be permitted to influence the amount of the withholding, if any, and the payment terms.

The Parties shall use all reasonable and legal efforts to reduce or eliminate Tax withholding or similar obligations in respect of all payments made by Licensee to Licensor under this Agreement. To the extent Licensee is required to deduct and withhold taxes on any payment to Licensor, Licensee shall pay the amounts of such Taxes to the proper Governmental Authority in a timely manner and promptly transmit to Licensor an official Tax certificate or other documentation of the payment of any such withholding Taxes, including copies of receipts or other evidence reasonably required and sufficient to enable Licensor to document such tax withholdings adequately for purposes of claiming foreign tax credits and similar benefits. Licensor shall provide Licensee any Tax forms that may be reasonably necessary in order for Licensee to not withhold tax or to withhold Tax at a reduced rate under an applicable bilateral income Tax treaty. Licensor desires that Licensee apply a reduced withholding rate. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable law, of withholding Taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding Tax or value added Tax. Licensee shall require its Sublicensees to cooperate with Licensee in a manner consistent with this Section 3.7.

3.8 To the extent legally enforceable, and as additional consideration for the exclusive license granted in Section 2.1, Licensee hereby agrees, during the Term, that if the validity, enforceability or patentability of any of the Licensed Patents is challenged by Licensee or any of its Sublicensees, and such challenge is not discontinued within thirty (30) days after initiation, Licensor reserves the right to immediately terminate this Agreement upon delivery of written notice of termination to Licensee.

#### 4. Records

4.1 Licensee will keep accurate books of account and records pertaining to all payment reports and payments due to Licensor under this Agreement ("Records"). Upon Licensor's written request, but not more frequently than once per calendar year, an independent accounting firm retained by Licensor, at Licensor's expense, will have the right during Licensee's normal business hours to examine such Records in the possession and under the control of Licensee. Such independent accounting firm may be required to execute a confidential disclosure agreement with Licensee. Such examination of Records will be conducted with at least twenty-one (21) days' prior written notice to Licensee (provided that the examination of Records shall never take place during the first calendar month following the end of a calendar quarter), for the sole purpose of and only to the extent necessary to verify such payment reports and payments required under this Agreement. Licensor has the right to examine Records that were created within five (5) years of the date of Licensor's request. Licensee will keep its Records in such a manner as to facilitate such examination. In the event that such independent accounting firm discovers any inconsistencies, mistakes, under-reporting or under-payment in such Records, a copy of the independent accounting firm's written report will be delivered to Licensee. Licensee will pay to Licensor, within thirty (30) days of Licensee's receipt of such written report, all such undisputed amounts overdue and unpaid, and Licensor will promptly grant a credit or refund to Licensee in the case of any overpayment. If it is determined that there is a deficiency of five percent (5%) or more in the payments actually paid to Licensor versus the amount of payments owed to Licensor in any given calendar quarter, then Licensee will bear all reasonable expenses related to such examination by Licensor's accounting firm. Licensee will conduct an examination of its Sublicensees' payment reports upon Licensor's reasonable written request, but not more frequently than once per calendar year for any given Sublicensees, which Licensor request shall identify the Sublicensee to be audited by Licensee.

4.2 All such Records pertaining to Reports and payments due to Licensor under this Agreement will be kept available for at least five (5) years after the calendar year to which they relate, and Licensor's right under this Agreement to examine such Records in accordance with Section 4.1 and this Section 4.2 will survive the expiration or termination of this Agreement.

#### 5. Patents and Trademarks.

- 5.1 Prosecution and Enforcement of Licensed Patents; Inventions and New IP.
  - As between the Parties, Licensor will have the sole right, at its sole expense, to prepare, file, prosecute and maintain all Pending Patent Applications and Issued Patents within the Licensed Patents. For preparation, filing, prosecution and maintenance costs incurred for Pending Patent Applications and Issued Patents in the countries of the Territory listed in Schedule D from and after the Effective Date ("Territory Patent Costs"), Licensee will reimburse such Territory Patent Costs within forty-five (45) days after receipt of invoice from Licensor, it being understood that the total Territory Patent Costs (not including the renewal fees) to be reimbursed by the Licensee during the Term shall be limited to a maximum of EUR [\*] and any Territory Patent Costs (other than renewal fees) exceeding the EUR [\*] shall be for the account of Licensor. For the avoidance of doubt, the maximum payment set forth above does not apply to renewal fees, if any, and the responsibility of Licensee for renewal fees shall continue until earlier of the expiration of the patent or the termination or expiration of this Agreement. [\*]
  - b. During the Term, Licensor will have the sole right, at its sole expense, to determine the appropriate course of action against any third parties infringing any Licensed Patents in the Field of Use in the Territory. All of the proceeds of any such enforcement action will be retained by Licensor. At Licensor's request and expense, Licensee shall reasonably cooperate with Licensor during the Term in connection with any enforcement action brought under this Section 5.1(b), and in particular, agrees to be joined as a party plaintiff, at Licensor's expense, if any such joinder is needed for Licensor to bring or continue an infringement action hereunder.
  - c. Licensor shall own all Inventions, and Licensee will cooperate, and cause its Sublicensees to cooperate, to ensure that all Inventions are assigned to Licensor. Any and all other new intellectual property rights (a) arising in the course of use, practice and/or exploitation of the license rights granted to Licensee under this Agreement (including but not limited to information, know-how, data, designs, methods, processes, techniques, materials, formulae, trade secrets, patents and patent applications and other proprietary information), (b) identified, developed, generated or obtained by Licensee or its Sublicensees, and (c) related to Licensee Patents, Licensed Technology or Licensed Products (collectively, (a-c) are referred to as "**New IP**") shall be owned by and assigned to Licensor. All Inventions and all New IP will be included automatically within Licensed Patents or Licensed Technology (as applicable) and included in the license granted to Licensee under Section 2.1.

- 5.2 Upon execution of this Agreement, Licensee will reimburse Licensor for past intellectual property costs associated with the Licensed Product incurred to date in the amount of [\*].
- 5.3 a. All Trademarks will be owned and maintained by Licensee, at its own expense. Licensee has the right to decide which Trademarks and artwork will be used for the Licensed Products.
  - b. Licensor acknowledges Licensee's rights to the artworks of the Licensed Products and the Trademarks affixed to the Licensed Products and all (other) intellectual property rights (including but not limited to copyrights and design rights) regarding the sale, marketing and distribution of the Licensed Products in the Territory. Licensor acknowledges that none of Licensee's rights in the artworks of the Licensed Products and the Trademarks affixed to the Licensed Products belong to Licensor. Licensee retains the right to use the Trademarks and the artwork during the term of this Agreement and after termination of this Agreement for whatever product it chooses, it being understood that Licensee's right to use the Trademarks and the artwork in connection with Licensor's applicator shall end upon the exhaustion of the remaining inventory as provided in Section 13.1.
  - c. During and after termination of the Agreement, Licensor shall not use any trademark, trade name and/or artworks similar to the Licensee's artworks of the Licensed Products and the Trademarks affixed to the Licensed Products in respect of any product and shall not register or procure the registration of any trademark similar to the Trademarks for any class of goods in any country of the world.
  - d. Licensee shall be entitled to conduct all proceedings relating to its intellectual property and shall at its sole discretion decide what action, if any, to take in respect of any infringement, enforcement or alleged infringement of such intellectual property or any other claim or counter-claim brought or threatened in respect of the use, prosecution or registration of the Licensee's intellectual property. Any such proceedings shall be conducted at Licensee's expense and for its own benefit.
  - e. Licensee is entitled to use its own name, the logo as described in Schedule E (the "**Omega Pharma Logo**"), variants of the Omega Pharma Logo or any other logo with a reasonable size on the Products. All such logos shall at all times remain the sole property of Omega Pharma NV, during and after expiry of this Agreement. Licensee shall be entitled to conduct all proceedings relating to the abovementioned logos and shall at its sole discretion decide what action, if any, to take in respect of any infringement, enforcement or alleged infringement of the abovementioned logos or any other claim or counter-claim brought or threatened in respect of the use, prosecution or registration of the abovementioned logos. Any such proceedings shall be conducted at Licensee's expense and for its own benefit.
  - f. On the termination of this Agreement for any reason, Licensor shall, to the extent applicable, immediately cease to use in any way any logo of Licensee.

#### 6. Manufacturing

- 6.1 a. Licensee will make all necessary efforts to launch a Licensed Product commercially in the Territory in 2016, including an obligation of Licensee to have secured sufficient Licensed Product supply to support such commercial launch. [\*]
  - b. If Licensee fails to launch a Licensed Product commercially in the Territory within the timing specified above and such failure is attributable to Licensee, Licensor shall have the right to terminate this Agreement. Licensee shall cause its agreement with any Third Party for the manufacture of Licensed Product to provide that in such event, (a) Licensor will have the right to request from such Third Party a new agreement for manufacturing services on terms at least as favorable as those set forth in Licensee's agreement for comparable volumes, and (b) the ownership of manufacturing equipment owned by Licensee (e.g., molds) shall be transferred to Licensor. The Parties agree that the remedies provided for in this Section shall be the only remedies for failure to launch a Licensed Product commercially in the Territory within the timing specified above. Licensor agrees that it cannot and shall not claim compensation of whatever kind if Licensee has not launched a Licensed Product commercially in the Territory during the timing specified above.

C. [\*]

6.2 Licensor will be provided full access to all know-how and information Controlled by Licensee and related to Licensed Product commercial manufacturing activities and technologies, including but not limited to the know-how and information needed to establish the relevant manufacturing facilities ("**Manufacturing Information**"). Without limiting the foregoing, Licensor may use such Manufacturing Information in connection with engagement of a contract manufacturing organization to produce Licensed Product for Licensor, such that Licensor (and/or its other licensees) are able to commercialize Licensed Product (a) in all fields in countries not included in the Territory, and (b) outside the Field of Use throughout the world (including, but not limited to, in the Territory). In order to carry out its obligations pursuant to this Section, Licensee will ensure that its agreements with Third Parties provide for access to such Third Parties' Manufacturing Information both during the term of any agreements with such Third Parties and thereafter (by means of escrow agreements or arrangements with a similar purpose). Upon Licensor's request, Licensee shall provide Licensor with a copy of each supply agreement with a Third Party.

#### 7. Development and Commercialization in the Territory; Diligence

7.1 During the Term, and provided that Licensee is not in material breach of the terms of this Agreement (and in particular, not in breach of Licensee's development, manufacturing investment and diligence obligations), Licensee will be the sponsor and legal manufacturer of Licensed Products in the Territory. Licensee is obligated to undertake, and to fully fund, the development activities that are required to obtain regulatory approval for Licensed Products throughout the Territory.

- 7.2 a. During the Term, Licensee will use its diligent and commercially reasonable best efforts to develop and obtain regulatory approval for at least one Licensed Product, for at least two OTC indications [\*], in the Field of Use in the Territory. If Licensee wishes to change either of such indications, it must obtain Licensor's prior written approval to do so. [\*]
  - b. In the event that any delays, which are not attributable to Licensee, prohibit Licensee to obtain the regulatory approval within the timing specified above, the Parties agree to negotiate an extension of the timing in good faith, provided that there may be only one such extension of not more than two calendar quarters.
  - c. If Licensee fails to obtain any of the regulatory approvals within the timing specified above and such failure is attributable to Licensee, Licensor shall have the right to terminate this Agreement. Licensee shall cause its agreement with any Third Party for the manufacture of Licensed Product to provide that in such event, Licensor will have the right to request from such Third Party a new agreement for manufacturing services on terms at least as favorable as those set forth in Licensee's agreement for comparable volumes. The Parties agree that the remedies provided for in this Section shall be the only remedies for failure to obtain any of the regulatory approvals within the timing specified above. Licensor agrees that it cannot and shall not claim compensation of whatever kind if Licensee has not obtained any of the regulatory approvals during the timing specified above.
- 7.3 During the Term, Licensee will use its diligent and commercially reasonable best efforts to commercialize at least one Licensed Product, for the same two OTC indications described in Section 7.2, in the Field of Use in the Territory. [\*] Upon regulatory approval for each Licensed Product, Licensee will use its diligent and commercially reasonable best efforts, and will cause its Sublicensees to use their diligent and commercially reasonable best efforts, to promote, market and sell such Licensed Product throughout the Territory. [\*]
- 7.4 Licensee shall prepare marketing plans for the Territory (the "Licensee Marketing Plans"), which shall include plans related to the pre-launch, launch, promotion and commercialization activities pertaining to each Licensed Product in the Territory. Licensee shall share with Licensor the Licensee pre-marketing and Marketing Plans on a regular basis. During the period between the Effective Date and the date of the First Sale, Licensee shall provide such Plans not less than once every six months; thereafter, the reports shall be provided not less than once per year. In addition, Licensee shall keep Licensor informed, upon reasonable request by Licensor, with respect to commercialization of the Licensed Products in the Territory. Licensee shall have full control and authority over of the day-to-day commercialization of the Licensed Products in the Territory and implementation of the corresponding Marketing Plans, at Licensee's sole expense.

- 7.5 For purposes of harmonization and coordination of global commercialization of the Licensed Products, each Party shall keep the other Party informed regarding the preparation of promotional materials, samples, advertising and materials for training sales representatives with respect to commercialization of the Licensed Products. Upon reasonable request of a Party, the other Party shall provide copies of such Product-related written materials. Licensee shall have sole responsibility for the Licensed Product marketing materials used in the Territory. Each Party shall preserve the confidentiality of information and materials exchanged.
- 7.5 The copyright in any advertising material (including commercials) and literature acquired or designed by or coming into the possession of Licensee and designed, written or produced specifically for the purpose of the promotion of sales of the Licensed Products shall be the sole and exclusive property of Licensee, unless specifically paid for by Licensor and agreed between the Parties that the material is the property of Licensor.

#### 8. Data Access and Sharing

- 8.1 Licensor will have full access, at no cost to Licensor, to all clinical and research and development data generated during Licensee's performance of its development plan for Licensed Product ("Licensee Data"). Licensor may use these Licensee Data in connection with development and/or licensing of Licensed Product in territories outside the Territory, and in fields outside of the Field of Use. Licensee Data also may be requested or used by Licensor to fulfill Licensor's obligations to the Upstream Licensor.
- 8.2 During the Term, Licensee will have access to any additional clinical and research and development data generated by Licensor following the Effective Date and pertinent to development and/or commercialization of Licensed Products.

#### 9. Confidential Information

9.1 The Parties agree that during the Term, and for a period of five (5) years after this Agreement expires or terminates, the Receiving Party will (a) maintain all Confidential Information of the Disclosing Party in confidence to the same extent the Receiving Party maintains its own confidential or proprietary information or trade secrets of similar kind and value; (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for Licensee's disclosures to its Sublicensees who agree to be bound by obligations of non-disclosure and non-use at least as stringent as those contained in this Article 9; and (c) not use such Confidential Information for any purpose except those purposes permitted by this Agreement. A Party will not knowingly disclose to the other Party any Third Party information or know-how that such Party does not have the legal right to disclose to the other Party and/or which it has a contractual obligation not to disclose to the other Party.

- 9.2 Notwithstanding the foregoing Section 9.1, a Receiving Party may disclose Confidential Information of the Disclosing Party:
  - a. to the extent and to the persons and entities as required by an applicable law, rule, regulation, legal process, court order or the rules (i) of the any securities exchange on which any security issued by either Party is traded or (ii) of a regulatory authority; or
  - b. in the case of Licensor, as necessary to file, prosecute or defend Licensed Patents; or
  - c. to prosecute or defend litigation or otherwise establish rights or enforce obligations under this Agreement, but only to the extent that any disclosure is necessary.

The Receiving Party required or intending to disclose the Disclosing Party's Confidential Information under Section 9.2(a) or (c) shall give advance written notice to the Disclosing Party of such required disclosure, so that the Disclosing Party may seek a protective order or other appropriate remedy or to undertake steps to avoid or limit disclosure. If, in the absence of a protective order or other remedy, or an avoidance of disclosure, the Receiving Party is nonetheless, in the reasonable opinion of Receiving Party's counsel, required to disclose Confidential Information of the Disclosing Party under Section 9.2(a) or (c), the Receiving Party may disclose only that portion of the Confidential Information of the Disclosing Party which such counsel advises in writing is legally required to be disclosed; provided that the Receiving Party shall preserve the confidentiality of such Confidential Information to the fullest extent possible, including, without limitation, by cooperating with the Disclosing Party in its efforts to secure confidential or protective treatment of such Confidential Information.

- 9.3 A Receiving Party may disclose Confidential Information received under this Agreement to existing or potential investors, acquirers, merger partners, collaborators, consultants, contractors, distributors or licensees, or to professional advisors (e.g., attorneys, accountants and investment bankers) involved in such activities, for the limited purpose of evaluating such investment, transaction, or license and under appropriate conditions of confidentiality, only to the extent necessary and with the agreement by these permitted individuals to maintain such Confidential Information in strict confidence.
- 9.4 The Parties have mutually agreed upon the text of a press release announcing the execution of this Agreement. Such press release is attached to this Agreement as Schedule F. Except for such mutually agreed initial press release, neither Party shall (a) originate any publicity, news release or other public announcement, written or oral, whether to the public press, stockholders or otherwise, relating to this Agreement, any amendment hereto or performance hereunder, or (b) use the name of the other Party in any publicity, news release or other public announcement, except (i) with the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed, or (ii) as required by applicable law (including securities laws and regulations), in which case the Party wishing to issue the public disclosure (the "**Initiating Party**") shall submit to the other Party (for review and any proposed modifications, as well as the Parties' coordination, prior to such disclosure or use) each such required disclosure, and shall comply with the terms of this Article 9. In this respect, the other Party will use its good faith and Commercially Reasonable Efforts to provide to the Initiating Party its comments on the proposed public disclosure within forty-eight (48) hours of receipt, and the Initiating Party will reasonably consider the other Party's comments thereon if such comments are received within such forty-eight (48) hour period. Either Party may disclose the existence of this Agreement; however, the terms and conditions of this Agreement shall be deemed to be the Confidential Information of each Party.

#### 10. Representations and Warranties; Indemnification

- 10.1 Each Party hereby represents and warrants to the other Party that, as of the Effective Date:
  - a. it is duly organized and validly existing under the laws of its state of incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
  - b. it is has taken all corporate action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;
  - c. this Agreement is legally binding upon it and enforceable in accordance with its terms; and
  - d. its execution, delivery and performance of this Agreement does not conflict with, constitute a breach of, or in any material way violate any arrangement, understanding or agreement to which it is a party or by which it is bound.
- 10.2 Licensor hereby represents and warrants that: (a) as of the Effective Date, (i) the Upstream License Agreement is in full force and effect; (ii) Licensor has been granted all the licenses and rights under the Upstream License Agreement which are necessary for granting the licenses and right to Licensee hereunder; (iii) Licensor is not in breach with respect to material obligations under the Upstream License Agreement; and (iv) execution and performance of this Agreement shall not constitute breach of any provisions of the Upstream License Agreement; and (b) during the Term, (i) Licensor shall fulfill its obligations under the Upstream License Agreement; (ii) if Licensor seeks any modification, amendment or revision to the Upstream License Agreement, Licensor shall obtain prior written consent of Licensee to the extent such modification, amendment or revision will affect Licensee's license and rights hereunder; and (iii) Licensor shall not terminate the Upstream License Agreement in whole or with respect to the Territory, without prior written consent of Licensee.

Licensor hereby furthermore: (i) warrants that it shall not grant to any Third Party any rights under the Licensed Patents and/or Licensed Technology to make, use, sell, offer to sell, import and otherwise exploit products within the Field of Use in the Territory during the term of the Agreement; and (ii) represents that as of the Effective Date, (a) the Licensed Technology complies with the specifications and characteristics as set forth in the documentation attached as Schedule G; and (b) to its knowledge, the Licensed Technology (as available on the Effective Date) and the Licensed Patents do not infringe any intellectual property rights of a Third Party.

- 10.3 a. Licensee will indemnify, hold harmless, and defend Licensor and its directors, officers, employees, agents, and independent contractors (collectively, the **"Licensor Indemnitees"**) from any and all liability, loss, damage, cost, and expense, including reasonable attorneys' fees and costs (collectively, **"Losses"**) that a Licensor Indemnitee becomes legally obligated to pay because of any Third Party claim or suit to the extent that such claim or suit arises from (a) the use, practice and/or exploitation of the Patents, Licensed Technology or Trademarks by Licensee or its Sublicensees, or by their respective directors, officers, employees, agents, independent contractors, or Sublicensees, (b) the manufacture, use, offer for sale, sale or importation of Licensed Products by or on behalf of Licensee or its Sublicensees, or otherwise in the conduct of Licensee's business, (c) Licensee's breach of its obligations or its representations and warranties under this Agreement, or (d) the negligence, recklessness, or willful misconduct of Licensee or any of its directors, officers, employees, agents, independent contractors and Sublicensees; except in each case to the extent that such Third Party claim or suit results from the negligence, recklessness, or willful misconduct of Licensor or any of its obligations or its representations and warranties under this Agreement.
  - b. Licensor will indemnify, hold harmless, and defend Licensee and its Sublicensees and their directors, officers, employees, agents, and independent contractors (collectively, the "Licensee Indemnitees") from any and all liability, loss, damage, cost, and expense, including reasonable attorneys' fees and costs (collectively, "Losses") that a Licensee Indemnitee becomes legally obligated to pay because of any Third Party claim or suit to the extent that such claim or suit arises from (a) Licensor's breach of its obligations or its representations and warranties under this Agreement or (b) the negligence, recklessness, or willful misconduct of Licensor or any of its directors, officers, employees, agents and independent contractors; except in each case to the extent that such Third Party claim or suit results from the negligence, recklessness, or willful misconduct of a Licensee Indemnitee or Licensee's breach of its obligations or its representations and warranties under this Agreement.
- 10.4 a. Licensee's agreement to indemnify, hold harmless and defend the Licensor Indemnitees is conditioned upon Licensor: (a) providing written notice to Licensee of any claim, demand, or action arising out of the indemnified activities within thirty (30) days after Licensor has knowledge of such claim, demand, or action; (b) permitting Licensee to assume full responsibility and authority to investigate, prepare for, and defend against any such claim or demand; and (c) assisting Licensee, at Licensee's reasonable expense, in the investigation of, preparation for, and defense of any such claim or demand.
  - b. Licensor's agreement to indemnify, hold harmless and defend the Licensee Indemnitees is conditioned upon Licensee: (a) providing written notice to Licensor of any claim, demand, or action arising out of the indemnified activities within thirty (30) days after Licensee has knowledge of such claim, demand, or action; (b) permitting Licensor to assume full responsibility and authority to investigate, prepare for, and defend against any such claim or demand; and (c) assisting Licensor, at Licensor's reasonable expense, in the investigation of, preparation for, and defense of any such claim or demand.

10.5 IN NO EVENT WILL A PARTY BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, PUNITIVE, INCIDENTAL, CONSEQUENTIAL, LOST PROFIT, OR INDIRECT DAMAGES OF ANY KIND ARISING IN ANY WAY OUT OF THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, AND REGARDLESS OF WHETHER THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE. THE FOREGOING LIMITATION SHALL NOT APPLY, HOWEVER, TO LICENSEE'S OR LICENSOR'S INDEMNIFICATION OBLIGATIONS PURSUANT TO THIS ARTICLE 10 OR TO LIMIT THE DAMAGES AVAILABLE FOR BREACHES OF CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 9.

#### 11. Term

This Agreement will commence on the Effective Date and will continue in effect until the cessation of all commercialization in the Territory, unless terminated by either Party by written notice in accordance with the provisions of Article 12. On the expiration of all the Licensed Patents applicable to a given country in the Territory, (a) the license granted to Licensee under such Licensed Patents and the Licensed Technology in such country shall become fully-paid, royalty-free (i.e., no further payment will be due by Licensee to Licensor as per Articles 3.1, 3.2, 3.3 and 3.4 except for any amounts for the which the obligation to pay arose before the expiration of the Licensed Patents) and non-exclusive, and (b) Licensor and the Upstream Licensor shall be free to use such Licensed Patents and the Licensed Technology to make, use, sell, offer to sell, import and otherwise exploit Products and to grant others licenses to do the same in the Territory.

#### 12. Termination

- 12.1 Following the fifth anniversary of the First Sale, either party shall be entitled to terminate this Agreement by written notice at least eighteen (18) months prior to the proposed date of termination.
- 12.2 This Agreement may be terminated by either Party upon sixty (60) days written notice to the other Party specifying a material breach of this Agreement by such other Party and demanding its cure, if such material breach has not been cured to the reasonable satisfaction of the non-breaching Party on or before such 60th day; provided, however, if such breach is not capable of cure within such 60-day period and the breaching Party is acting diligently to accomplish a timely cure, this Agreement will not terminate until the expiration of a reasonable period for the completion of the cure to the reasonable satisfaction of the non-breaching Party, but, in any event, not more than 90 days after the date the notice of breach is delivered to the breaching Party.

- 12.3 If Licensee files a petition in bankruptcy or is adjudicated as bankrupt or if a petition in bankruptcy is filed against Licensee or if it becomes insolvent, or makes an assignment for the benefit of its creditors or an arrangement pursuant to any bankruptcy law, and such proceeding is not dismissed within 60 days, or if Licensee discontinues all of its business or if a receiver is appointed for it or its business, this Agreement will terminate immediately upon written notice by Licensor.
- 12.4 This Agreement may be terminated with immediate effect by either Party upon written notice to the other Party if there is a Change of Control of the other Party. If a Change of Control occurs on a Party, such Party shall provide written notice to the other Party of the Change of Control event no later than three (3) business days after the occurrence of such Change of Control event.

The Licensor acknowledges that the shareholders of Licensee have publicly announced that they have entered into a definitive agreement on the acquisition by Perrigo Company Plc of the share capital of Omega Pharma Invest NV (Licensee's ultimate holding company) (the "Perrigo Transaction"). Licensor furthermore acknowledges and accepts that the closing of the Perrigo Transaction will give rise to a Change of Control event of Licensee, of which Licensor shall be notified pursuant to this Section12.4 (the "Perrigo Change of Control Event"). It is explicitly confirmed between the Parties that the occurrence of the Perrigo Change of Control Event shall not give rise to a right to terminate this Agreement. The Agreement shall remain in full force and effect and each of Licensor and Licensee shall continue after the Perrigo Change of Control Event to fulfil their respective rights and obligations under this Agreement.

12.5 Other than as expressly provided for in this Agreement and except in the event of termination because of breach, it is expressly agreed and accepted by the Parties that under no circumstances will the act of termination of this Agreement in accordance with the provisions of this Article 12 entitle either Party to any kind of compensation, damages, loss of profits, or otherwise. Notwithstanding the foregoing, the termination of this Agreement in accordance with the provisions of this Article 12 will be without prejudice to the accrued or antecedent rights and obligations of the Parties as of the effective date of termination.

#### 13. Effect of Termination or Expiration

13.1 Upon termination of this Agreement in accordance with Article 12, the license granted under Section 2.1 will automatically terminate and Licensee will cease all use of the Licensed Patents and Licensed Technology. Notwithstanding anything to the contrary in the foregoing, except in the event of Licensor's termination of this Agreement for Licensee's uncured breach, Licensee and its Sublicensees shall be allowed to sell all remaining Licensed Product units in their respective inventory within six (6) months after the effective date of termination and within twelve (12) months after the effective date of termination if Licensee has terminated the Agreement for Licensor's uncured breach, subject to Licensee's payment(s) to Licensor pursuant to Article 3.

13.2 Upon termination or expiration of this Agreement, Licensee shall deliver to Licensor all data, results, technology, and information of any type whatsoever, in any tangible or intangible form, that is Controlled by Licensee and is necessary or useful for research, development, regulatory or clinical activities, manufacture, commercialization or other use or exploitation of Licensed Product in the Field of Use, including (but not limited to) know-how, trade secrets, practices, techniques, methods, devices, instruments, designs, systems, materials, strategies and expertise, test data and other technical data, as well as regulatory filings and draft applications for regulatory filings and manufacturing rights and technology (including complete Manufacturing Information and the right of Licensor to become the legal manufacturer of Licensed Products (with the full cooperation of Licensee)).

#### 14. Notices

- 14.1 All notices, requests, consents and other communications given or made by a Party under this Agreement shall be in writing and shall be deemed given (a) five (5) days after mailing when mailed (by registered or certified mail, postage paid, only), (b) on the date sent when made by facsimile transmission with confirmation of receipt (with hard copy to follow by registered or certified mail, postage paid, only), or (c) on the date received when delivered in person or by reputable overnight courier; provided that notices and communications with respect to administrative matters under this Agreement (but not legal matters or matters pertaining to rights or obligations under this Agreement), may be provided by e-mail and will be deemed given when sent. All notices shall be provided to the address set forth below or such other place as such Party may from time to time designate in writing:
  - If to Licensor: BioLineRx, Ltd. 19 Hartum Street Jerusalem 9777518, Israel Attention: Chief Financial and Operating Officer Facsimile: +972-2-548-9101 E-Mail: phils@biolinerx.com If to Licensee: Wartner Europe BV
    - Kralingseweg 201, 3062 CE Rotterdam, The Netherlands Attention: Facsimile: E-Mail:
      - With a copy to: Omega Pharma NV Venecoweg 26 9810 Nazareth Belgium Attention: Legal Department Facsimile: +32 9 381 02 68 E-Mail: anja.vanwinsberghe@omega-pharma.com
        - 21

- a. All such notices, requests, and other communications are deemed received on the date of receipt by the recipient thereof if received prior to 5:00 p.m. in the place of receipt and such day is a business day in the place of receipt. Otherwise, any such notice, request, or communication is deemed not to have been received until the next succeeding business day in the place of receipt.
- b. The provisions above governing the date on which a notice is deemed to have been received by a recipient Party means and refers to the date on which a recipient Party, and not its counsel or other recipient to which a copy of the notice may be sent, is deemed to have received the notice.
- c. If a notice is tendered pursuant to the provisions of this Agreement and is refused by the intended recipient, the notice will nonetheless be deemed to have been given and is effective as of the date provided in this Agreement.

#### 15. Assignment

This Agreement may not be assigned or otherwise transferred by Licensee without the prior written consent of Licensor, which will not be unreasonably withheld or delayed. Any permitted assignee of Licensee shall assume all obligations of Licensee under this Agreement in writing. In the event of a permitted assignment by Licensee, Licensee hereby guarantees the performance by such assignee of Licensee's obligations under this Agreement. Any breach by such assignee of any of Licensee's obligations under this Agreement shall be deemed a breach by Licensee, and Licensor may proceed directly against Licensee without any obligation to first proceed against such assignee.

This Agreement may be assigned or otherwise transferred by Licensor without the prior written consent of Licensee, except in the circumstance where there is publicly available information and evidence that Licensor's proposed assignee is a direct competitor of Licensee's business to which this Agreement relates ("**Competitor**"). If, based upon such publicly available information and evidence, the proposed assignee is likely to be a Competitor, Licensor shall inform Licensee in writing of such proposed assignment to such Competitor. The Parties shall discuss in good faith and agree on whether or not such proposed assignee is in fact a Competitor, and if so, Licensor shall obtain Licensee's prior written consent to such assignment to such Competitor, which consent may be withheld in the sole discretion of Licensee. Any assignee of Licensor shall assume all obligations of Licensor under this Agreement in writing. Licensor will give Licensee notice of an assignment no later than three (3) business days after the occurrence of such assignment.



#### 16. Dispute Resolution

- 16.1 The Parties shall attempt in good faith to resolve any and all disputes that arise between them promptly, voluntarily and amicably. Any dispute arising between the Parties relating to, arising out of, or in any way connected with this Agreement, or any term or condition hereof, or the performance by either Party of its obligations hereunder (a "**Dispute**"), whether before or after expiration or termination of this Agreement, which is not settled by the Parties within thirty (30) days after written notice of such Dispute is first given by one Party to the other Party in writing, will be referred to a senior executive designated by Licensor and a senior executive designated by Licensee who are authorized to settle such Dispute on behalf of their respective companies ("**Senior Executives**"). The Senior Executives will meet (or confer by telephone or video conference) within thirty (30) days after the end of the initial 30-day period referred to above, at a time and place mutually acceptable to both Senior Executives. If the Dispute has not been resolved by the Senior Executives within thirty (30) days after the remainder of this Agreed upon by the Senior Executives), the Dispute will be resolved in accordance with the remainder of this Article 16.
- 16.2 If a Dispute is not resolved in accordance with Section 16.1, the Parties hereby agree to resolve such Dispute by final and binding arbitration administered under the then-current Rules of Arbitration of the International Chamber of Commerce ("ICC").
  - a. <u>Commencement of Arbitration Proceeding; Arbitrator</u>. Following failure of the Senior Executives to resolve a Dispute under Section 16.1, either Party may commence such arbitration proceeding in accordance with this Section 16.2 and the ICC rules, and shall simultaneously notify the other Party in writing of such commencement. The arbitration shall be conducted by one (1) neutral arbitrator, to be mutually selected by the Parties within thirty (30) days of the commencement of the proceeding; provided that if the Parties are unable to mutually select such arbitrator within such 30-day period, then the Parties shall either mutually agree to extend such period or one neutral arbitrator will be selected by Licensor within such thirty (30) day period, one neutral arbitrator will be selected by Licensee within such thirty (30) day period, and such two selected arbitrators shall, within thirty (30) days after the first two arbitrators have been selected, appoint the single neutral arbitrator who shall preside over the arbitration proceeding.
  - b. <u>Arbitration Proceeding and Venue</u>. The arbitration and all related hearings, proceedings and written submissions will be in the English language. The arbitration proceeding shall be held in London, England (unless the Parties mutually agree in writing on a different venue). Each Party shall bear its own expenses (including the fees and expenses of its attorneys, consultants and witnesses) in connection with the arbitration proceeding, and each Party shall, on an ongoing basis, pay one-half (½) the fees and expenses of the ICC and the arbitrator(s).
  - c. <u>Decision; Enforcement</u>. The decision of the arbitrator shall be the sole and exclusive remedy of the Parties, shall be final and shall be fully and irrevocably accepted by the Parties. The arbitrator shall announce his/her decision and award, and the reasons therefor, in writing. The prevailing Party may enforce such decision against the other Party in any court having jurisdiction. In any arbitration proceeding hereunder, the arbitrator will not have the right to modify the terms and conditions of this Agreement. The Parties will exert reasonable efforts to have the decision and award rendered within six (6) months after a Party commences the arbitration proceeding.

16.3 Notwithstanding the above, to the full extent allowed by law, either Party may bring an action in any court of competent jurisdiction for injunctive relief (or any other provisional remedy) to protect the Parties' rights or enforce the Parties' obligations under Article 10 or 13 of this Agreement. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of patents or other proprietary or intellectual property rights.

#### 17. Miscellaneous

- 17.1 <u>Entire Agreement</u>. This Agreement, including the attached schedules, constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all previous oral and written agreements, proposals, negotiations, representations, commitments and other communications between the Parties with respect to its subject matter, except the Confidentiality Agreement between the Parties, dated January 14, 2014, which shall continue in full force and effect with respect to disclosures of Confidential Information made prior to the Effective Date of this Agreement. In the event of any conflict or inconsistency between any provision of any schedule hereto and any provision of this Agreement, the provisions of this Agreement shall prevail.
- 17.2 Force Majeure. Neither Party shall be held liable or responsible to the other Party, nor be deemed to have defaulted under or breached this Agreement, for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including but not limited to fire, floods, earthquake, embargoes, war, acts of war (whether war is declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party; provided, however, that the Party so affected shall use commercially reasonable efforts to avoid or remove such causes of nonperformance, and shall continue to perform hereunder with reasonable dispatch whenever such causes are removed. Either Party shall provide the other Party with prompt written notice of any delay or failure to perform that occurs by reason of force majeure. The Parties shall mutually seek a resolution of the delay or the failure to perform as noted above.
- 17.3 <u>Governing Law</u>. This Agreement and any Dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with the laws of England and Wales, without reference to conflicts of laws principles.
- 17.4 <u>Waiver</u>. The waiver by either Party hereto of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

- 17.5 <u>Severability</u>. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of this Agreement in any other jurisdiction.
- 17.6 <u>Amendment</u>. This Agreement may be amended, or any term hereof may be modified, only by a written instrument duly executed by an authorized representative of each of the Parties.
- 17.7 <u>Official Language</u>. The language of this Agreement and of any documents, papers or proceedings required by or under this Agreement, including any such documents, papers or proceedings that arise under Article 16, shall be English. Any Party requesting or requiring translations of such documents, papers or proceedings shall bear all costs and expenses of such translations.
- 17.8 <u>Independent Contractors</u>. It is expressly agreed that Licensor and Licensee shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Licensor nor Licensee shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so.
- 17.9 <u>Fees and Expenses</u>. Each Party will pay its respective transaction expenses incident to the execution of this Agreement.
- 17.10 <u>Headings</u>. Headings used in this Agreement are for reference purposes only and will not be deemed a part of this Agreement or used in the interpretations of the substantive provisions of it.
- 17.11 <u>Counterparts</u>. This Agreement may be executed in one or more counterparts by original, facsimile or electronic (for example, PDF) signature, each of which is deemed an original and all of which together constitute one and the same instrument.
- 17.12 <u>Surviving Provisions</u>. All provisions of this Agreement which by their nature survive the expiration or termination of this Agreement will survive expiration or termination including, but not limited to, Articles 1, 4, 5, 9, 10, 13, 16 and 17; and Sections 2.3, 2.4, 6.2, and 8.1.

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

#### BioLineRx Ltd.

#### /s/ Kinneret Savitsky /s/ Philip Serlin Signature

Kinneret Savitsky, Ph.D. CEO Philip Serlin Chief Financial and Operating Officer

22 December 2014

#### Wartner Europe BV

/s/ Freya Loncin Signature Aubisque BVBA (represented by Freya Loncin, permanent representative) Director 22 December 2014

### Schedule A Licensed Patents

Patent or Patent Application No.	Publication No.	Date of Filing	Title
European Patent No. 02775182.5	EP 1,450,771	02 October 2002	Pharmaceutical Preparations Useful for Treating Tumors and Lesions of the Skin and the Mucous Membranes and Methods and Kits Using Same
Israel Patent No. 161177	IL 161,177	02 October 2002	Pharmaceutical Preparations Useful for Treating Tumors and Lesions of the Skin and the Mucous Membranes and Methods and Kits Using Same
PCT/IL2013/ 050783		15 September 2013	Medical Applicator

	Schedule B Territory
[*]	

#### Schedule C Core Countries (Section 2.2.c)





For Immediate Release

### BioLineRx Out-Licenses Novel Skin Lesion Treatment to Omega Pharma

- Omega Pharma to develop and commercialize novel skin treatment for OTC use in Europe and additional selected countries -

#### - First product expected to reach the market in 2016 -

Jerusalem, December 23, 2014 – BioLineRx Ltd. (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today that it has entered into an exclusive out-licensing agreement with Omega Pharma, one of the largest OTC healthcare companies in Europe, for the rights to BioLineRx's BL-5010, a novel product for the non-surgical removal of benign skin lesions, for OTC indications in the territory of Europe, Australia and additional selected countries. BioLineRx will retain the rights to BL-5010 in the United States and the rest of the world. This licensing agreement significantly accelerates the pathway to commercialization for this asset, with the first OTC products expected to enter the market in 2016.

Under the terms of the agreement, Omega Pharma will be responsible for all development activities required to obtain regulatory approval in the licensed territory for at least two OTC indications. In addition, Omega Pharma will sponsor and manufacture the product in the relevant regions, and will have exclusive responsibility for commercialization.

The specific financial terms of the licensing agreement were not disclosed. Omega Pharma will pay BioLineRx an undisclosed amount for each unit sold and BioLineRx will be entitled to certain commercial milestone payments. In addition, BioLineRx will have full access to all clinical and R&D data generated during the performance of the development plan and may use these data in order to develop and/or license the product in other territories and fields of use where it retains the rights.

"We are very pleased to partner with Omega Pharma, a top consumer healthcare company and a leading provider of over-the-counter medicines and healthcare products," stated Kinneret Savitsky, Ph.D., Chief Executive Officer of BioLineRx. "BL-5010 for the non-surgical removal of benign skin lesions offers a promising alternative to painful and invasive removal treatments. We are looking forward to collaborating with Omega in bringing the first product, based on our effective non-invasive solution, to market as early as 2016."

Mr. Marc Coucke, Chief Executive Officer of Omega Pharma, added, "We are happy to collaborate with BioLineRx in adding this promising skin lesion treatment to our leading skin care brands. We were very impressed with the data from the product's clinical trials to date, and believe it can quickly gain a prominent position as an over-the-counter treatment for a variety of benign skin lesions."

Dr. Savitsky concluded, "While our strategic focus remains on advancing our lead clinical programs in oncology and inflammation, we believe this partnership, as well as our recent multi-year collaboration with Novartis, add significant value to BioLine and are a testament to our proven ability to identify and develop promising product candidates. In addition to providing capital that allows BioLine to accelerate development of our lead assets, high-profile partnerships such as these validate our business model globally and we believe this makes us well positioned to continue to attract prospective partners for future candidates."

#### About BL-5010

BL-5010 is a novel product 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. Because the treatment is non-invasive, it poses minimal infection risk and eliminates the need for anesthesia or bandaging. The product has completed a phase 1/2 pilot clinical study for the removal of seborrheic keratosis, which showed excellent efficacy and cosmetic results, and has received confirmation in Europe for the regulatory pathway classification as a medical device Class 2a.

#### **About Omega Pharma**

Omega Pharma is an OTC healthcare company headquartered in Belgium with operations in 35 countries across Europe and selected emerging markets. Its products are sold across an extensive network of pharmacies and related retail outlets. With over 2,500 employees, Omega generated sales of more than  $\pounds$ 1.2 billion in 2013, with more than half of these sales made by its top 20 brands. Perrigo Company plc and Omega recently announced the signing of a definitive agreement for the acquisition of Omega by Perrigo for  $\pounds$ 3.6 billion.

#### About BioLineRx

BioLineRx is a publicly-traded, clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates. The Company in-licenses novel compounds primarily from academic institutions and biotech companies based in Israel, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's current portfolio consists of a variety of clinical and pre-clinical projects, including: BL-1040 for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Bellerophon BCM (f/k/a Ikaria) and is in the midst of a pivotal CE-Mark registration trial scheduled for completion in mid-2015; BL-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for acute myeloid leukemia (AML) as well as a Phase 1 study for stem cell mobilization; and BL-7010 for celiac disease, which has successfully completed a Phase 1/2 study.

For more information on BioLineRx, please visit <u>www.biolinerx.com</u> or download the investor relations mobile device app, which allows users access to the Company's SEC documents, press releases, and events. BioLineRx's IR app is available on the iTunes App Store as well as the Google Play Store.

Various statements in this release concerning BioLineRx's future expectations, including specifically those related to the development and commercialization of BL-5010, constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. These and other factors are more fully discussed in the "Risk Factors" section of BioLineRx's most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 12, 2013. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

#### Contact:

Tiberend Strategic Advisors, Inc. Joshua Drumm, Ph.D. <u>jdrumm@tiberend.com</u> (212) 375-2664 Andrew Mielach <u>amielach@tiberend.com</u> (212) 375-2694

#### Or

Tsipi Haitovsky Public Relations +972-3-6240871 tsipih@netvision.net.il



## Schedule G SPECIFICATIONS, AND CHARACTERISTICS

[\*]

## CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT

I, Kinneret Savitsky, certify that:

- 1. I have reviewed this annual report on Form 20-F/A of BioLineRx Ltd.;
- 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;
- 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: September 22, 2015

<u>/s/ Kinneret Savitsky</u> Kinneret Savitsky, Ph.D. Chief Executive Officer

# CERTIFICATION OF THE CHIEF FINANCIAL OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT

I, Philip Serlin, certify that:

- 1. I have reviewed this annual report on Form 20-F/A 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;
- 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: September 22, 2015

<u>/s/ Philip Serlin</u> Philip Serlin Chief Financial and Operating Officer