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UNITED STATES

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SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM 20-F/A  
Amendment No. 1

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(Mark One)

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

OR

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

For the fiscal year ended **December 31, 2015**

OR

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

OR

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

Date of event requiring this shell company report

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number \_\_\_\_\_

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**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)

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**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:

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

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

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

None  
(Title of Class)

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

None  
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report. 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  No

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

Yes  No

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

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

Yes  No

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

Yes  No

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

Accelerated filer

Non-accelerated filer

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

U.S. GAAP

International Financial Reporting Standards as issued  
by the International Accounting Standards Board

Other

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

Item 17  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  No

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

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

Yes  No

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## EXPLANATORY NOTE

This Amendment No. 1 (the "Amendment") amends our Annual Report on Form 20-F for the year ended December 31, 2015 (the "Annual Report"), as filed with the U.S. Securities and Exchange Commission (the "Commission") on March 10, 2016 (the "Original Filing Date"). This Amendment No. 1 is being filed solely to amend Exhibit 4.33 originally filed on Form 6-K dated October 16, 2012, and Exhibit 4.40 originally filed with the Annual Report (collectively, the "Exhibits").

The Registrant had previously submitted a request for confidential treatment to the Commission concerning Exhibit 4.33, and confidential treatment was granted by the SEC on March 1, 2013. The confidential treatment period expired on December 20, 2015 and the unredacted agreement has been included in this Amendment.

The Registrant had previously submitted a request for confidential treatment to the Commission concerning Exhibit 4.40, and the final redacted agreement has been included in this Amendment.

The Exhibits filed herewith supersede in their entirety the Exhibits originally filed with the Form 6-K dated October 16, 2012 and 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. 1, 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. 1.

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ITEM 19. EXHIBITS

Exhibit Number	Exhibit Description
2.1 <sup>(5)</sup>	Articles of Association, as amended May 31, 2015
2.2 <sup>(2)</sup>	Form of Deposit Agreement dated as of July 21, 2011 among the Registrant, The Bank of New York Mellon, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder
2.3 <sup>(2)</sup>	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† <sup>(1)</sup>	License Agreement entered into as of January 10, 2005, between BioLine Innovations Jerusalem L.P. and B.G. Negev Technologies and Applications Ltd.
4.7 <sup>(1)</sup>	Assignment Agreement entered into as of January 1, 2009 entered into between BioLine Innovations Jerusalem L.P. and the Registrant
4.16† <sup>(1)</sup>	License Agreement entered into as of November 25, 2007 between BioLine Innovations Jerusalem L.P. and Innovative Pharmaceutical Concepts, Inc.
4.17† <sup>(10)</sup>	Amended and Restated License and Commercialization Agreement among Ikaria Development Subsidiary One LLC, the Registrant and BioLine Innovations Jerusalem L.P. dated August 26, 2009, as amended and supplemented
4.18 <sup>(11)</sup>	BioLineRx Ltd. Amended and Restated 2003 Share Incentive Plan
4.20 <sup>(1)</sup>	Amendment to Employment Agreement with Kinneret Savitsky, Ph.D., dated January 2, 2004.
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
4.32 <sup>(7)</sup>	Form of Warrant to purchase American Depositary Shares
4.33	License Agreement entered into as of September 2, 2012 by and between the Registrant and Biokine Therapeutics Ltd.
4.34 <sup>(9)</sup>	Consulting Agreement with Arnon Aharon, M.D., dated January 1, 2014
4.35† <sup>(9)</sup>	License Agreement entered into as of February 15, 2011 between the Registrant and Valorisation-Recherche, Limited Partnership
4.36 <sup>(8)</sup>	Executive Compensation Plan
4.37 <sup>(10)</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 (English summary of the Hebrew original)
4.38† <sup>(10)</sup>	Investment and Collaboration Agreement entered into as of December 16, 2014 between the Registrant and Novartis Pharma AG

Exhibit Number	Exhibit Description
4.39†(11)	License Agreement entered into as of December 22, 2014 between the Registrant and Wartner Europe BV
4.40†	Clinical Trial Collaboration and Supply Agreement entered into as of January 11, 2016 between Merck Sharp & Dohme B.V. and the Registrant
4.41(12)	Employment Agreement with Merrill Gersten, dated March 1, 2016
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(12)	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(12)	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(3)	Form of Purchase Agreement between the Registrant and the Purchasers named therein, dated February 2012
15.4(7)	Subscription Agreement entered into as of February 6, 2013 between the Registrant and OrbiMed Israel Partners Limited Partnership
15.5(12)	Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Registrant
15.6(6)	Purchase Agreement entered into as of May 28, 2014 between the Registrant and Lincoln Park Capital Fund, LLC
15.7(6)	Registration Rights Agreement entered into as of May 28, 2014 between the Registrant and Lincoln Park Capital Fund, LLC

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

- (1) Incorporated by reference to the Registrant's Registration Statement on Form 20-F (No. 001-35223) filed on July 1, 2011.
- (2) Incorporated by reference to Exhibit 1 of the Registration Statement on Form F-6 (No. 333-175360) filed by the Bank of New York Mellon with respect to the Registrant's American Depositary Receipts.
- (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 F-3 (No. 333-205700) filed on July 16, 2015.
- (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 November 13, 2013.
- (9) Incorporated by reference to Amendment No. 1 to the Registrant's Annual Report on Form 20-F/A filed on May 15, 2014.
- (10) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 23, 2015.
- (11) Incorporated by reference to Amendment No. 2 to the Registrant's Annual Report on Form 20-F/A filed on September 22, 2015.
- (12) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 10, 2016.

**SIGNATURES**

The Registrant hereby certifies that it meets all of the requirements for filing this Amendment No. 1 on Form 20-F/A and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

BIOLINERX LTD.

Date: May 31, 2016

By: /s/ Kinneret Savitsky  
Kinneret Savitsky, Ph.D.  
Chief Executive Officer

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**LICENSE AGREEMENT**

This License Agreement is entered into as of September 2, 2012 (the “**Execution Date**”), by and among **BioLineRx Ltd.**, a company formed pursuant to the laws of the State of Israel, having a place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel (together with any of its affiliates, including any company, partnership or corporation under its control, “**BioLine**”), and **Biokine Therapeutics Ltd.**, a company formed pursuant to the laws of the State of Israel and having a place of business at Weizmann Science Park, P.O. Box 2213, Rehovot, 76120, Israel (“**Licensors**”).

WHEREAS, Licensors is the owner of an invention relating to the Drug and associated rights and know-how (the “**Licensed Technology**”, as further defined below); and

WHEREAS, BioLine wishes to obtain an exclusive license with respect to the Licensed Technology in order to develop and commercialize products based on the Licensed Technology, and Licensors wishes to grant BioLine an exclusive license with respect to the Licensed Technology, all in accordance with the terms and conditions of this Agreement;

NOW, THEREFORE, the parties hereto, intending to be legally bound, hereby agree as follows:

- Definitions.** Whenever used in this Agreement with an initial capital letter, the terms defined in this Section 1, whether used in the singular or the plural, shall have the meanings specified below.

“**Additional Ingredient**” shall mean any compound or substance which is not any of (x) a Licensed Product, (y) a New Development or (z) developed in the Contemplated Clinical Trials or otherwise results from the development of the Drug hereunder, and (i) which is contained in a product and (ii) when administered to a patient has a therapeutic or prophylactic clinical effect independent of a Licensed Product, either directly or by acting synergistically with or otherwise enhancing the effect of other compounds or substances contained in such product.

“**Affiliate**” shall mean, with respect to a party, any person, organization or entity controlling, controlled by or under common control with, such party, including, with respect to a limited partnership, its limited partners, general partners. For purposes of this definition only, “control” of another person, organization or entity shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the activities, management or policies of such person, organization or entity, whether through the ownership of voting securities, by contract or otherwise. Without limiting the foregoing, control shall be presumed to exist when a person, organization or entity (i) owns or directly controls the Relevant Percentage of the outstanding voting stock or other ownership interest of the other organization or entity, or (ii) possesses, directly or indirectly, the power to elect or appoint the Relevant Percentage of the members of the governing body of the organization or other entity. BioLine may, from time to time, update such list in which case it will provide notice thereof to Licensors. The “**Relevant Percentage**” means 50% or more of the applicable amount, except with respect to Sections 2.3, 2.4, 7.3 and 7.4, 8.1.3, 12.4.2 and 13.9 where it means more than 50% of the applicable amount.



**“Calendar Quarter”** shall mean the respective periods of 3 consecutive calendar months ending on March 31, June 30, September 30 or December 31, for so long as this Agreement is in effect.

**“Combination Product”** shall mean a product, substance or device which comprises a Licensed Product and at least one Additional Ingredient.

**“Contemplated Clinical Trial”** shall mean one of the two non-comparative clinical trials managed by Licensor as of the Execution Date, studying the effects of the Drug on two indications as set forth in the Development Plan. A Contemplated Clinical Trial shall be deemed as having “commenced” if a single patient has (i) entered the treatment phase of such trial and (ii) received at least one (1) injection of the Drug. A Contemplated Clinical Trial shall be deemed “completed” when a final report of such trial shall be submitted to the board of directors of each of the Licensor and BioLine.

**“Core Patents”** means the patents and patent application expressly listed in Exhibit E.

**“Development Plan”** shall have the meaning given to it in Section 5.1.

**“Drug”** means 4F-benzoyl- TN14003.

**“Effective Date”** means the date on which the written consent of the OCS with respect to this Agreement has been obtained in accordance with Section 2 (whether such OCS consent is granted for an associated form of Agreement modified in accordance with Section 2.1 or for the Execution Date Agreement, as such term is defined in Section 2.1).

**“Execution Date”** shall have the meaning given to it in Preamble.

**“Execution Date Agreement”** shall have the meaning given to it in Section 2.1.

**“First Commercial Sale”** shall mean the first sale of a Licensed Product by BioLine, anyone on its behalf, an Affiliate of BioLine or a Sublicensee, in any form or manner, to an unaffiliated third party (those parties not regarded to as BioLine Affiliates, Sublicensees or Affiliates of Sublicensees), after Regulatory Approval has been achieved in the country in which such Licensed Product is sold. The provision of Licensed Product for test marketing, sampling and promotional uses, clinical trial purposes, compassionate or similar use shall not be considered to constitute a First Commercial Sale, unless the Licenses Product has been sold for consideration.

**“FDA”** shall mean the United States Food and Drug Administration.

**“Grants”** shall mean any funds, research grants, or benefits received by BioLine from governmental, quasi-governmental or other non-profit sources for the development and/or commercialization of Licensed Products or other benefits.

**“Hadasit”** means Hadasit Medical Research Services & Development Ltd.

**“Infringement”** shall have the meaning given to it in Section 9.1.1.

**“Joint Development Committee”** or **“JDC”** shall have the meaning given to it in Section 5.3.

“**License**” shall mean the license granted to BioLine pursuant to Section 2.2.

“**Licensed Know-How**” shall mean all inventions, know-how and other intellectual property controlled by Licensor, in written, electronic or other form, and relating to the Drug.

“**Licensed Patents**” shall mean (i) the U.S., foreign or international patents and/or patent applications set forth on **Exhibit A** attached hereto, (ii) any patent or patent application that claims priority to and is a divisional, continuation, reissue, renewal, reexamination, substitution or extension of any patent application identified in (i); (iii) any patents issuing on any patent application identified in (i) or (ii), including any reissues, renewals, reexaminations, substitutions or extensions thereof; (iv) any claim of a continuation-in-part application or patent that is entitled to the priority date of, and is directed specifically to subject matter specifically described in, at least one of the patents or patent applications identified in (i), (ii) or (iii); (v) any foreign counterpart (including PCTs) of any patent or patent application identified in (i), (ii) or (iii) or of the claims identified in (iv); (vi) any U.S. or foreign patents and patent applications that claim, but only with respect to those claims that claim subject matter specifically included in, the invention set out in the patents and/or patent applications set forth on **Exhibit A** attached hereto; and (vii) any supplementary protection certificates, any other patent term extensions and exclusivity periods and the like of any patents and patent applications identified in (i) through (vi). **Exhibit A** attached hereto sets forth the Licensed Patents, and shall be updated from time to time to reflect inclusion of new Licensed Patents.

“**Licensed Product**” shall mean any product, in any indication, that comprises, contains, incorporates or is covered by Licensed Technology.

“**Licensed Technology**” shall mean the Licensed Patents and the Licensed Know-How.

“**Licensor Indemnitees**” shall have the meaning given to it in Section 11.1

“**M&A Transaction**” shall mean (a) a transaction in which all or substantially all of the assets to which the subject matter of this Agreement relates are acquired by or assigned to party that is not an Affiliate, or (b) a sale of all or substantially all of the share capital of BioLine (or its Affiliates), (c) the merger of BioLine (or its Affiliates) with any other entity, or any other similar corporate action, except an internal reorganization of BioLine (or its Affiliates) for tax-related reasons otherwise.

“**Net Sales**” shall mean the gross amount billed or invoiced by or on behalf of BioLine and/or its Affiliates (the “**Invoicing Entity**”) on sales of Licensed Products (whether made before or after the First Commercial Sale of the Licensed Product), less the following: (a) customary and reasonable trade, quantity, or cash discounts to the extent actually allowed and taken; (b) amounts repaid or credited by reason of rejection or return; (c) to the extent separately stated on purchase orders, invoices, or other documents of sale, any taxes or other governmental charges levied on the production, sale, transportation, import, export, delivery, or use of a Licensed Product which is paid by or on behalf of the Invoicing Entity; and (d) outbound transportation, packing and delivery charges, as well as prepaid freight (including shipping insurance) actually incurred. No other expenses or payments, of any kind, including any payments due to the OCS with respect to Grants in relation to the sales of Licensed Products, shall be deducted for the purposes of calculating Net Sales.

- (i) In any transfers of Licensed Products between the Invoicing Entity and an Affiliate of the Invoicing Entity not for the purpose of resale by such Affiliate, Net Sales shall be equal to the fair market value of the Licensed Products so transferred, assuming an arm's length transaction made in the ordinary course of business;
- (ii) Good faith sales of Licensed Products by an Invoicing Party to an Affiliate of such Invoicing Party, for resale by such Affiliate, shall not be deemed Net Sales and Net Sales shall be determined based on the total amount invoiced or billed by such Affiliate on resale to an independent third party purchaser; and
- (iii) In the event that the Invoicing Entity, or the Affiliate of the Invoicing Entity, receives non-monetary consideration for any Licensed Products or in the case of transactions not at arm's length with a non-Affiliate of the Invoicing Entity, Net Sales shall be calculated based on the fair market value of such consideration or transaction, assuming an arm's length transaction made in the ordinary course of business.

“**New Developments**” shall have the meaning set forth in Section 3.2.

“**OCS**” shall mean the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor of the State of Israel.

“**Phase II Clinical Trial**” shall mean a human clinical trial in any country conducted to evaluate the effectiveness of a drug for a particular indication or indications in patients with the disease or condition under study and, possibly, to determine the common short-term side effects and risks associated with the drug. In the United States, “Phase II Clinical Trial” means a human clinical trial that satisfies the requirements of 21 C.F.R. § 312.21 (b).

“**Regulatory Agency**” shall mean the FDA or equivalent agency or government body of another country.

“**Regulatory Approval**” shall mean (i) approval by the FDA permitting commercial sale of a Licensed Product, or (ii) any comparable approval permitting commercial sale of a Licensed Product granted by the applicable Regulatory Agency in any other country or jurisdiction.

“**Representative**” shall have the meaning given to it in Section 5.3.

“**Sublicense**” shall mean any right granted, license given, or agreement entered into, by BioLine to or with any other person or entity, under, or with respect to, or permitting any use of, any of the Licensed Technology or otherwise permitting the development, manufacture, marketing, distribution and/or sale of Licensed Products (regardless of whether such grant of rights, license given or agreement entered into is referred to or is described as a sublicense or as an agreement with respect to the development and/or manufacture and/or sale and/or distribution and/or marketing of Licensed Products). For the avoidance of doubt, an M&A Transaction will not be regarded as a Sublicense.

“**Sublicense Receipts**” shall mean any payments or other consideration that BioLine or an Affiliate of BioLine or any entity on their behalf (excluding a Sublicensee) actually received in connection with a Sublicense, or the grant of an option to obtain a Sublicense, including without limitation royalties, license fees, milestone payments, license maintenance fees and equity (or securities convertible into equity or other equity-related instruments); *provided, however*, that in the event that BioLine or an Affiliate of BioLine or any entity on their behalf (excluding a Sublicensee) receives non-monetary consideration in connection with a Sublicense or the grant of an option to obtain a Sublicense or in the case of transactions not at arm’s length, Sublicense Receipts shall be calculated based on the fair market value of such consideration or transaction, assuming an arm’s length transaction made in the ordinary course of business; and *provided further* that Sublicensing Receipts will be reduced by any amounts paid by BioLine or an Affiliate of BioLine to a Sublicensee on account of refunds or rebates given in respect of Sublicense Receipts and payments to one or more third parties to obtain a Third Party License from such third party(ies) in order to practice the Licensed Technology. For the avoidance of doubt, Sublicensing Receipts shall not include any amounts received as Grants.

“**Sublicensee**” shall mean a person or entity granted a Sublicense in accordance with Section 2.3, including any sublicensees of other Sublicensees.

“**Third Party License**” shall mean a license from an unaffiliated third party (those parties not regarded as BioLine Affiliates) to one or more valid and enforceable patents issued in the United States or any other jurisdiction, the claims of which cover one or more functional components that is essential for the efficacy of the Licensed Product.

## 2. License Grant.

2.1. **Effective Date.** The parties acknowledge that the OCS must consent to this Agreement before this Agreement is made effective. As such, immediately following the Execution Date, BioLine shall take the actions required to request the written consent of the OCS to this Agreement in the form executed by the parties as of the Execution Date (“**Execution Date Agreement**”) and shall make reasonable commercial efforts to obtain such OCS consent. Licensor shall provide reasonable cooperation therewith and shall file all documents and execute all documents reasonably required to be submitted to the OCS in connection with such consent. Subsequent to the Execution Date, and until termination of this Agreement, Licensor shall not develop the Drug or grant any rights with respect thereto except pursuant to the provisions hereof or with the prior written consent of BioLine. The parties acknowledge that it may be necessary prior to the Effective Date to modify the Execution Date Agreement to comply with the specific, formal written requests of the OCS and the parties shall consider any such proposed modifications in good faith; *provided, however*, that (a) subject to this entire Agreement being in full force and effect, all financial obligations that may be imposed by the OCS as a pre-condition to obtaining OCS consent to this Agreement shall be the sole responsibility of the party to which such obligation is allocated by the OCS; (b) the parties will cooperate in good faith to minimize financial and non-financial obligations (which obligations must be commercially reasonable) that may be imposed by the OCS as a pre-condition to obtaining OCS consent to this Agreement; and (c) after the parties have considered any such proposed modifications in good faith, neither party shall be required to agree to either financial obligations that may be imposed by the OCS as a pre-condition to obtaining OCS consent or any modifications to the Execution Date Agreement that would have, or would be likely to have, a material adverse impact on the rights or obligations of either party as set forth in the Execution Date Agreement, and for the avoidance of doubt, Licensor shall not be required to agree to any modifications that change the payment schedule in Section 6 hereof. To the extent the OCS consent is not obtained within three months of the date that Licensor has filed all required reports and documents with the OCS and closed such OCS files, the parties obligations hereunder shall terminate, except as provided in the next sentence. Notwithstanding anything herein to the contrary, the provisions of this Execution Date Agreement other than this Section 2 and Sections 6.1, 8 and 12.3.4, shall not be effective until the Effective Date. From and after the Effective Date, the entire Agreement shall be in full force and effect. In addition, at the Execution Date the parties shall commence working on the Development Plan, to the extent the same is possible absent a license hereunder, substantially in accordance with the provisions of Sections 5.2 and 5.3, applied *mutatis mutandis*.

- 2.2. **License.** Subject to terms and conditions hereof, Licensor hereby grants to BioLine an exclusive, royalty-bearing, worldwide license under Licensor's rights in the Licensed Technology to research, have researched, develop, have developed, manufacture, have manufactured, use, market, distribute, offer for sale, sell, have sold, export and import Licensed Products and/or provide services relating thereto. For purposes of this Section 2.2, the term "exclusive" means that Licensor shall not have any right to grant such licenses or rights to any third party with respect to the foregoing or engage in any of the foregoing except with the written permission of BioLine, except as set forth in the Development Plan.
- 2.3. **Sublicenses.** BioLine shall be entitled to grant Sublicenses to third parties under the License, it being clarified that Sublicenses shall be granted for consideration and in arm's length transactions, and that sublicenses to Affiliates of BioLine shall not be considered Sublicenses under this Agreement. Notwithstanding the foregoing, and notwithstanding the fact that BioLine is solely responsible for the commercialization of Licensed Products, prior to granting any Sublicense to a third party (the "**Prospective Sublicensee**"), the provisions of this Section 2 will apply to any Sublicense grant.
- 2.3.1. **Sublicense Prior to Completion of Development Plan.** Prior to the date that at least one Contemplated Clinical Trial has commenced and at least one Contemplated Clinical Trial has been completed, any grant of a Sublicense shall require the prior written consent of Licensor, which may be withheld in its sole discretion.
- 2.3.2. **Sublicense after Completion of Development Plan.** After the date set forth in Section 2.3.1, any grant of a Sublicense shall not require the prior written consent of Licensor but shall be subject to the following:
- 2.3.2.1. BioLine will provide Licensor with a written notice (the "**Notice**") that will include: (a) BioLine's desire to grant a Sublicense to the Prospective Sublicensee; and (b) the principal commercial terms of the proposed Sublicense. Within 7 days of receipt of the Notice, Licensor may provide a written notice (the "**Response**") to BioLine indicating that Licensor has identified an alternative third party (the "**Alternative Prospective Sublicensee**") who has provided Licensor with a term sheet containing financial terms objectively more favorable than those set out in the Notice (such terms to be included in the Response), in which case BioLine will commence negotiations with the Alternative Prospective Sublicensee for the grant of the Sublicense, provided that should such negotiations fail to generate a binding, written and definitive sublicense agreement within 30 days, BioLine shall be free to proceed to grant a Sublicense to the Prospective Sublicensee.

- 2.3.2.2. In the event that Licensor notifies BioLine in writing that it does not wish to propose an Alternative Prospective Sublicensee or fails to provide BioLine with a Response within the aforementioned 7 day period, BioLine shall be entitled to grant the aforementioned Sublicense to the Prospective Sublicensee with no further obligations in respect thereof to Licensor (save and except for the remaining provisions of this Article).
- 2.3.2.3. If the consent of the OCS is required for a Sublicense, Licensor shall have the right to have a non-participating observer present at all meetings, conference calls and any other interactions between BioLine's representatives and the OCS relating to obtaining such consent, *provided* that all correspondence and discussions with the OCS shall be carried out solely by BioLine, and any decisions with respect to obtaining consent shall be taken in the sole discretion of BioLine. BioLine shall (a) make reasonable efforts to reduce amounts payable to the OCS, and consult with Licensor regarding negotiations with the OCS to reduce such amounts, *provided* that in any such event and subject to the consultation hereunder BioLine shall have no obligation to obtain Licensor's approval (b) provide Licensor with a reasonable opportunity to review any communications related to the request for consent submitted to the OCS and (c) keep Licensor fully informed as to the progress of such request for consent.
- 2.3.3. *Sublicense Agreements.* Sublicenses shall only be granted pursuant to written agreements. BioLine shall provide Licensor with a copy of (i) the proposed final draft of each sublicense agreement into which it intends to enter for Licensor's review 7 days prior to the contemplated date of execution thereof, it being recognized that due to the nature of commercial negotiations such draft may be subject to change immediately prior to the execution thereof and BioLine may not be able to provide Licensor with such absolute final draft prior to execution, and (ii) the final executed version of each sublicense agreement into which it enters within 7 days after receipt of an executed draft thereof from the Sublicensee. For avoidance of doubt, it is hereby clarified that should the final executed version include material changes from the proposed final draft provided to Licensor for review pursuant to the foregoing, Licensee shall specifically notify Licensor of such material changes within reasonable time prior to execution. The Licensor shall have a right to comment on, and to object to the sublicense agreement to the extent that it provides rights to the Sublicensee that are inconsistent with, or deviate from, the terms of this Agreement, in which case such Sublicense Agreement shall not come into effect. Each such sublicense agreement shall be consistent with the terms of the Agreement and shall contain, *inter alia*, provisions to the following effect:

- 2.3.3.1. All provisions necessary to ensure BioLine's ability to perform its obligations under this Agreement, including reporting and audit requirements; and
- 2.3.3.2. In the event of termination of the license set forth in Section 2.2 above (in whole or in part – e.g. termination in a particular country), any existing agreements that contain a Sublicense of, or other grant of right with respect to, Licensed Technology shall terminate to the extent of such Sublicense or other grant of right; *provided, however*, that, for each Sublicensee, upon termination of the Sublicense agreement with such Sublicensee, if the Sublicensee is not then in breach of such Sublicense agreement with BioLine such that BioLine would have the right to terminate such Sublicense, Licensor shall be obligated, at the request of such Sublicensee, to enter into a new agreement with such Sublicensee on substantially the same terms as those contained in such Sublicense agreement (including with respect to New Developments, and to the extent such terms are consistent with the terms of this Agreement); and *provided, further*, that such terms shall be amended, if necessary, to the extent required to ensure that such Sublicense agreement does not impose any obligations or liabilities on Licensor which are not included in this Agreement. Licensor's consent to such Sublicensee request shall not be unreasonably withheld.
- 2.3.4. A Sublicensee shall be entitled to Sublicense its rights under a Sublicense agreement, and so forth through a chain of sublicenses, provided that each such sublicense shall be subject to the terms specified in Section 2.3 above.
- 2.4. **Contractors and Affiliates.** BioLine shall have the right to utilize third party contractors in connection with BioLine's activities in exploiting the License. Provided that such contractors perform activities on BioLine's behalf, and BioLine maintains control of and remains solely responsible for such activities, the provisions of Section 2.3 shall not apply with respect to such contractors. For the avoidance of doubt, Sublicenses to Affiliates of BioLine shall not be considered Sublicenses under this Agreement; provided that upon such transaction such Affiliate shall be bound by all of BioLine's obligations hereunder.

3. **Title.**
- 3.1. **Title.** Subject to the License granted to BioLine pursuant to the terms of this Agreement, all rights, title and interest in and to the Licensed Technology shall be owned solely and exclusively by Licensor.
- 3.2. **New Developments.** As between the parties, any inventions developed, made, conceived or created by BioLine or its Affiliates as a result of the exercise of the License that relate directly to the Licensed Technology or the Licensed Products (including but not limited to any improvement of the performance or efficacy of the Licensed Products, a reduction of any side effects, drug interactions or other adverse effects of the Licensed Products, or an increase in the efficiency or productivity of the manufacturing and production process for the Licensed Products) and all intellectual property rights therein (all of the foregoing, “**New Developments**”) shall be the sole property of BioLine, subject to Section 12.4.1.
- 3.3. **Additional Funding for Licensor.** Licensor shall not accept any funding from any third party for research or any other activity relating or connected to the Licensed Technology without the prior written consent of BioLine.

4. **Patent Filing, Prosecution and Maintenance.**

- 4.1. **Filing.** BioLine shall be obligated to prosecute and maintain the Core Patents. In respect of patents and patent application that are not included in the Core Patents, BioLine shall, subject to its right to abandonment under Section 4.2, prepare, file, prosecute and maintain any patent applications and patents in respect of the Licensed Technology and/or any part thereof which is not part of the Core Patents, and at BioLine’s sole expense. BioLine shall provide Licensor with copies of all patent applications reasonably in advance of any submission thereof to allow a reasonable and adequate discussion of patent strategies. Licensor undertakes to cooperate in a timely manner with BioLine’s efforts to register the patent, including by executing any documents as may be required for such purpose. BioLine shall consider in good faith all of Licensor’s comments.
- 4.2. **Abandonment.** If BioLine decides that it does not wish to pay for the preparation, filing, prosecution, protection or maintenance of any patents or patent applications that are not Core Patents (“**Abandoned Patent Rights**”), BioLine shall provide Licensor with notice of such election within 30 days of BioLine’s firm decision to abandon the patent (and in the case of an existing patent or patent application, at least 30 business days prior to the expiration thereof). BioLine shall then be released from any obligation to bear any costs or expenses in respect of such Abandoned Patent Rights. At the written request of Licensor provided to BioLine within 30 days of the receipt of the foregoing election, BioLine shall cooperate with Licensor, and take actions necessary to transfer responsibility for such payments to Licensor. In such event, any license granted by Licensor to BioLine hereunder with respect to such Abandoned Patent Rights will terminate, and BioLine will have no rights whatsoever to exploit such Abandoned Patent Right. Licensor shall then be free, without further notice or obligation to BioLine, to grant rights in and to such Abandoned Patent Rights to third parties.



4.3. **No Warranty.** Nothing contained herein shall be deemed to be a warranty by any of the parties that they can or will be able to obtain patents on patent applications included in the Licensed Patents, or that any of the Licensed Patents will afford adequate or commercially worthwhile protection.

5. **Development and Project Management.**

5.1. **Development Plan.** The parties hereto have agreed on a plan for the development of Licensed Products, including a related budget, which is incorporated into this Agreement as Exhibit B and which forms an integral part hereof (the “**Development Plan**”). The Development Plan describes (i) the proposed overall program of development, including clinical trials and associated timelines; (ii) timelines for key Regulatory Authority meetings, filing of applications for Regulatory Approval, and receipt of Regulatory Approvals, (iii) the anticipated tasks, responsibilities, and obligations of Licensor and BioLine under the Development Plan, and (iv) an associated estimated budget for all related development costs. In the event of any inconsistency between the Development Plan and this Agreement, the terms of this Agreement shall prevail. The Development Plan addresses the period commencing as of seven days subsequent to the Effective Date and ending upon the completion of the Contemplated Clinical Trials.

5.2. **Performance of Development Plan.** Each of Licensor and BioLine shall perform its respective obligations under the Development Plan in accordance with the terms thereof and cooperate with the other party in order to satisfy the requirements of the Development Plan. In connection with the foregoing, Licensor shall cooperate with BioLine in uploading all data, information, documents and agreements regarding the Drug and the Contemplated Clinical Trials to BioLine’s data management system. In addition, Licensor shall provide BioLine’s project manager with prompt and regular updates concerning the progress of the Contemplated Clinical Trials, as requested by BioLine, including without limitation all data, documentation and results relating to or produced by such trials. BioLine shall designate a project manager who will work with the Licensor’s team in the performance of the Development Plan. Licensor’s team shall provide prompt and regular updates to BioLine’s project manager regarding the progress of the Development Plan, as reasonably requested. The failure of one of the Contemplated Clinical Trials to hew to the schedule set forth in the Development Plan shall not be deemed a breach of this Agreement so long as the applicable party is making reasonable commercial efforts to perform its obligations thereunder.

- 5.3. **Joint Development Committee, Consultation and Progress Reports.** The parties shall establish a joint development committee (the “**Joint Development Committee**” or “**JDC**”) to oversee the development of the Licensed Product according to the Development Plan, the implementation of the Development Plan and the management of the Contemplated Clinical Trials. Each party shall be entitled to designate two representatives to the JDC (each a “**Representative**”). The JDC shall meet no less frequently than monthly, and shall produce in each such meeting a written workplan in respect of the period until the next meeting of the JDC. The Representatives shall be bound by the confidentiality arrangements set out in this Agreement. The parties agree to consult, via their respective Representatives, in respect of material decisions related to the exercise of the License and/or the Licensed Technology and/or Licensed Products. In the context of the JDC, each party shall provide the other party, via their respective Representatives, with quarterly reports which shall summarize the material activities undertaken by such party (or in the case of BioLine, its Affiliates and/or contractors), as applicable, with respect to the Licensed Technology, the Development Plan and/or the Licensed Products during the period which the report covers. All activities and work undertaken by the parties according to this Agreement and the Development Plan shall be fully transparent to the parties. While the parties shall strive to achieve consensus on any material decision regarding the implementation of the development of the Drug (including any matter in respect of the Contemplated Clinical Trials, the Development Plan or any modification thereto) in the event that, after a period of 7 days, the Representatives are unable to reach such consensus on such matters, either party’s Representatives may refer such matter to their respective chief executive officer (or his or her designee) who will be then have 7 days to attempt to resolve such matter with the chief executive officer (or his or her designee) of the other party. In the event that, after such 7 day period, the parties cannot resolve such matter, either party - via such party’s chief executive officer - may refer such matter for definitive resolution to Dr. Aharon Schwartz (or his successor in the position of chairman of the board of BioLine). The dispute resolution mechanism herein shall not apply to change of indication (except in the case of the initial determination of the second indication), material changes to the budget under the Development Plan or changes to the number of patients under the Development Plan. To avoid doubt, subject to the express terms and conditions of this Agreement, as between the parties, BioLine shall be solely responsible for all decisions regarding the commercialization of Licensed Products, and all commercialization and business development activities under the License and with respect to Licensed Products. The Joint Development Committee shall be disbanded on the earlier to occur of (i) the completion of the Development Plan, or (ii) the grant by BioLine of a Sublicense.
- 5.4. **Change of Indication.** The targeted indication of one of the Contemplated Clinical Trials shall be AML (Acute Myeloid Leukemia) and the indication of the second Contemplated Clinical Trial shall be determined as set forth in the Development Plan. In the event BioLine believes that any indication of a trial should be changed, it will promptly notify Licensor and the parties shall make efforts to achieve consensus on a replacement indication. In the event that the parties are unable to reach consensus after a period of 7 days, either of the parties may refer the matter to their respective chief executive officer (or his or her designee) who will be then have 7 days to attempt to resolve the matter with the chief executive officer (or his or her designee) of the other party. In the event that, after such 7 day period, the parties cannot resolve the matter, either party - via such party’s chief executive officer - may refer the matter for definitive resolution by expert determination according to the World Intellectual Property Expert Arbitration Rules. The expert shall be chosen by mutual agreement of the parties within 14 days of the referral of the matter to expert arbitration by one of the parties. The referral to the expert shall not derogate from the parties obligations and rights hereunder.

- 5.5. **No Funding from Licensor; Grants and Government Programs.** The parties hereby agree that, except for compensation to Dr. Irit Avivi and Dr. Arnon Nagler in accordance with Section 6.2.2 below, Licensor shall not be required to provide any funding in connection with this Agreement. Licensor acknowledges and agrees that BioLine may apply for Grants for the funding of the development and commercialization of Licensed Products and Licensor agrees to perform such further acts and execute such further documents as may reasonably be necessary to support the preparation and submission of applications for the aforementioned Grants. Licensor acknowledges and agrees that if BioLine receives Grants with respect to the Licensed Technology or Licensed Products, this Agreement will become subject to the applicable laws and regulations governing such Grants, if any.
- 5.6. **Non-Solicitation.** Each of BioLine and Licensor agrees that during the term of the Development Plan and for a period of 18 months thereafter it shall not recruit the personnel of the other party without such party's written approval.
- 5.7. **Removal of Restrictions.** The parties agree to cooperate in good faith in order to remove any restrictions on Licensor's rights in and to the Drug or Licensed Technology arising from arrangements with Hadasit and Kyoto University, as set forth in **Exhibit C** attached hereto.
- 5.8. **Third Party Agreements; Manufacture.** Licensor shall make all commercial efforts to assign or transfer to BioLine all agreements with third parties concerning the manufacture of the Drug, or any other agreements related to the Drug or the Contemplated Clinical Trials reasonably required or deemed helpful by BioLine in order to perform its obligations under the Development Plan. Licensor represents that it has produced under Good Manufacturing Practices a certain quantity of the Drug. Licensor shall make available to BioLine all amounts of the Drug in its possession or control. BioLine shall use such amounts of the Drug as determined by the JDC. The parties hereby acknowledge that such quantity of the Drug shall not suffice for the performance of the Contemplated Clinical Trials and the Development Plan and that BioLine may independently contract for the manufacture of additional quantities of the Drug, as set forth in the Development Plan.
- 5.9. **Other Projects.** BioLine represents that it has no current projects in the fields of stem cell mobilization, non-Hodgkins lymphomas, and/or acute myeloid leukemia. Until the earlier of (i) the completion of the Development Plan, or (ii) the grant of a Sublicense hereunder, BioLine shall not acquire or continue developing any projects in the fields of non-Hodgkins lymphomas and/or acute myeloid leukemia, except that BioLine may acquire and continue developing any such projects until the commencement of Phase II Clinical Trials for such projects (or any earlier stage). A breach of this Section 5.8 shall be deemed a material breach of this Agreement which shall entitle Licensor to terminate this Agreement pursuant to Section 12.3.2.1.

- 5.10. **Follow-on.** Subsequent to the completion of the Development Plan, (a) BioLine shall continue to have an obligation to make commercially reasonable good faith efforts to commercialize the Drug pursuant to Section 5.11 hereof, and (b) except as expressly set forth herein, Licensor shall have no further right or obligation to perform any matters in respect of the development of the Drug. If BioLine requests that Licensor continue to perform actions in respect of the development of the Drug, the parties shall come to a mutual written agreement regarding the terms and conditions thereof.
- 5.11. **Good Faith Efforts to Develop.** BioLine undertakes to make commercially reasonable good faith efforts to Sublicense or commercialize the Drug for fair consideration.
- 5.12. **Sublicense of Arms Length Basis.** Any Sublicense granted by BioLine hereunder shall be granted on arms length basis.
- 5.13. **Provision of Information.** Licensor shall promptly disclose to BioLine, on an ongoing basis, any material information regarding the Drug including, without limitation, the development thereof and the Contemplated Clinical Trials, arising after the Execution Date of this Agreement of which Licensor becomes aware. In addition, Licensor shall promptly provide to BioLine any information in its possession reasonably requested by BioLine in order to meet its legal obligations as sponsor of the applicable study.

## 6. Fees and Consideration.

- 6.1. *Project Management Fee.* In consideration for Licensor's performance of its obligations pursuant to the Development Plan, BioLine shall pay Licensor a project management fee (the "**Project Management Fee**") as follows:
- 6.1.1. For the initial 12 month period commencing as of the Execution Date, BioLine shall pay Licensor the amount of US \$100,000 per month.
- 6.1.2. Following the aforementioned 12 month period, and continuing until the earlier of (i) the completion of the Contemplated Clinical Trials or (ii) the grant of a Sublicense hereunder, BioLine shall pay Licensor:
- (a) The amount of \$65,000 per month, for a subsequent period of 12 months;
  - (b) Following such subsequent 12 month period and for a period of 6 months, an amount of \$60,000 per month; and
  - (c) Following such 6 month period, an amount of \$50,000 per month.

In the event that both Contemplated Clinical Trials are completed within the applicable Clinical Trial Period as defined in this section, BioLine shall make a one-time payment to Licensor in the amount of \$250,000. "**Clinical Trial Period**" means either (i) 24 months from the Execution Date; or (ii) in the event BioLine contracts or otherwise arranges for the manufacture of the Drug through any party other than Licensor or Novetide, Ltd. (including BioLine itself or any of its Affiliates), a period of 28 months from the Execution Date.

The Project Management Fees set forth above are subject to Licensor's continued employment of both a Chief Medical Director and a VP Regulation and Clinical Affairs as managers of the Contemplated Clinical Trials (each, a "**Trial Manager**"), as provided below: Failure of Licensor, in the event of the termination of the employment of either of the Trial Managers, to hire a replacement with substantially equivalent experience within the Replacement Period shall result in the reduction of the ongoing Project Management Fees by 50% during the period commencing upon the end of the applicable Replacement Period and ending upon the date that a suitable replacement for such Trial Manager has been hired and commenced working. No Project Management Fees shall be paid during the period commencing upon the end of the applicable Replacement Period and ending upon the date that suitable replacements have been hired and commenced working to the extent that the employment of both Trial Managers has been terminated and no suitable replacements have been hired or commenced working. In the event a suitable full-time replacement for the position of VP Regulation and Clinical Affairs has not commenced working within the end of the Replacement Period, the Contemplated Clinical Trials shall be managed by BioLine or its designee until such replacement has commenced working. The "**Replacement Period**" means, with respect to each Trial Manager, the period commencing on the termination of the employment relationship of such Trial Manager and ending on the later of (i) a period of one month later or (ii) three months subsequent to the date that either the Licensor or the Trial Manager gave notice to terminate the employment of such Trial Manager.

6.2. **Development Costs.**

- 6.2.1. *General Costs.* BioLine shall be solely responsible for all development costs incurred pursuant to the budget included as part of the Development Plan, subject to the following provisions. With respect to the implementation of the Development Plan, should Licensor need to contract with or issue purchase orders to third party contractors, suppliers, service providers and institutions involved with the implementation of the Development Plan (for the purpose hereof, such third parties are referred to as "**Third Party Contractors**"), Licensor shall promptly disclose to BioLine such need. The JDC shall determine which party shall act as such Third Party Contractor. If BioLine is reasonably able and prepared to provide the required services, the JDC shall favorably consider BioLine therefor. If the parties shall use a Third Party Contractor that is not BioLine, upon agreement by BioLine of such need for the proposed Third Party Contractor, BioLine (i) shall promptly manage the negotiations with such Third Party Contractor, (ii) shall be the contracting party with such Third Party Contractor, and (iii) shall make payment to such Third Party Contractors.

6.2.2. *Consultants.* Written consulting agreements between Licensor and Dr. Irit Avivi and Dr. Arnon Nagler are currently in effect, both of whom act as consultants to the Licensor in respect of the development of the Drug. Licensor shall be solely responsible for and shall solely bear all costs in respect of any payments to be made to these consultants pursuant to such agreements or otherwise in connection with or as a result of the Development Plan.

6.2.3. *Hadasit Research.* BioLine will make commercially reasonable efforts to reach a binding agreement with Hadasit which shall explicitly permit Professor Amnon Peled to continue his pre-clinical work related to the Drug at Hadassah Medical Organization. Any such agreement shall provide that BioLine shall be responsible for expenses related to the research at Professor Peled's laboratory at Hadasit, and Licensor shall have no responsibility therefor.

6.3. **Payments on Sublicense Receipts.** BioLine shall pay Licensor sublicense fees derived from exploitation of the License as follows:

6.3.1. 60% of Sublicense Receipts where the aggregate amount of investment by BioLine in connection with this Agreement is less than \$3 million; or

6.3.2. 55% of Sublicense Receipts where the aggregate amount of investment by BioLine in connection with this Agreement is \$3 million or more but less than \$7 million; or

6.3.3. 50% of Sublicense Receipts where the aggregate amount of investment by BioLine in connection with this Agreement is \$7 million or more but less than \$12 million; or

6.3.4. 40% of Sublicense Receipts where the aggregate amount of investment by BioLine in connection with this Agreement is \$12 million or more.

The term "aggregate amount of investment by BioLine in connection with this Agreement" shall include all amounts invested by BioLine and/or its Affiliates in the development and commercialization of Licensed Products, including without limitation payments made to Licensor pursuant to Section 6.1.

6.4. BioLine shall assume Licensor's payment obligations to the OCS in respect of grants received and directly attributable to the Licensed Technology, (amounts received by Licensor pursuant to such grants are referring to herein as "**Licensor Grants**"). In the event that BioLine or an Affiliate of BioLine is legally required to make payments to the OCS in respect of Licensor Grants, BioLine may deduct the amount of such Licensor Grants from any payments otherwise due to Licensor in respect of Sublicense Receipts hereunder. In the event amounts payable by BioLine in respect of Licensor Grants exceeds amounts otherwise payable by BioLine to Licensor hereunder, the excess amount of Licensor Grants otherwise deductible shall be deferred and deducted from future payments by BioLine to Licensor in respect of Sublicense Receipts hereunder. Subject to the foregoing right of BioLine to deduct such amounts from Sublicense Receipts, Licensor shall not be obligated to make any payments to BioLine in respect of amounts paid by BioLine in respect of Licensor Grants.

- 6.5. BioLine may not make deduction or offsets from payments to Licensor except as expressly provided in this Agreement.
- 6.6. The parties agree that if BioLine is legally required to make payments to third parties, where such payments are required as a result of such third parties providing Grants to BioLine for research and development activities relating to the Licensed Technology (including payments due to the OCS as a result of BioLine's receipt of funds from the OCS), such amounts shall be paid for solely by BioLine from its share of Sublicense Receipts and it shall not be entitled to offset such payments to third parties from amounts due to Licensor hereunder.
- 6.7. **Royalty Payments.** In the event that BioLine itself or any of its Affiliates or any entity on their behalf (excluding a Sublicensee) will actually manufacture and/or sell Licensed Products under the license granted in this Agreement, then BioLine will pay to Licensor royalties on Net Sales on a Licensed Product-by-Licensed Product and country-by-country basis until the later of (i) last to expire of any patent included within the Licensed Technology in such country or (ii) the availability in a country of a product competitive with a Licensed Product, at the following rates:
- 6.7.1. 12% where the aggregate amount of investment by BioLine in connection with this Agreement is less than \$12 million; or
- 6.7.2. 10% where the aggregate amount of investment by BioLine in connection with this Agreement is or exceeds \$12 million.

The term "aggregate amount of investment by BioLine in connection with this Agreement" shall have the meaning set forth in Section 6.3.

- 6.8. **Third Party Royalty Payments.** In the event that BioLine or an Affiliate of BioLine is legally required to make royalty payments, at fair market terms after arms' length negotiations, to one or more third parties to obtain a Third Party License from such third party(ies) in order to practice the Licensed Technology in a particular country, BioLine may offset such third-party payments against the royalty payments that are due to Licensor pursuant to Section 6.7 with respect to sales in such country.

- 6.9. **Combination Products.** Notwithstanding anything to the contrary set forth herein, in the event either (a) a Licensed Product is sold by BioLine or an Affiliate of BioLine, or any entity on their behalf, in the form of a Combination Product or (b) the grant of a Sublicense hereunder is part of a larger transaction also involving the grant by BioLine (or its Affiliates) of sublicenses in respect of Additional Ingredients for a Combination Product, then Net Sales and Sublicense Receipts, as applicable, from such Combination Product, for purposes of determining payments hereunder, shall be determined by multiplying the actual Net Sales or Sublicense Receipts, as applicable, of such Combination Product during the applicable royalty reporting period, by the fraction  $A/(A+B)$  where: "A" is the average sale price of the Licensed Product contained in the Combination Product when sold separately by such entity; and "B" is the average price of the other Additional Ingredients included in the Combination Product when sold separately by its supplier, in each case during the applicable royalty reporting period or if sales of both the Licensed Product and/or other Additional Ingredients did not occur in such period, then in the most recent royalty reporting period in which sales of both occurred. In the event that such average sale price cannot be determined for both the Licensed Product and all other Additional Ingredients included in the Combination Product, then Net Sales or Sublicense Receipts, as applicable, for the purpose of determining royalty payments shall be calculated by multiplying the Net Sales or Sublicense Receipts, as applicable, of the Combination Products by the fraction of  $C/(C+D)$  where "C" is the fair market value of the Licensed Product; and "D" is the fair market value of all other Additional Ingredients included in the Combination Product. In such event, the parties shall negotiate in good faith to arrive at a determination of the respective fair market values of the Licensed Product and all other Additional Ingredients included in the Combination Product. Nothing in this section shall be interpreted as limiting or otherwise affecting Licensor's ownership rights in the Licensed Technology as set forth in Section 3.1.
- 6.10. **Payment in the Event of an M&A Transaction.** In the event BioLine effects an M&A Transaction, within 30 days from the closing date of such M&A Transaction (or earlier) the Licensor may request in writing that the parties shall make good faith efforts to determine the portion of the purchase price in such M&A Transaction which is attributable to the Licensed Technology (the "**Relative Value**"), and to the extent the parties cannot agree thereto, such Relative Value shall be determined by a third-party independent appraiser jointly appointed by the parties. In such event, within thirty (30) days from the day that the parties determine the Relative Value pursuant to the procedure set forth herein, BioLine shall pay to Licensor a percentage of the Relative Value in accordance with the payment schedule in Section 6.4 (as if the Relative Value was Sublicense Receipts). Any amounts payable by BioLine in respect of the Relative Value shall be deducted from future payments by BioLine to Licensor hereunder.
- 6.11. **Reversal of Parties Rights' and Obligations.** Notwithstanding anything to the contrary set forth in this Agreement, in the event that, within 24 months from the completion of the Development Plan (the "**Reversal Date**"), BioLine: (a) has not granted a Sublicense to any third party, in an arm's length good faith transaction, and is not diligently pursuing such a transaction (ie, has signed a non-binding term sheet with a potential Sublicensee or a potential Sublicensee is actively performing due diligence with respect to the Licensed technology), and (b) is not commercializing the Drug (i.e., has presented a development plan and is diligently and substantively executing the same) then, upon written notice by Licensor which must be given within 7 days of the Reversal Date, all of BioLine's rights and responsibilities with respect to commercialization of the Licensed Products shall revert to Licensor, *provided however* that (a) Licensor shall have no further obligation to commercialize the Drug and (b) Licensor shall assume all of BioLine's rights and obligations with respect to OCS and other Grants (including Grants of Licensor previously assumed by BioLine hereunder), *mutatis mutandis*. In such event, BioLine's obligation to pay Sublicense Receipts and royalty payments hereunder shall pass from BioLine to Licensor, such that Licensor will make such payments to BioLine in the same manner, amounts and times as BioLine would have been required to make payments to Licensor hereunder, *mutatis mutandis*.



**7. Reports; Payments; Records.**

**7.1. Reports.**

7.1.1. Commencing upon the Effective Date, BioLine shall deliver to Licensor, within 10 days after the end of each Calendar Quarter, a report regarding the efforts undertaken by BioLine to commercialize the Licensed Products and any further information reasonably requested by Licensor with respect thereto.

7.1.2. Commencing with the first Calendar Quarter in which BioLine, any party acting on its behalf, a Sublicensee or an Affiliate of BioLine first receives Net Sales or Sublicense Receipts, as the case may be, BioLine shall deliver to Licensor within 60 days after the conclusion of each Calendar Quarter, a report containing the following information:

(a) the number of units of Licensed Products sold by BioLine or any party acting on its behalf, its Affiliates or a Sublicensee in each country for the applicable Calendar Quarter;

(b) the gross amount billed for the Licensed Product sold by BioLine or any party acting on its behalf, its Affiliates or a Sublicensee in each country during the applicable Calendar Quarter;

(c) a calculation of Net Sales for the applicable Calendar Quarter in each country, including a listing of applicable deductions;

(d) the total amount payable to Licensor in U.S. dollars on Net Sales for the applicable Calendar Quarter, together with the exchange rates used for conversion; and

(e) a calculation of any Sublicense Receipts for the applicable Calendar Quarter.

The report shall state if no amounts are due to Licensor for any Calendar Quarter.

7.2. **Payment.** Concurrent with the delivery of each report delivered pursuant to Section 7.1.2, BioLine shall remit to Licensor all amounts due pursuant to Section 6 for the applicable Calendar Quarter.

- 7.3. **Records.** BioLine shall maintain, and shall cause anyone acting on its behalf, its Affiliates and Sublicensees to maintain, complete and accurate records of Licensed Products that are made, used, marketed or sold under this Agreement, any amounts payable to Licensor in relation to such Licensed Products and all Sublicense Receipts received by BioLine, anyone acting on its behalf and its Affiliates, which records shall contain sufficient information to permit the Licensor to confirm the accuracy of any reports or notifications delivered to Licensor under Section 7.1. The relevant party shall retain such records relating to a given Calendar Quarter for at least 3 years after the conclusion of that Calendar Quarter. During such 3 year period, Licensor shall have the right, at Licensor's expense, to cause an independent, certified public accountant, who is bound by a suitable confidentiality arrangement with BioLine, to inspect BioLine's or its Affiliates' records during normal business hours for the sole purpose of verifying any reports and payments delivered under this Agreement. Such accountant shall not disclose to Licensor or any third party any information gained during the course of such inspection, except that such accountant may disclose to Licensor and BioLine information gained during the course of such inspection relating to the accuracy of reports and payments delivered under this Agreement. The parties shall reconcile any underpayment or overpayment within 30 days after the accountant delivers the results of the audit. In the event that any audit performed under this Section 7.3 reveals an underpayment in excess of 5% in any calendar year, the audited party shall bear the full cost of such audit. Licensor may exercise its rights under this Section 7.3 only once every year per audited party and only with reasonable prior notice to the audited party. BioLine shall cause its Affiliates to comply with the terms of this Section 7.3.
- 7.4. **Audited Report.** BioLine shall furnish Licensor, and shall cause anyone acting on its behalf, its Affiliates or Sublicensees who make, use, market or sell Licensed Products to furnish Licensor, within 90 days after the end of each calendar year, commencing at the end of the calendar year of the First Commercial Sale, with a report, certified by an independent certified public accountant, relating to royalties and other payments due to Licensor pursuant to this Agreement in respect of the previous calendar year and containing the same details as those specified in Section 7.1.2 in respect of the previous calendar year.
- 7.5. **Payment Method.** Each payment due to Licensor under this Agreement shall be made by wire transfer of funds to Licensor's accounts in accordance with written instructions provided by Licensor.
- 7.6. **Withholding and Similar Taxes.** If applicable laws require that taxes be withheld from any amounts due to Licensor under this Agreement, BioLine shall (a) deduct these taxes from the remittable amount, (b) pay the taxes to the proper taxing authority, and (c) promptly deliver to Licensor a statement including the amount of tax withheld and justification therefore, and such other information as may be necessary for tax credit purposes; *provided* that Licensor may provide BioLine with a tax withholding exemption acceptable to the Israeli Tax Authority, in which case BioLine shall not make such deductions. For the avoidance of doubt, all amounts to be paid to Licensor pursuant to this Agreement are exclusive of Value Added Tax. BioLine shall add value added tax, as required by law, to all such amounts.

## 8. Confidential Information

### 8.1. Confidentiality.

- 8.1.1. *Licensor Confidential Information.* BioLine agrees that, without the prior written consent of Licensor, in each case, during the term of this Agreement and for a period of 5 years from date of disclosure, it will keep confidential, and not disclose or use Licensor Confidential Information (as defined below) other than for the purposes of this Agreement. BioLine shall treat such Licensor Confidential Information with the same degree of confidentiality as it keeps its own confidential information, but in all events no less than a reasonable degree of confidentiality. BioLine may disclose the Licensor Confidential Information only (a) to employees and consultants of BioLine or of its Affiliates or Sublicensees who have a “need to know” such information in order to enable BioLine to exercise its rights or fulfill its obligations under this Agreement and are legally bound by agreements which impose confidentiality and non-use obligations comparable to those set forth in this Agreement, and (b) to actual and potential business partners, collaborators, investors, contractors, service providers and consultants, *provided, however*, in each case, that such recipient of Confidential Information first enters into a legally binding agreement with BioLine which (i) imposes confidentiality and non-use obligations with respect to Confidential Information comparable to those set forth in this Agreement; and (ii) has a minimum term of 5 years from date of signature of the binding agreement. For purposes of this Agreement, “**Licensor Confidential Information**” means any scientific, technical, trade or business information relating to the subject matter of this Agreement designated as confidential or which otherwise should reasonably be construed under the circumstances as being confidential disclosed by or on behalf of the Licensor or any of its employees, researchers or students to BioLine, whether in oral, written, graphic or machine-readable form, except to the extent such information: (i) was known to BioLine at the time it was disclosed, other than by previous disclosure by or on behalf of the Licensor or any of its employees, researchers to students, as evidenced by BioLine’s written records at the time of disclosure; (ii) is at the time of disclosure or later becomes publicly known under circumstances involving no breach of this Agreement, as evidenced by BioLine’s written records at the time of disclosure; (iii) is lawfully and in good faith made available to BioLine by a third party who is not subject to obligations of confidentiality to the Licensor with respect to such information, as evidenced by BioLine’s written records at the time of disclosure; or (iv) is independently developed by BioLine without the use of or reference to the Licensor Confidential Information, as demonstrated by documentary evidence.
- 8.1.2. *BioLine Obligation to Take Action.* In the event of a breach or threatened breach of any confidentiality agreement between BioLine and a third party relating to Licensor Confidential Information, that has or is likely to have, in Licensor’s reasonable opinion, a material adverse effect on Licensor’s business, BioLine shall, at the written request of Licensor and at Licensor’s expense, use commercial efforts to obtain an injunction or other similar equitable relief in order to prevent such disclosure of Licensor Confidential Information.

- 8.1.3. *BioLine Confidential Information.* Licensor agrees that, without the prior written consent of BioLine, in each case, during the term of this Agreement and for 5 years thereafter, it will keep confidential, and not disclose or use BioLine Confidential Information (as defined below) other than for the purposes of this Agreement. Licensor shall treat such BioLine Confidential Information with the same degree of confidentiality as it keeps its own confidential information, but in all events no less than a reasonable degree of confidentiality. Licensor may disclose the BioLine Confidential Information only to employees and consultants of Licensor or of its Affiliates who have a “need to know” such information in order to enable Licensor to exercise its rights or fulfill its obligations under this Agreement and are legally bound by agreements which impose confidentiality and non-use obligations comparable to those set forth in this Agreement. For purposes of this Agreement, “**BioLine Confidential Information**” means any scientific, technical, trade or business information relating to the subject matter of this Agreement designated as confidential or which otherwise should reasonably be construed under the circumstances as being confidential disclosed by or on behalf of BioLine pursuant to this Agreement, whether in oral, written, graphic or machine-readable form, except to the extent such information: (i) was known to Licensor at the time it was disclosed, other than by previous disclosure by or on behalf of BioLine as evidenced by Licensor’s written records at the time of disclosure; (ii) is at the time of disclosure or later becomes publicly known under circumstances involving no breach of this Agreement, as evidenced by Licensor’s written records at the time of disclosure; (iii) is lawfully and in good faith made available to Licensor by a third party who is not subject to obligations of confidentiality to BioLine with respect to such information, as evidenced by Licensor’s written records at the time of disclosure; or (iv) is independently developed by Licensor without the use of or reference to the BioLine Confidential Information, as demonstrated by documentary evidence.
- 8.1.4. *Licensor’s Obligation to Take Action.* In the event of a breach or threatened breach of any confidentiality agreement between Licensor and a third party relating to BioLine Confidential Information, that has or is likely to have, in BioLine’s reasonable opinion, a material adverse effect on BioLine’s business, Licensor shall, at the written request of BioLine and at BioLine’s expense, use commercial efforts to obtain an injunction or other similar equitable relief in order to prevent such disclosure of BioLine Confidential Information.
- 8.2. *Disclosure of Agreement.* Each party may disclose this Agreement to the extent required, in the reasonable opinion of such party’s legal counsel, to comply with applicable laws, as well as to prospective Sublicensees and prospective and current investors, pursuant to appropriate non-disclosure arrangements. If a party discloses this Agreement or any of the terms hereof in accordance with this Section 8.2, such party agrees, at its own expense, to seek confidential treatment of portions of this Agreement or such terms, as may be reasonably requested by the other party.

- 8.3. *Publicity.* Without derogating from Section 8.2, each party whose share capital is publicly traded on a recognized stock exchange may make announcements, publications, presentations and similar disclosures (i) relating to the general subject matter of this Agreement, (ii) in connection with the marketing or sale of any Licensed Products, (iii) in respect of the progress of the exercise of the License, or (iv) as necessary or required under applicable laws and regulations, including Israeli and other applicable securities laws and the regulations of the Tel-Aviv Stock Exchange and other applicable exchanges. Except as provided in the immediately preceding sentence, neither party will make any public announcement regarding this Agreement without the prior written approval of the other party.
- 8.4. *Publications.* Commencing upon the Execution Date, Licensor shall not, nor permit any third party, to make any presentation or publication in connection with or related to the Drug or the Contemplated Clinical Trials, except in connection with the terms and conditions of this Section. Licensor shall provide manuscripts, abstracts, or the full text of any other intended disclosure (including without limitation a poster presentation, invited speaker or guest lecturer presentation) ("**Notice**") to BioLine at least 90 days before they are submitted for publication or otherwise disclosed ("**Notice Period**"); provided that this Section 8.4 shall not apply to publications submitted prior to the Execution Date but published thereafter. BioLine shall review any such disclosure to ensure that no action is required to protect any intellectual property rights or other Confidential Information included in such disclosure. In any event, no such disclosure shall be made without the prior written consent of BioLine. Licensor shall ensure that no disclosure approved by BioLine shall include any BioLine Confidential Information or Licensor Confidential Information. This Section 8.4 shall expire to the extent this Agreement does not come into effect in accordance with Section 2 hereof.

## 9. **Infringement.**

### 9.1. **Enforcement of Licensed Technology.**

- 9.1.1. *Notice.* In the event any party becomes aware of any possible or actual infringement or unauthorized possession, knowledge or use of any Licensed Technology (collectively, an "**Infringement**"), that party shall promptly notify the other party and provide it with details regarding such Infringement.
- 9.1.2. *Suit by BioLine.* BioLine shall have the right, but not the obligation, to take action in the prosecution, prevention, or termination of any Infringement. Should BioLine elect to bring suit against an infringer and Licensor is joined as party plaintiff in any such suit, Licensor shall have the right to approve the counsel selected by BioLine to represent BioLine and Licensor, such approval not to be unreasonably withheld. The expenses of such suit or suits that BioLine elects to bring, including any reasonable expenses of Licensor incurred in conjunction with actions requested by BioLine in connection with the prosecution of such suits or the settlement thereof, shall be paid for entirely by BioLine and BioLine shall hold Licensor free, clear and harmless from and against any and all costs of such litigation, including reasonable attorneys' fees. BioLine shall not compromise or settle such litigation without the prior written consent of Licensor, which consent shall not be unreasonably withheld or delayed. In the event BioLine exercises its right to sue pursuant to this Section 9.1.2, it shall first reimburse itself out of any sums recovered in such suit or in settlement thereof for all costs and expenses of every kind and character, including reasonable attorneys' fees, necessarily involved in the prosecution of any such suit. If, after such reimbursement, any funds shall remain from said recovery, then Licensor shall receive an amount equal to what would be due to Licensor if such remaining amount were considered as Sublicense Receipts pursuant to Section 6.4 above.

- 9.1.3. *Suit by Licensor.* If BioLine does not take action in the prosecution, prevention, or termination of any Infringement pursuant to Section 9.1.2 above, and has not commenced negotiations with the infringer for the discontinuance of said Infringement, within 90 days after receipt of notice to BioLine by Licensor of the existence of an Infringement, Licensor may elect to do so. Should Licensor elect to bring suit against an infringer and BioLine is joined as party plaintiff in any such suit, BioLine shall have the right to approve the counsel selected by Licensor to represent Licensor and BioLine, such approval not to be unreasonably withheld. The expenses of such suit or suits that Licensor elects to bring, including any reasonable expenses of BioLine incurred in conjunction with actions requested by Licensor in connection with the prosecution of such suits or the settlement thereof, shall be paid for entirely by Licensor and Licensor shall hold BioLine free, clear and harmless from and against any and all costs of such litigation, including reasonable attorneys' fees. Licensor shall not compromise or settle such litigation without the prior written consent of BioLine, which consent shall not be unreasonably withheld or delayed. In the event Licensor exercises its right to sue pursuant to this Section 9.1.3, all reimbursement due to such actions shall be retained by Licensor.
- 9.1.4. *Own Counsel.* Each party shall always have the right to be represented by counsel of its own selection and at its own expense in any suit instituted under this Section 9 by another party for Infringement.
- 9.1.5. *Cooperation.* Each party agrees to cooperate fully in any action under this Section 9 which is controlled by another party, provided that the controlling party reimburses the cooperating party promptly for any costs and expenses incurred by the cooperating party in connection with providing such assistance.
- 9.1.6. *Standing.* If a party lacks standing and the other party has standing to bring any such suit, action or proceeding, then such other party shall do so at the request of and at the reasonable expense of the requesting party. If a party determines that it is necessary or desirable for the other party to join any such suit, action or proceeding, the other party shall execute all papers and perform such other acts as may be reasonably required in the circumstances.

9.2. **Legal Action against a Party.** Each party will provide the other party with prompt written notice of any action, suit or proceeding brought against it, alleging the infringement of the intellectual property rights of a third party by reason of the discovery, development, manufacture, use, sale, importation, or offer for sale of a Licensed Product or otherwise due to the use or practice of the Licensed Technology.

## 10. Representations and Warranties; Limitation of Liability.

10.1. **Representations and Warranties.** Licensor hereby represents and warrants that (i) it has sole and exclusive ownership of the patents and/or patent applications listed in **Exhibit A** attached hereto and all right, title and interest in and to the Drug; (ii) except as set forth on **Exhibit C** attached hereto, it has not granted any rights in or to Licensed Technology or the Drug that are inconsistent with the rights granted to BioLine under this Agreement or that would in any manner impact on or affect the performance of the parties' respective obligations under this Agreement; (iii) it has the right to grant the License granted pursuant to this Agreement, and the right and ability to supply the Drug for the purpose of implementing the Development Plan, free and clear of any restrictions (including any third party rights or claims); (iv) all quantities of the Drug currently in the possession of Licensor have been manufactured at the GMP level; (v) it has disclosed to BioLine all material information regarding the Drug in its possession or control and has disclosed to BioLine the existence of any material information regarding the Drug of which it is has knowledge (including preclinical, clinical, legal and regulatory information), including without limitation all documents, agreements and data in its possession or control in respect of the Drug and the Contemplated Clinical Trials; and (vi) it has no knowledge of any legal claims, demands, threats or proceeding of any sort by any third party against the Licensor contesting the ownership or validity of the Licensed Technology, or claiming that the practice of the Licensed Technology or the Drug in the manner contemplated by this Agreement (including the performance of the Development Plan and the manufacture of the Drug) would infringe the rights of such third party, nor any reason to expect the same. Licensor further undertakes not to transfer, assign, grant rights to, sell, lease or otherwise dispose of or encumber the Licensed Technology, or permit any third party to use the Drug other than as may be expressly permitted in this Agreement.

10.2. **Termination of Certain Agreements.** Licensor hereby represents and warrants that the notice period under certain agreements of Licensor are set forth in **Exhibit D**.

- 10.3. **Compliance with Law.** BioLine undertakes that it will comply with applicable laws and regulations relating to the development, manufacture, use, and sale of Licensed Products.
- 10.4. **No Warranty.** Except as otherwise expressly provided in this Agreement, neither party makes any representation or warranty, express or implied, with respect to any technology, patents, goods, services, rights or other subject matter of this Agreement, and each party hereby disclaims warranties of merchantability, fitness for a particular purpose and non-infringement with respect to any and all of the foregoing.
- 10.5. **Limitation of Liability.** Notwithstanding anything else in this Agreement or otherwise, neither Licensor nor BioLine will be liable to the other with respect to any subject matter of this Agreement under any contract, negligence, strict liability or other legal or equitable theory for (i) any indirect, incidental, consequential or punitive damages or lost profits or (ii) cost of procurement of substitute goods, technology or services.

11. **Indemnification; Insurance.**

11.1. **Indemnity in Favor of Licensor.**

11.1.1. BioLine shall indemnify, defend, and hold harmless Licensor, its directors, officers, employees and agents and their respective successors, heirs and assigns (the "**Licensor Indemnitees**"), from and against any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon any of the Licensor Indemnitees in connection with any claims, suits, actions, demands or judgments ("**Claims**") arising out of any theory of liability (including without limitation actions in the form of tort, warranty, or strict liability and regardless of whether such action has any factual basis) concerning (i) the use of any Licensed Technology by BioLine, or any of its Affiliates or Sublicensees, or (ii) any product, process, or service that is made, used, or sold pursuant to any right or license granted by Licensor to BioLine under this Agreement (except in cases where, and to the extent that, such Claims fall within the scope of the indemnity in favor of BioLine pursuant to Section 11.2 below).

11.1.2. **Procedures.** If any Licensor Indemnitee receives notice of any Claim, Licensor shall, as promptly as is reasonably possible, give BioLine written notice of such Claim; *provided, however*, that failure to give such notice promptly shall only relieve BioLine of any indemnification obligation it may have hereunder to the extent such failure materially prejudices the ability of BioLine to respond to or to defend the Licensor Indemnitee against such Claim. Licensor and BioLine shall consult and cooperate with each other regarding the response to and the defense of any such Claim and BioLine shall, upon its acknowledgment in writing of its obligation to indemnify the Licensor Indemnitee, be entitled to and shall assume the defense or represent the interests of the Licensor Indemnitee in respect of such Claim, that shall include the right to select and direct legal counsel and other consultants to appear in proceedings on behalf of the Licensor Indemnitee and to propose, accept or reject offers of settlement, all at its sole cost; *provided, however*, that where any such settlement impacts upon any of Licensor's rights, involves any admission of wrong-doing by Licensor or any of the Licensor Indemnitees, or involves any other obligation or undertaking on the part of Licensor or any of the Licensor Indemnitees, Licensor's written consent shall be required, such consent not to be unreasonably withheld. Nothing herein shall prevent the Licensor Indemnitee from retaining its own counsel and participating in its own defense at its own cost and expense.



11.2. **Indemnity in Favor of BioLine.**

- 11.2.1. Licensor shall indemnify, defend, and hold harmless BioLine, its directors, officers, employees and agents and their respective successors, heirs and assigns (the “**BioLine Indemnitees**”), from and against any liability, damage, loss, or expense (including reasonable attorneys’ fees and expenses of litigation) incurred by or imposed upon any of the BioLine Indemnitees in connection with any Claims arising out of any theory of liability (including without limitation actions in the form of tort, warranty, or strict liability and regardless of whether such action has any factual basis) to the extent such Claims result from or are based on the gross negligence or willful misconduct on the part of any of the Licensor Indemnitees with respect to the Licensed Technology or the performance of the Contemplated Clinical Trials, or a breach of the Licensor’s representations, warranties or undertakings pursuant to Section 10.1 above.
- 11.2.2. **Procedures.** If any BioLine Indemnitee receives notice of any Claim, BioLine shall, as promptly as is reasonably possible, give Licensor written notice of such Claim; *provided, however*, that failure to give such notice promptly shall only relieve Licensor of any indemnification obligation it may have hereunder to the extent such failure materially prejudices the ability of Licensor to respond to or to defend the BioLine Indemnitee against such Claim. BioLine and Licensor shall consult and cooperate with each other regarding the response to and the defense of any such Claim and Licensor shall, upon its acknowledgment in writing of its obligation to indemnify the BioLine Indemnitee, be entitled to and shall assume the defense or represent the interests of the BioLine Indemnitee in respect of such Claim, that shall include the right to select and direct legal counsel and other consultants to appear in proceedings on behalf of the BioLine Indemnitee and to propose, accept or reject offers of settlement, all at its sole cost; *provided, however*, that where any such settlement impacts upon any of BioLine’s rights, involves any admission of wrong-doing by BioLine or any of the BioLine Indemnitees, or involves any other obligation or undertaking on the part of BioLine or any of the BioLine Indemnitees, BioLine’s written consent shall be required, such consent not to be unreasonably withheld. Nothing herein shall prevent the BioLine Indemnitee from retaining its own counsel and participating in its own defense at its own cost and expense.

11.3. **Insurance.** Each party shall maintain appropriate insurance that is customary in the biotechnology industry to cover the activities under this Agreement and the Development Plan, provided that the costs of obtaining an insurance policy covering the Licensor's activities under the Development Plan shall be paid for solely by BioLine.

12. **Term and Termination.**

12.1. **Term.** The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Section 12, shall continue in full force and effect on a Licensed Product-by-Licensed Product and country-by-country basis until the expiration of all payment obligations pursuant to Section 6 for such Licensed Product.

12.2. **Effect of Expiration.** Following the expiration of this Agreement pursuant to Section 12.1 on a Licensed Product-by-Licensed Product and country-by-country basis (and provided the Agreement has not been earlier terminated pursuant to Section 12.3, in which case Section 12.4.1 shall apply), BioLine shall have a royalty-bearing, non-exclusive, worldwide license under the same terms stated above in Section 2 (with the right to grant sublicenses) under the Licensed Technology to research, have researched, develop, have developed, manufacture, have manufactured, use, market, distribute, offer for sale, sell, have sold, export and import Licensed Products and/or provide services relating thereto. In addition, following any expiration as aforesaid, each party will return to the other party, or destroy or have destroyed any Confidential Information of the other party.

12.3. **Termination.**

12.3.1. *Termination without Cause.* BioLine may terminate this Agreement upon 90 days prior written notice to Licensor.

12.3.2. *Termination for Default.*

12.3.2.1. In the event that BioLine commits a material breach of its obligations under this Agreement and fails to cure that breach within 30 days after receiving written notice thereof from Licensor, Licensor may terminate this Agreement immediately upon written notice to BioLine. Notwithstanding the foregoing, in the event that any breach is not susceptible of cure within the stated period and BioLine uses diligent good faith efforts to cure such breach, the stated period will be extended by an additional 30 days.

12.3.2.2. In the event that Licensor commits a material breach of its obligations under this Agreement and fails to cure that breach within 30 days after receiving written notice thereof from BioLine, BioLine may terminate this Agreement immediately upon written notice to Licensor. Notwithstanding the foregoing, in the event that any breach is not susceptible of cure within the stated period and Licensor uses diligent good faith efforts to cure such breach, the stated period will be extended by an additional 30 days.

12.3.3. *Bankruptcy.*

- 12.3.3.1. Either BioLine or Licensor may terminate this Agreement upon notice to the other if the other party becomes insolvent, is adjudged bankrupt, applies for judicial or extra-judicial settlement with its creditors, makes an assignment for the benefit of its creditors, voluntarily files for bankruptcy or has a receiver or trustee (or the like) in bankruptcy appointed by reason of its insolvency, or in the event an involuntary bankruptcy action is filed against the other party and not dismissed within 90 days, or if the other party becomes the subject of liquidation or dissolution proceedings (other than in the context of a solvent internal restructuring), admits in writing its inability to pay its debts or otherwise discontinues business.
- 12.3.3.2. Notwithstanding the foregoing, in the event a receiver or trustee (or the like) is appointed or either party has entered into a settlement with its creditors and the other party is otherwise meeting its obligations pursuant to this Agreement, and such trustee (or the like) or creditors assume all the obligations set forth in this Agreement, this Agreement may not be terminated as contemplated under Section 12.3.3.1 during such period as long as it is not breached in any way or manner.
- 12.3.4. *Termination Prior to Effective Date.* Notwithstanding anything to the contrary in this Article 12, either party may terminate this Agreement following a response from the OCS and each party's discharge of its obligations under Section 2, with no liability to the other party, if (i) such party exercises its right to withhold agreement to modifications to the Execution Date Agreement in accordance with Section 2.1(c); or (ii) the OCS does not grant its consent to the Execution Date Agreement or a modified Execution Date Agreement, as such modified Execution Date Agreement and the process for modification are described in Section 2.1. The provisions of Section 8.1 and this Section 12.3.4 shall survive such termination, but all other terms, provisions, representations, rights and obligations contained in this Agreement shall terminate.

12.4. **Effect of Termination.**

- 12.4.1. *Termination of Rights.* Upon termination by BioLine pursuant to Section 12.3.1, 12.3.2.2 or 12.3.3 hereof (except in the circumstances set out in Section 12.3.3.2), or by Licensor pursuant to Sections 12.3.2.1 or 12.3.3 hereof (except in the circumstances set out in Section 12.3.3.2): (a) the rights and licenses granted to BioLine under Section 2 shall terminate; (b) subject to the assumption by Licensor of all of BioLine's obligations to the OCS, including BioLine's obligations pursuant to the Licensor Grants, as contemplated in Section 6.4, all rights in and to the Licensed Technology and any documents concerning work performed under the Development Plan or intellectual property developed by Licensor (including under the Development Plan) shall revert to Licensor, and BioLine shall not be entitled to make any further use whatsoever of the Licensed Technology or such documents nor shall BioLine research, develop, manufacture, use, market, distribute, offer for sale, sell, export or import Licensed Products and/or provide services relating thereto; and (c) any existing agreements that contain a sublicense of the Licensed Technology shall terminate to the extent of such sublicense; subject to Section 2.3.3.2; and *provided further*, that such terms shall be amended, if necessary, to the extent required to ensure that such sublicense agreement does not impose any obligations or liabilities on Licensor which are not included in this Agreement. Licensor's consent to such Sublicensee request shall not be unreasonably withheld. In addition, following any termination as aforesaid, each party will return or cause to be returned to the other party, or destroy or have destroyed any Confidential Information of the other Party, and without limiting the foregoing, BioLine shall make commercially reasonable efforts to deliver to Licensor any documents or other materials relating to work performed under the Development Plan or to business development or commercial contacts with respect to the Licensed Technology or Licensed Products. A recipient of Confidential Information shall however be entitled to retain one copy of the Confidential Information in its legal files for the purpose of determining its obligations under this Agreement. BioLine and its Affiliates shall discontinue any manufacture, distribution or use of the Licensed Technology, including in relation to the Licensed Product.
- 12.4.2. *New Developments.* Upon termination of this Agreement, except by reason of a material breach of this Agreement by Licensor, and, except for termination by reason of a material breach by BioLine, subject to the assumption by Licensor of all of BioLine's obligations to the OCS (including BioLine's obligations pursuant to the Licensor Grants) BioLine will grant Licensor an exclusive, royalty-bearing license under BioLine's rights in any New Developments solely to develop, make and have made, market, offer for sale, sell and import Licensed Products (a "**BioLine License**"). If Licensor or its Affiliates thereafter either receive consideration in respect of Licensed Products or grants a sublicense under the BioLine License, Licensor shall make payment to BioLine of 30% of all of Licensor's Net Proceeds. "**Net Proceeds**" means all net consideration (but not including Grants) received by Licensor (or its Affiliates) in connection with a BioLine License, it being clarified that for the purpose hereof, net consideration shall mean Net Sales (as defined above in Article 1), *mutatis mutandis*.
- 12.4.3. *Accruing Obligations.* Termination of this Agreement shall not relieve the parties of obligations occurring prior to such termination, including obligations to pay amounts accruing hereunder up to the date of termination.

12.5. **Survival.** The parties' respective rights, obligations and duties under Sections 8, 10, 11, 12, and 13, as well as any rights, obligations and duties which by their nature extend beyond the expiration or termination of this Agreement, shall survive any expiration or termination of this Agreement including any obligation to pay any fees due to Licensor, arising from the provisions of this Agreement, and being received following termination or expiration.

13. **Miscellaneous.**

13.1. **Entire Agreement.** This Agreement is the sole agreement with respect to the subject matter hereof and except as expressly set forth herein or otherwise agreed between the parties in writing, supersedes all other agreements and understandings between the parties with respect to same.

13.2. **Notices.** Unless otherwise specifically provided, all notices required or permitted by this Agreement shall be in writing and may be delivered personally, or may be sent by facsimile, email or certified mail, return receipt requested, to the following addresses, unless the parties are subsequently notified of any change of address in accordance with this Section 13.2:

If to BioLine:           BioLineRx Ltd.  
                                  19 Hartum Street  
                                  P.O. Box 45158  
                                  Jerusalem 91450  
                                  Israel  
                                  Attention: Chief Financial Officer  
                                  Fax: +972-2-548-9101  
                                  Email: phils@biolinerx.com

With a copy               General Counsel  
(which shall              BioLineRx Ltd.  
not                            Same address and fax number as above  
constitute  
notice) to:

If to the                    Biokine Therapeutics Ltd.  
Licensor:                   Weizmann Science Park  
                                  Building 13A, Einstein Street  
                                  POB 2213, Rehovot, 76120, Israel  
                                  Attention: Chief Executive Officer  
                                  Fax: +972-8-930-1016  
                                  Email: office@biokine.com

With a copy                Meitar Liquornik Geva & Leshem Brandwein, Law Offices  
(which shall              16 Abba Hillel Rd. Ramat Gan 52506, Israel  
not                            Attention: Hodiya Schnider, Adv.  
constitute                 Fax: +972-3-610-3111  
notice) to:                 Email: hodiyas@meitar.com

Any notice shall be deemed to have been received as follows: (i) by personal delivery, upon receipt; (ii) by facsimile or email, receipt confirmed, one business day after transmission or dispatch; (iii) by airmail, 3 business days after delivery to the postal authorities by the party serving notice.

**13.3. Governing Law and Dispute Resolution.**

- 13.3.1. This Agreement shall be governed by and construed in accordance with the laws of the State of Israel, without regard to the application of principles of conflicts of law, except for matters of patent law, which, other than for matters of inventorship on patents, shall be governed by the patent laws of the relevant country of the patent.
- 13.3.2. Subject to the provisions of Section 5.3, the parties hereby consent to personal jurisdiction in Israel and agree that any lawsuit they file to enforce their respective rights under this Agreement shall be brought exclusively in the competent courts in Jerusalem, Israel.
- 13.3.3. Notwithstanding anything to the contrary herein, disputes regarding the matters set forth in Section 5.3 (and not expressly excluded therein) shall be resolved exclusively by the JDC according to the procedures set forth in Section 5.3. Any decision made pursuant to the procedure set forth in Section 5.3 shall be final, and neither party shall challenge such decision in court or by arbitration, unless the challenging party can show that the actions of the other party being challenged were taken in bad faith or as a result of a material conflict of interest.
- 13.3.4. Any dispute that both (i) concerns whether a party has made commercially reasonable diligent efforts to commercialize the Drug and (ii) is not otherwise governed by the dispute resolution mechanism set forth in Sections 5.3 and Section 13.3.3 shall be resolved pursuant to the following procedure. The dispute shall be first referred to the JDC which shall promptly meet, either personally or via electronic means, in a good faith effort to resolve the dispute. If the JDC cannot resolve such dispute within 4 business days after the matter is referred to it, the dispute shall be referred to the respective chairman of the boards of each of the parties which shall promptly meet, either personally or via electronic means, in a good faith effort to resolve the dispute. If the chairmen of the boards do not resolve such dispute within 4 calendar days after the matter is referred to them, the dispute shall be submitted to binding arbitration as set forth in Section 13.3.5 below.

- 13.3.5. In the event of a dispute which is specified in Section 13.3.4 and fails to be resolved by the chairmen of the boards as described therein such dispute shall be submitted to binding arbitration to be conducted in Jerusalem, Israel, before one arbitrator in accordance with the World Intellectual Property Organization Expedited Arbitration Rules. The language of the arbitration shall be English. The identity of the arbitrator shall be mutually agreed upon by the Licensor and BioLine. In connection with any arbitration proceeding pursuant to this Agreement, unless the arbitrators shall determine otherwise, each party shall bear its own costs and expenses. The submission of any dispute to arbitration in and of itself shall not derogate from BioLine's rights to develop and commercialize the Licensed Technology hereunder, subject to the decision of the arbitrator.
- 13.3.6. Any dispute concerning a change in the indication of one of the Contemplated Clinical Trials from the current indication of AML (Acute Myeloid Leukemia) or the indication of the other Contemplated Clinical Trial from the one determined in accordance with the procedure set forth in the Development Plan shall be resolved pursuant to the procedure set forth in Section 5.4.
- 13.4. **Binding Effect.** This Agreement shall be binding upon and inure to the benefit of the parties and their respective legal representatives, successors and permitted assigns.
- 13.5. **Headings.** Section and subsection headings are inserted for convenience of reference only and do not form a part of this Agreement.
- 13.6. **Counterparts.** This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed an original.
- 13.7. **Amendment; Waiver.** This Agreement may be amended, modified, superseded or canceled, and any of the terms may be waived, only by a written instrument executed by each party or, in the case of waiver, by the party waiving compliance. The delay or failure of any party at any time or times to require performance of any provisions hereof shall in no manner affect the rights at a later time to enforce the same. No waiver by either party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.
- 13.8. **No Agency or Partnership.** Nothing contained in this Agreement shall give any Party the right to bind another, or be deemed to constitute either Party as agent for the other or as partner with the other Party or any third party.
- 13.9. **Assignment and Successors.** This Agreement may not be assigned by either party, without the consent of the other, which consent shall not be unreasonably withheld, except that each party may, without such consent, assign this Agreement and the rights, obligations and interests of such party, in whole or in part, to any of its Affiliates, to any purchaser of all or substantially all of its assets or research to which the subject matter of this Agreement relates, or to any successor corporation resulting from any merger or consolidation of such party with or into such corporation.

- 13.10. **Force Majeure.** Neither party will be responsible for delays resulting from causes beyond the reasonable control of such party, including without limitation, regulatory delay, fire, explosion, flood, war, strike, or riot, provided that the non-performing party uses commercially reasonable efforts to avoid or remove such causes of non-performance and continues performance under this Agreement with reasonable dispatch whenever such causes are removed.
- 13.11. **Interpretation.** The parties hereto acknowledge and agree that: (i) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting party shall not be employed in the interpretation of this Agreement; and (iii) the terms and provisions of this Agreement shall be construed fairly as to both parties hereto and not in favor of or against either party, regardless of which party was generally responsible for the preparation of this Agreement.
- 13.12. **Severability.** If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the parties that such provision shall be interpreted as necessary to give maximum effect to such provision as permitted under law and that the remainder of this Agreement shall not be affected.
- 13.13. **Execution.** This Agreement may be executed in any number of counterparts and by facsimile, each of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document. Signatures to this Agreement transmitted by facsimile, by email in “portable document format” (pdf), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

*[Remainder of page intentionally left blank]*



IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

**Biokine Therapeutics Ltd.**

By: /s/ Amnon Peled /s/ H L Shaw

Name: Amnon Peled, CEO  
H L Shaw, Chairman

Title: \_\_\_\_\_

**BioLineRx Ltd.**

By: /s/ Kinneret Savitsky /s/ Philip Serlin

Name: Kinneret Savitsky, CEO  
Philip Serlin, Chief Financial & Operating Officer

Title: \_\_\_\_\_

## Patents and Patent Applications

**STATUS REPORT**  
**Biokine Therapeutics Ltd.**

CXCR4 ANTAGONIST AND USE THEREOF								
Our Ref Client Ref	Country	Earliest Priority	Entry Date	Filing Date Application No.	Issue Date Patent No.	Next Action	Status	Owner
52837 BKN/001	Japan Basic			27-Aug-2002 2002-247843			Abandoned	TAKEDA CHEMICAL INDUSTRIES LTD.
52840 BKN/001 PCT	PCT	27-Aug-2002 2002-247843		26-Aug-2003 JP2003/010753	Publ. Date: 11- Mar-2004 Publ. #: WO2004/020462		Expired	FUJII Nobutaka
52849 BKN/001 JP	Japan NP	27-Aug-2002 2002-247843		26-Aug-2003 2003-301176	15-Jul-2011 4781621	Tax 4 15-Jul-2014	Granted	Biokine Therapeutics Ltd.
52850 BKN/001 JP-1	Japan DIV	27-Aug-2002 2002-247843		26-Aug-2003 2011-060367			Pending	Biokine Therapeutics Ltd.
52842 BKN/001 CA	Canada NP	27-Aug-2002 2002-247843	24-Feb-2006	26-Aug-2003 2,537,158		Tax 10 26-Aug-2012	Pending	Biokine Therapeutics Ltd.
52845 BKN/001 EP	Europe NP	27-Aug-2002 2002-247843	24-Mar-2005	26-Aug-2003 03791288.8		Grant Fee due 16-Aug- 2012 Tax 10 26-Aug-2012	Allowed	Biokine Therapeutics Ltd.
52848 BKN/001 EP- 1	Europe DIV	27-Aug-2002 2002-247843	14-Sep-2010	26-Aug-2003 10176632.7		Respond to Proceed Office Action 07-Sep- 2012 Tax 10 26-Aug-2012	Pending	Biokine Therapeutics Ltd.
52851 BKN/001 US	USA NP	27-Aug-2002 2002-247843	14-Oct-2005	26-Aug-2003 10/525,838	09-Sep-2008 7,423,007	Tax 7.5 09-Mar-2016	Granted	Biokine Therapeutics Ltd.
52852 BKN/001 US- 1	USA DIV	27-Aug-2002 2002-247843	11-Jul-2008	26-Aug-2003 12/172,007	13-Sep-2011 8,017,585	Tax 3.5 13-Mar-2015	Granted	Biokine Therapeutics Ltd.
52853 BKN/001 US- 2	USA DIV	27-Aug-2002 2002-247843	08-Jul-2011	26-Aug-2003 13/178,737			Pending	Biokine Therapeutics Ltd.

NOVEL POLYPEPTIDES AND ANTI-HIV DRUGS CONTAINING THE SAME								
Our Ref Client Ref	Country	Earliest Priority	Entry Date	Filing Date Application No.	Issue Date Patent No.	Next Action	Status	Owner
52871 BKN/002	Japan Basic			05-Sep-2000 2000-269296			Withdrawn	Seikagaku Corporation
52872 BKN/002	Japan (Paris)	05-Sep-2000 2000-269296		28-Mar-2001 2001-92306			Withdrawn	Seikagaku Corporation
52873 BKN/002 PCT	PCT	05-Sep-2000 2000-269296		05-Sep-2001 JP01/07668	Publ. Date: 14- Mar-2002 Publ. #: WO02/20561		Expired	Seikagaku Corporation
52882 BKN/002 JP	Japan NP	05-Sep-2000 2000-269296	26-Feb-2003	05-Sep-2001 2002-525180	26-Aug-2011 4808363	Tax 4 26-Aug-2014	Granted	Biokine Therapeutics Ltd.
52876 BKN/002 CA	Canada NP	05-Sep-2000 2000-269296	04-Mar-2003	05-Sep-2001 2,421,183		Tax 12 05-Sep-2012	Pending	Biokine Therapeutics Ltd.
52880 BKN/002 EP	Europe NP	05-Sep-2000 2000-269296	04-Apr-2003	05-Sep-2001 01963414.6	21-Apr-2010 1323730	CH-DE-FR-GB-IE	Granted	Biokine Therapeutics Ltd.
52880 BKN/002 EP	Switzerland + Lichtenstein [Europe] NP	05-Sep-2000 2000-269296	04-Apr-2003	05-Sep-2001 01963414.6	21-Apr-2010 1323730	Tax 12 05-Sep-2012	Granted	Biokine Therapeutics Ltd.
52880 BKN/002 EP	Germany [Europe] NP	05-Sep-2000 2000-269296	04-Apr-2003	05-Sep-2001 01963414.6	21-Apr-2010 1323730	Tax 12 05-Sep-2012	Granted	Biokine Therapeutics Ltd.
52880 BKN/002 EP	France [Europe] NP	05-Sep-2000 2000-269296	04-Apr-2003	05-Sep-2001 01963414.6	21-Apr-2010 1323730	Tax 12 05-Sep-2012	Granted	Biokine Therapeutics Ltd.
52880 BKN/002 EP	Great Britain [Europe] NP	05-Sep-2000 2000-269296	04-Apr-2003	05-Sep-2001 01963414.6	21-Apr-2010 1323730	Tax 12 05-Sep-2012	Granted	Biokine Therapeutics Ltd.
52880 BKN/002 EP	Ireland [Europe] NP	05-Sep-2000 2000-269296	04-Apr-2003	05-Sep-2001 01963414.6	21-Apr-2010 1323730	Tax 12 05-Sep-2012	Granted	Biokine Therapeutics Ltd.
52883 BKN/002 US	USA NP	05-Sep-2000 2000-269296	05-Mar-2003	05-Sep-2001 10/363,209	21-Nov-2006 7,138,488	Tax 7.5 21-May-2014	Granted	Biokine Therapeutics Ltd.
52886 BKN/002 US- 1	USA DIV	05-Sep-2000 2000-269296	01-Aug-2006	05-Sep-2001 11/497,225	29-Sep-2009 7,595,298	Tax 3.5 29-Mar-2013	Granted	Biokine Therapeutics Ltd.
52887 BKN/002 US- 1	USA CIP	05-Sep-2000 2000-269296		25-Aug-2009 12/583,746		6 Month due date for Response 28-Jun-2012	Pending	Biokine Therapeutics Ltd.

**T-140 PEPTIDE ANALOGS HAVING CXCR4 SUPER-AGONIST ACTIVITY AND USES THEREOF**

Our Ref Client Ref	Country	Earliest Priority	Entry Date	Filing Date Application No.	Issue Date Patent No.	Next Action	Status	Owner
52792 BKN/003-005 USP	USA PRO			21-Dec-2006 60/876,145			Expired	Biokine Therapeutics Ltd.

**T-140 PEPTIDE ANALOGS HAVING CXCR4 SUPER-AGONIST ACTIVITY FOR BONE MARROW RECOVERY**

Our Ref Client Ref	Country	Earliest Priority	Entry Date	Filing Date Application No.	Issue Date Patent No.	Next Action	Status	Owner
52805 BKN/003 PCT	PCT	21-Dec-2006 60/876,145		23-Dec-2007 IL2007/001596	Publ. Date: 26-Jun-2008 Publ. #: WO2008/075369		Expired	Biokine Therapeutics Ltd.
52806 BKN/003 CA	Canada NP	21-Dec-2006 60/876,145	19-Jun-2009	23-Dec-2007 2,673,719		Tax 6 + Request Examination Due 23-Dec-2012	Pending	Biokine Therapeutics Ltd.
52807 BKN/003 EP	Europe NP	21-Dec-2006 60/876,145	18-Jun-2009	23-Dec-2007 07849622.1		Tax 6 23-Dec-2012	Pending	Biokine Therapeutics Ltd.
52808 BKN/003 IL	Israel NP	21-Dec-2006 60/876,145	21-Jun-2009	23-Dec-2007 199468			Pending	Biokine Therapeutics Ltd.
53175 BKB003 IL Div-1	Israel DIV	21-Dec-2006 60/876,145	29-Feb-2012	23-Dec-2007 218405			Pending	Biokine Therapeutics Ltd.
52809 BKN/003 US	USA NP	21-Dec-2006 60/876,145	18-Nov-2009	23-Dec-2007 12/520,699		Respond to Office Action 04-Aug-2012	Pending	Biokine Therapeutics Ltd.

<b>T-140 PEPTIDE ANALOGS HAVING CXCR4 SUPER-AGONIST ACTIVITY FOR CANCER THERAPY</b>								
<b>Our Ref Client Ref</b>	<b>Country</b>	<b>Earliest Priority</b>	<b>Entry Date</b>	<b>Filing Date Application No.</b>	<b>Issue Date Patent No.</b>	<b>Next Action</b>	<b>Status</b>	<b>Owner</b>
52810 BKN/004 PCT	PCT	21-Dec-2006 60/876,145		23-Dec-2007 IL2007/001597	Publ. Date: 26- Jun-2008 Publ. #: WO2008/075370		Expired	Biokine Therapeutics Ltd.
52814 BKN/004 US	USA NP	21-Dec-2006 60/876,145	26-Oct-2009	23-Dec-2007 12/520,803		3 Month Due Date for Response 05-Jun-2012	Pending	Biokine Therapeutics Ltd.
53113 BKN004 US Div-1	USA DIV	21-Dec-2006 60/876,145	29-Jan-2012	23-Dec-2007 13/360,751			Pending	Biokine Therapeutics Ltd.
52811 BKN/004 CA	Canada NP	21-Dec-2006 60/876,145	19-Jun-2009	23-Dec-2007 2,673,484		Tax 6 + Request Examination Due 23-Dec-2012	Pending	Biokine Therapeutics Ltd.
52812 BKN/004 EP	Europe NP	21-Dec-2006 60/876,145	18-Jun-2009	23-Dec-2007 07849623.9		Tax 6 23-Dec-2012	Pending	Biokine Therapeutics Ltd.
52813 BKN/004 IL	Israel NP	21-Dec-2006 60/876,145	21-Jun-2009	23-Dec-2007 199469			Pending	Biokine Therapeutics Ltd.

<b>T-140 PEPTIDE ANALOGS HAVING CXCR4 SUPER-AGONIST ACTIVITY FOR IMMUNOMODULATION</b>								
<b>Our Ref Client Ref</b>	<b>Country</b>	<b>Earliest Priority</b>	<b>Entry Date</b>	<b>Filing Date Application No.</b>	<b>Issue Date Patent No.</b>	<b>Next Action</b>	<b>Status</b>	<b>Owner</b>
52793 BKN/005 PCT	PCT	21-Dec-2006 60/876,145		23-Dec-2007 IL2007/001598	Publ. Date: 26- Jun-2008 Publ. #: WO2008/075371		Expired	Biokine Therapeutics Ltd.
52794 BKN/005 US	USA NP	21-Dec-2006 60/876,145	16-Feb-2010	23-Dec-2007 12/520,811			Pending	Biokine Therapeutics Ltd.

T-140 PEPTIDE ANALOGS FOR INCREASING PLATELET LEVELS								
Our Ref Client Ref	Country	Earliest Priority	Entry Date	Filing Date Application No.	Issue Date Patent No.	Next Action	Status	Owner
52790 BKN/006 USP	USA PRO			14-Jun-2009 61/186,857			Expired	Biokine Therapeutics Ltd.
PEPTIDE THERAPY FOR INCREASING PLATELET LEVELS								
Our Ref Client Ref	Country	Earliest Priority	Entry Date	Filing Date Application No.	Issue Date Patent No.	Next Action	Status	Owner
52791 BKN/006 PCT	PCT	14-Jun-2009 61/186,857		13-Jun-2010 IL2010/000466	Publ. Date: 23- Dec-2010 Publ. #: WO2010/146578		Expired	Biokine Therapeutics Ltd.
52889 BKN/006 US	USA NP	14-Jun-2009 61/186,857	14-Dec-2011	13-Jun-2010 13/378,061			Pending	Biokine Therapeutics Ltd.
52891 BKN/006 EP	Europe NP	14-Jun-2009 61/186,857	10-Jan-2012	13-Jun-2010 10789103.8		Hong Kong Registration 25-Oct-2012 Tax 4 13-Jun-2013	Pending	Biokine Therapeutics Ltd.
52892 BKN/006 CA	Canada NP	14-Jun-2009 61/186,857	12-Dec-2011	13-Jun-2010 2,765,345		Tax 4 13-Jun-2013	Pending	Biokine Therapeutics Ltd.
52893 BKN/006 IN	India NP	14-Jun-2009 61/186,857	09-Jan-2012	13-Jun-2010 75/MUMNP/2012		Request Examination Due 14-Jun-2013	Pending	Biokine Therapeutics Ltd.
52894 BKN/006 BR	Brazil NP	14-Jun-2009 61/186,857	14-Dec-2011	13-Jun-2010		Tax 4 + Request Examination 13-Jun-2013	Pending	Biokine Therapeutics Ltd.
52895 BKN/006 MX	Mexico NP	14-Jun-2009 61/186,857	13-Dec-2011	13-Jun-2010 MX/a/2011/013459			Pending	Biokine Therapeutics Ltd.
52896 BKN/006 KR	Republic of Korea NP	14-Jun-2009 61/186,857	12-Jan-2012	13-Jun-2010 2012-7000921		Request Examination Due 13-Jun-2015	Pending	Biokine Therapeutics Ltd.
52897 BKN/006 JP	Japan NP	14-Jun-2009 61/186,857	14-Dec-2011	13-Jun-2010 2012-515626		Request Examination Due 13-Jun-2013	Pending	Biokine Therapeutics Ltd.
52899 BKN/006 IL	Israel NP	14-Jun-2009 61/186,857	12-Dec-2011	13-Jun-2010 216912			Pending	Biokine Therapeutics Ltd.
52900 BKN/006 CN	China NP	14-Jun-2009 61/186,857	13-Feb-2012	13-Jun-2010 201080035931.5			Pending	Biokine Therapeutics Ltd.

PEPTIDES AND COMPOSITIONS FOR THE TREATMENT OF NEUROECTODERMAL DERIVED TUMORS AND RETINOBLASTOMA								
Our Ref Client Ref	Country	Earliest Priority	Entry Date	Filing Date Application No.	Issue Date Patent No.	Next Action	Status	Owner
52788 BKN/007 USP	USA PRO			10-Jan-2011 61/431,068			Expired	Biokine Therapeutics Ltd.
52789 BKN/007 USP-1	USA PRF	10-Jan-2011 61/431,068		19-Jan-2011 61/433,983			Expired	Biokine Therapeutics Ltd.
52943 BKN/007 PCT	PCT	10-Jan-2011 61/431,068		10-Jan-2012 IL2012/050008		Request Examination due 10-Aug-2012 National Phase due 10-Jul-2013	Filed	Biokine Therapeutics Ltd.

## **Development Plan**

This Development Plan sets forth the complete program of development of the Drug, including the Contemplated Clinical Trials, to be conducted by BioLine and Licensors pursuant to the terms and conditions of the License Agreement

### **Clinical Trial Indication 1 – Acute Myeloid Leukemia (AML)**

Study treatment involves administration of 2 doses of BKT140 on consecutive days during the prophase, followed immediately by 5 consecutive days of salvage chemotherapy, each daily dose of chemotherapy preceded by a dose of BKT140. It is estimated that 25 qualified subjects shall be enrolled in this clinical trial.

The study endpoints:

#### **Primary**

1. To assess the safety and tolerability of multiple and repeated doses of BKT140 in AML patients when given in combination with standard salvage chemotherapy

#### **Secondary**

1. Treatment response following administration of BKT140 in combination with standard salvage chemotherapy (OR, CR and PR)
2. BKT-induced apoptosis of AML cells in the peripheral blood and bone marrow
3. BKT-induced mobilization of AML blasts and leukemic stem cells measured in the peripheral blood by FACS and FISH analysis (FISH will be performed in suitable cases exhibiting a unique, identifiable chromosomal abnormality)

Treatment response (secondary endpoint 1) will be evaluated approx. 4-6 weeks following the start of salvage chemotherapy.

The apoptosis and mobilization endpoints are collected during the prophase of the study and combination treatment with Chemo + BKT140.

A bone marrow sample is also collected approx. 4-6 weeks following the start of salvage chemotherapy.

The estimated budget of such clinical trial is USD 1.5 million, such costs and expenses to be borne by BioLine.

### **Clinical Trial Indication 2**

The Joint Development Committee shall determine the second indication and draft a work plan for the Contemplated Clinical Trial studying such indication within 45 days of the Effective Date. Subject to the guidelines in the following sentence which may not be amended thereunder, any disagreement regarding the determination of the second indication shall be in accordance with Section 5.3 of the Agreement. It is estimated and agreed that a total of 25 patients will complete this study within the Clinical Trial Period as defined in the License Agreement plus the aforementioned 45 days.

The budget of such clinical trial is estimated to be up to USD 2.4 million, such costs and expenses to be borne by BioLine.



**Grants of Rights in Licensed Technology and/or Drug**

In accordance with Section 6 of the Research, Development and License Agreement by and between Hadasit and Licensor dated March 15, 2005 (as amended on March 9, 2010, January 1, 2011, and January 1, 2012), Licensor shall have no rights to inventions that underlie the wound-healing patents relating to the Drug and have no other uses.

Notice Periods under Licensor Consulting Agreements

<u>Position</u>	<u>Name</u>	<u>Notice Period</u>
CEO and CSO	Prof. Amnon Peled	2 month
VP regulatory and clinical affairs	Dr. Sigal Aviel	2 month
Clinical Director	Dr. Irit Avivi	2 month
Clinical Advisor	Prof Arnon Nagler	1 month

## Core Patents

Title (E&F Ref.)	Territory	Application/ Patent Number	Filing Date	Status (Pending unless stated otherwise)	Expiration Date (without extension)
NOVEL POLYPEPTIDES AND ANTI-HIV DRUGS CONTAINING THE SAME		PCT/JP01/07668 WO 02/20561	05 Sep 2001	National Phase	05 Sep 2021
	Japan	4808363		<b>Granted</b>	
	Canada	2,421,183			
	Switzerland, Germany, France, UK, Ireland	EP 01963414.6		<b>Granted</b>	
	USA	7,138,488		<b>Granted</b>	05 Sep 2021 + 338 days PTA
	USA-CIP	12/583,746			
CXCR4 ANTAGONIST AND USE THEREOF		PCT/JP2003/010753 WO 2004/020462	26 Aug 2003	National Phase	26 Aug 2023
	Japan	2003-301176		<b>Granted</b>	
	Japan-DIV	2011-060367			
	Canada	2,537,158			
		03791288.8		<b>Allowed</b>	
		10176632.7			
	USA	7,423,007		<b>Granted</b>	26 Aug 2023 + 0 days PTA
USA-DIV	13/178,737				

[\*] 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.

**CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT**  
(FOR PANCREATIC CANCER STUDY)  
(as amended)

This CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT (this “**Agreement**”), made as of January 11, 2016 (the “**Effective Date**”), is by and between Merck Sharp & Dohme B.V., having a place of business at Waarderweg 39, 2031 BN Haarlem, Netherlands (“**Merck**”) and BioLineRx Ltd., having a place of business at Modi’in Technology Park, 2 HaMa’ayan Street, Modi’in 7177871, Israel (“**BioLineRx**”). Merck and BioLineRx are each referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

RECITALS

- A. BioLineRx is developing the BioLineRx Compound (as defined below) for the treatment of certain tumor types.
- B. Merck is developing the Merck Compound (as defined below) for the treatment of certain tumor types.
- C. BioLineRx desires to sponsor a clinical trial in which the BioLineRx Compound and the Merck Compound would be dosed concurrently or in combination.
- D. Merck and BioLineRx, consistent with the terms of this Agreement, desire to collaborate as more fully described herein, including by providing the Merck Compound and the BioLineRx Compound for the Study (as defined below).

NOW, THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions, the Parties, intending to be legally bound, mutually agree as follows:

1. Definitions.

For all purposes of this Agreement, the capitalized terms defined in this Article 1 and throughout this Agreement shall have the meanings herein specified.

**1.1** “**Affiliate**” means, with respect to either Party, a firm, corporation or other entity which directly or indirectly owns or controls said Party, or is owned or controlled by said Party, or is under common ownership or control with said Party. As used in this Section 1.1, the word “**control**” means (i) the direct or indirect ownership of more than fifty percent (50%) of the outstanding voting securities of a legal entity, or (ii) possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities, contract rights, voting rights, corporate governance or otherwise.

**1.2** “**Agreement**” means this agreement, as amended by the Parties from time to time, and as set forth in the preamble.

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1.3 “Alliance Manager” has the meaning set forth in [Section 3.10](#).

1.4 “Applicable Law” means all federal, state, local, national and regional statutes, laws, rules, regulations and directives applicable to a particular activity hereunder, including performance of clinical trials, medical treatment and the processing and protection of personal and medical data, that may be in effect from time to time, including those promulgated by the United States Food and Drug Administration (“FDA”), national regulatory authorities, the European Medicines Agency (“EMA”) and any successor agency to the FDA or EMA or any agency or authority performing some or all of the functions of the FDA or EMA in any jurisdiction outside the United States or the European Union (each a “Regulatory Authority” and collectively, “Regulatory Authorities”), and including cGMP and GCP (each as defined below); all data protection requirements such as those specified in the EU Data Protection Directive and the regulations issued under the United States Health Insurance Portability and Accountability Act of 1996 (“HIPAA”); export control and economic sanctions regulations which prohibit the shipment of United States-origin products and technology to certain restricted countries, entities and individuals; anti-bribery and anti-corruption laws pertaining to interactions with government agents, officials and representatives; laws and regulations governing payments to healthcare providers; and any United States or other country’s or jurisdiction’s successor or replacement statutes, laws, rules, regulations and directives relating to the foregoing.

1.5 “BioLineRx” has the meaning set forth in the preamble.

1.6 [Deleted]

1.7 “BioLineRx Class Compound” means any small or large molecule that [\*]

1.8 “BioLineRx Compound” means BioLineRx’s BL-8040, a short synthetic peptide, which is a CXCR4 inhibitor.

1.9 “BioLineRx Inventions” is defined in [Section 10.2](#).

1.10 “Business Day” means any day other than a Friday (in the case of BioLineRx), Saturday, Sunday, or a day on which commercial banks located in the country where the applicable obligations are to be performed are authorized or required by law to be closed.

1.11 “cGMP” means the current Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities that may be in effect from time to time and are applicable to the Manufacture of the Compounds.

1.12 “Clinical Data” means all data (including raw data) and results generated by or on behalf of either Party or at either Party’s direction, or by or on behalf of the Parties together or at their direction, in the course of each such Party’s performance of the Study; excluding, however, Sample Testing Results.

1.13 “Clinical Quality Agreement” has the meaning set forth in [Section 8.2](#).

1.14 “CMC” means “Chemistry Manufacturing and Controls” as such term of art is used in the pharmaceutical industry.

**1.15** “**Compounds**” means the BioLineRx Compound and the Merck Compound. A “**Compound**” means either the BioLineRx Compound or the Merck Compound, as applicable.

**1.16** “**Combination**” means the use or method of using the BioLineRx Compound and the Merck Compound in concomitant or sequential administration.

**1.17** “**Confidential Information**” means any information, Know-How or other proprietary information or materials furnished to one Party (“**Receiving Party**”) by or on behalf of the other Party (“**Disclosing Party**”) pursuant to this Agreement, except to the extent that such information or materials: (a) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party, as demonstrated by competent evidence; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement; (d) was disclosed to the Receiving Party by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or (e) was subsequently developed by the Receiving Party without use of the Disclosing Party Confidential Information, as demonstrated by competent evidence.

**1.18** “**Continuing Party**” has the meaning set forth in Section 10.1.3.

**1.19** “**Control**” or “**Controlled**” means, with respect to particular information or intellectual property, that the applicable Party owns or has a license to such information or intellectual property and has the ability to grant a right, license or sublicense to the other Party as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

**1.20** “**CTA**” means an application to a Regulatory Authority for purposes of requesting the ability to start or continue a clinical trial.

**1.21** “**Data Sharing and Sample Testing Schedule**” means the schedule attached hereto as Schedule I.

**1.22** “**Defending Party**” has the meaning set forth in Section 14.2.3.

**1.23** “**Delivery**” has the meaning set forth in Section 8.4.1.

**1.24** “**Direct Manufacturing Costs**” has the meaning set forth in Section 6.12.

**1.25** “**Disposition Package**” has the meaning set forth in Section 8.8.1.

**1.26** “**Dispute**” has the meaning set forth in Section 22.1.

**1.27** “**Effective Date**” has the meaning set forth in the preamble.

**1.28** “**EMA**” has the meaning set forth in the definition of Applicable Law.

**1.29** “**Exclusion List**” has the meaning set forth in the definition of Violation.

**1.30** “**FDA**” has the meaning set forth in the definition of Applicable Law.

**1.31** “**Filing Party**” has the meaning set forth in Section 10.1.3.

- 1.32 “**Force Majeure**” has the meaning set forth [Section 16](#).
- 1.33 “**GAAP**” has the meaning set forth in [Section 6.12](#).
- 1.34 “**GCP**” means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the testing of the Compounds.
- 1.35 “**Government Official**” means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any Person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organization such as the World Bank or United Nations; (e) any officer or employee of a political party or any Person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office; who, when such Government Official is acting in an official capacity, or in an official decision-making role, has responsibility for performing regulatory inspections, government authorizations or licenses, or otherwise has the capacity to make decisions with the potential to affect the business of either of the Parties.
- 1.36 “**HIPAA**” has the meaning set forth in the definition of Applicable Law.
- 1.37 “**IND**” means any Investigational New Drug Application filed or to be filed with the FDA as described in Title 21 of the U.S. Code of Federal Regulations, Part 312, and/or the equivalent application in the jurisdictions outside the United States, including an “Investigational Medicinal Product Dossier” filed or to be filed with Regulatory Authorities in the European Union.
- 1.38 “**Indirect Manufacturing Costs**” has the meaning set forth in [Section 6.12](#).
- 1.39 “**Inventions**” means all inventions and discoveries, whether or not patentable, that are made, conceived, or first actually reduced to practice by or on behalf of a Party, or by or on behalf of the Parties together, (i) in the design or performance of the Study, or in the design or performance of any Phase III registration study for the Combination performed pursuant to [Section 3.14](#), or (ii) through use of any unpublished Clinical Data or Sample Testing Results.
- 1.40 “**Joint Development Committee**” or “**JDC**” has the meaning set forth in [Section 3.10](#).
- 1.41 “**Joint Patent Application**” has the meaning set forth in [Section 10.1.3](#).
- 1.42 “**Joint Patent**” means a patent that issues from a Joint Patent Application.
- 1.43 “**Jointly Owned Invention**” has the meaning set forth in [Section 10.1.1](#).
- 1.44 “**Know-How**” means any proprietary invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, that is not generally known or otherwise in the public domain.

- 1.45 “**Liability**” has the meaning set forth in [Section 14.2.1](#).
- 1.46 “**Manufacture**,” “**Manufactured**,” or “**Manufacturing**” means all activities related to the manufacture of a Compound, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply, as applicable.
- 1.47 “**Manufacturer’s Release**” or “**Release**” has the meaning ascribed to such term in the Clinical Quality Agreement.
- 1.48 “**Manufacturing Costs**” has the meaning set forth in [Section 6.12](#).
- 1.49 “**Manufacturing Site**” means the facilities where a Compound is Manufactured by or on behalf of a Party, as such Manufacturing Site may change from time to time in accordance with [Section 8.7](#).
- 1.50 “**Merck**” has the meaning set forth in the preamble.
- 1.51 [Deleted]
- 1.52 “**Merck Compound**” means pembrolizumab, a humanized anti-human PD-1 monoclonal antibody [\*]
- 1.53 “**Merck Inventions**” is defined in [Section 10.3](#).
- 1.54 “**NDA**” means a New Drug Application, Biologics License Application, Worldwide Marketing Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the United States Federal Food, Drug and Cosmetic Act, or similar application or submission for a marketing authorization of a product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.
- 1.55 “**Non-Conformance**” means, with respect to a given unit of Compound, (i) a deviation from an approved cGMP requirement with respect to the applicable Compound, such as a procedure, Specification, or operating parameter, or a circumstance that requires an investigation to assess impact to the quality of the applicable Compound or (ii) that such Compound failed to meet the applicable representations and warranties set forth in [Section 2.3](#). Classification of the Non-Conformance is detailed in the Clinical Quality Agreement.
- 1.56 “**Non-Filing Party**” has the meaning set forth in [Section 10.1.3](#).
- 1.57 “**Opting-out Party**” has the meaning set forth in [Section 10.1.3](#).
- 1.58 “**Other Party**” has the meaning set forth in [Section 14.2.3](#).
- 1.59 “**Party/Parties**” has the meaning set forth in the preamble.
- 1.60 “**PD-1 Antagonist**” means any small or large molecule that [\*].
- 1.61 “**Permitted Use**” has the meaning set forth in [Section 3.7](#).
- 1.62 “**Person**” means any individual, sole proprietorship, partnership, corporation, business trust, joint stock company, trust, unincorporated organization, association, limited liability company, institution, public benefit corporation, joint venture, entity or governmental entity.



- 1.63 “**Pharmacovigilance Agreement**” has the meaning set forth in Section 5.1.
- 1.64 “**Project Manager**” has the meaning set forth in Section 3.10.
- 1.65 “**Protocol**” means the written documentation that describes the Study and sets forth specific activities to be performed as part of the Study conduct, to be finalized and agreed upon within sixty (60) calendar days after the Effective Date pursuant to Section 4.1.
- 1.66 “**Regulatory Approvals**” means, with respect to a Compound, any and all permissions (other than the Manufacturing approvals) required to be obtained from Regulatory Authorities and any other competent authority for the development, registration, importation, sale and distribution of such Compound in the United States, Europe or other applicable jurisdictions for use in the Study.
- 1.67 “**Regulatory Documentation**” means, with respect to the Compounds, all submissions to Regulatory Authorities in connection with the development of such Compounds, including all INDs and amendments thereto, NDAs and amendments thereto, drug master files, correspondence with regulatory agencies, periodic safety update reports, adverse event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including documents that include Clinical Data).
- 1.68 “**Regulatory Authorities**” has the meaning set forth in the definition of Applicable Law.
- 1.69 “**Related Agreements**” means the Pharmacovigilance Agreement and the Clinical Quality Agreement.
- 1.70 “**Right of Reference**” means the “right of reference” defined in 21 CFR 314.3(b), including with regard to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to a Party’s Compound, only to the extent necessary for the conduct of the Study in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder.
- 1.71 “**SAEs**” has the meaning set forth in Section 5.1.
- 1.72 “**SADRs**” has the meaning set forth in Section 5.1.
- 1.73 “**Samples**” means biological specimens collected from subjects participating in the Study, including urine, blood and tissue samples.
- 1.74 “**Sample Testing**” means the analyses to be performed by each Party using the applicable Samples, as described in the Data Sharing and Sample Testing Schedule (Schedule I).

1.75 “**Sample Testing Results**” means those results arising from the Sample Testing which are shared between Merck and BioLineRx, as set forth in the Data Sharing and Sample Testing Schedule.

1.76 “**Specifications**” means, with respect to a given Compound, the set of requirements for such Compound as set forth in the Clinical Quality Agreement.

1.77 “**Study**” means a Phase IIa clinical trial carried out in accordance with the Protocol to evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of the concomitant and/or sequenced administration of the Merck Compound and the BioLineRx Compound in subjects with pancreatic cancer.

1.78 “**Study Completion**” has the meaning set forth in [Section 3.11](#).

1.79 “**Subcontractors**” has the meaning set forth in [Section 2.4](#).

1.80 “**Term**” has the meaning set forth in [Section 6.1](#).

1.81 “**Territory**” means anywhere in the world.

1.82 “**Third Party**” means any Person or entity other than BioLineRx, Merck or their respective Affiliates.

1.83 “**VAT**” has the meaning set forth in [Section 8.16](#).

1.84 “**Violation**” means that a Party or any of its officers or directors or any other personnel (or other permitted agents of a Party performing activities hereunder) has been: (1) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (<http://oig.hhs.gov/exclusions/authorities.asp>); (2) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (<http://exclusions.oig.hhs.gov/>) or listed as having an active exclusion in the System for Award Management (<http://www.sam.gov>); or (3) listed by any US Federal agency as being suspended, proposed for debarment, debarred, excluded or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under 21 U.S.C. 335a ([http://www.fda.gov/ora/compliance\\_ref/debar/](http://www.fda.gov/ora/compliance_ref/debar/)) (each of (1), (2) and (3) collectively the “**Exclusions Lists**”).

## 2 [Scope of the Agreement](#).

2.1 [Generally](#). Each Party shall contribute to the Study such resources as are necessary to fulfill its obligations set forth in this Agreement and more specifically described in [Article 7](#).

2.2 [Obligations](#). Each Party shall act in good faith in performing its obligations under this Agreement and each Related Agreement, and shall notify the other Party as promptly as possible in the event of any Manufacturing delay that is likely to adversely affect supply of its Compound as contemplated by this Agreement.

2.3 [Compound Commitments](#). BioLineRx shall Manufacture and supply the BioLineRx Compound for purposes of the Study in accordance with [Article 8](#), and BioLineRx hereby represents and warrants to Merck that, at the time of Delivery of the BioLineRx Compound, such BioLineRx Compound shall have been Manufactured and supplied in compliance with: (i) the Specifications for the BioLineRx Compound; (ii) the Clinical Quality Agreement; and (iii) all Applicable Law, including cGMP and health, safety and environmental protections. Merck shall Manufacture and supply the Merck Compound for purposes of the Study in accordance with [Article 8](#), and Merck hereby represents and warrants to BioLineRx that, at the time of Delivery of the Merck Compound, such Merck Compound shall have been Manufactured and supplied in compliance with: (a) the Specifications for the Merck Compound; (b) the Clinical Quality Agreement; and (c) all Applicable Law, including cGMP and health, safety and environmental protections. Without limiting the foregoing, each Party is responsible for obtaining all regulatory approvals (including facility licenses) that are required to Manufacture its Compound in accordance with Applicable Law (provided that for clarity, BioLineRx shall be responsible for obtaining Regulatory Approvals for the Study as set forth in [Section 3.4](#)).

**2.4** Subcontracting. Each Party shall have the right to subcontract any portion of its obligations hereunder: (i) to its own Affiliates, without the other Party's written consent; or (ii) to Third Parties; provided that the JDC has approved (in a written document) the use of such Third Parties in the performance of such activities prior to such Third Parties performing such activities; [\*] (such Third Parties described above, "Subcontractors"). In any event, each Party shall remain solely and fully liable for the performance of its Affiliates and Subcontractors to which such Party delegates the performance of its obligations under this Agreement. Each Party shall ensure that each of its Affiliates and Subcontractors performs such Party's obligations pursuant to the terms of this Agreement, including the Appendices attached hereto. For clarity, to the extent that a Party has an obligation under this Agreement to perform an action or to meet a standard, and such Party subcontracts such obligation, such Party shall be responsible for any failure by such Party's Affiliates or Subcontractor to perform the action or meet the standard. Each Party shall use reasonable efforts to obtain and maintain copies of documents relating to the obligations performed by such Affiliates and Subcontractors that are required to be provided to the other Party under this Agreement.

**2.5** Compounds. This Agreement does not create any obligation on the part of Merck to provide the Merck Compound for any activities other than the Study, nor does it create any obligation on the part of BioLineRx to provide the BioLineRx Compound for any activities other than the Study, except as expressly set forth in Section 3.14.

**2.6** Relationship. Other than as expressly set forth in this Agreement, including Sections [\*] and [\*], or this Section 2.6, nothing in this Agreement shall (i) prohibit either Party from performing clinical studies other than the Study relating to its own Compound, either individually or in combination with any other compound or product, in any therapeutic area, or (ii) create an exclusive relationship between the Parties with respect to any Compound.

### **3** Conduct of the Study.

**3.1** Sponsor. BioLineRx shall act as the sponsor of the Study under a new solid tumors IND for the BioLineRx Compound with a Right of Reference to the IND of the Merck Compound as further described in Section 3.4; provided, however, that in no event shall BioLineRx file an additional IND for the Study unless required by Regulatory Authorities to do so. If a Regulatory Authority requests an additional IND for the Study the Parties shall meet and mutually agree on an approach to address such requirement.

**3.2** Performance. BioLineRx shall ensure that the Study is performed in accordance with this Agreement, the Protocol and all Applicable Law, including GCP. BioLineRx shall follow all applicable directions from applicable Regulatory Authorities, ethics committees and institutional review boards with jurisdiction over the Study, and shall obtain all applicable Regulatory Approvals required by applicable Regulatory Authorities, ethics committees and institutional review boards with jurisdiction over the Study prior to initiating performance of the Study.

**3.3** Debarred Personnel; Exclusion Lists. A Party shall not employ or subcontract with any Person or Third Party that is excluded, debarred, suspended, proposed for suspension or debarment, in Violation or otherwise ineligible for government programs for the performance of the Study or any other activities under this Agreement or the Related Agreements. Each Party hereby certifies that it has not employed or otherwise used in any capacity and will not employ or otherwise use in any capacity, the services of any Person suspended, proposed for debarment, or debarred under United States law, including 21 USC 335a, or any foreign equivalent thereof, in performing any portion of the Study or other activities under this Agreement or the Related Agreements and that such Party has, as of the Effective Date, screened itself, and its officers and directors, against the Exclusions Lists and that it has informed the other Party in writing whether it or any of its officers or directors has been in Violation. A Party shall notify the other Party in writing immediately if any such suspension, proposed debarment, debarment or Violation occurs or comes to its attention, and shall, with respect to any Person so suspended, proposed for debarment, debarred or in Violation, promptly remove such Person from performing activities, function or capacity related to the Study or otherwise related to activities under this Agreement or the Related Agreements.

**3.4** Regulatory Matters. BioLineRx shall ensure that all Regulatory Approvals from any Regulatory Authority, ethics committees and/or institutional review boards with jurisdiction over the Study are obtained prior to initiating performance of the Study. Merck shall have the right (but no obligation) to participate in any discussions with a Regulatory Authority regarding matters related to the Merck Compound. Each Party shall provide to the other, as necessary, a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate the Right of Reference. Notwithstanding anything to the contrary in this Agreement, neither Party shall have any right to access the other Party's CMC data with respect to its Compound. Merck shall authorize FDA and other applicable Regulatory Authorities to cross-reference the appropriate Merck Compound INDs and CTAs to provide data access to BioLineRx sufficient to support conduct of the Study. If Merck's CTA is not available in a given country, Merck will file its CMC data with the Regulatory Authority for such country, referencing BioLineRx's CTA as appropriate (however, BioLineRx shall have no right to directly access the CMC data).

**3.5** Documentation. Each Party shall maintain reports and all related documentation in good scientific manner and in compliance with Applicable Law. Each Party shall provide to the other Party Study information and documentation reasonably requested by the other Party to enable the other Party to (i) comply with any of its legal, regulatory and/or contractual obligations, or any request by any Regulatory Authority, related to the such other Party's Compound, and (ii) in the case of Merck, to determine whether the Study has been performed in accordance with this Agreement.

**3.6** Copies. BioLineRx shall provide to Merck copies of all Clinical Data, in electronic form or other mutually agreeable alternate form and on the timelines specified in the Data Sharing and Sample Testing Schedule (if applicable) or upon mutually agreeable timelines [\*]. BioLineRx shall ensure that all patient authorizations and consents required under HIPAA, the EU Data Protection Directive or any other similar Applicable Law in connection with the Study permit such sharing of Clinical Data with Merck.

**3.7** Samples. BioLineRx shall provide Samples to Merck as specified in the Protocol or as agreed to by the Joint Development Committee. Each Party shall use the Samples only for the Sample Testing and each Party shall conduct the Sample Testing solely in accordance with the Data Sharing and Sample Testing Schedule (Schedule I) and the Protocol. Merck shall own all data arising from the Sample Testing conducted in accordance with this Section 3.7 by or on behalf of Merck, and such data shall be Merck's Confidential Information. Merck shall provide to BioLineRx the Sample Testing Results for such Sample Testing conducted by or on behalf of Merck, in electronic form or other mutually agreeable alternate form, and on the timelines specified in the Data Sharing and Sample Testing Schedule or other mutually agreed timelines. Likewise, BioLineRx shall own all data arising from the Sample Testing conducted in accordance with this Section 3.7 by or on behalf of BioLineRx, and such data shall be BioLineRx's Confidential Information. BioLineRx shall provide to Merck the Sample Testing Results for such Sample Testing conducted by or on behalf of BioLineRx, in electronic form or other mutually agreeable alternate form, and on the timelines specified in the Data Sharing and Sample Testing Schedule or other mutually agreed timelines. Except to the extent otherwise agreed in a writing signed by authorized representatives of each Party, each Party shall use the other Party's unpublished Sample Testing Results only for [\*] (collectively, the "**Permitted Use**"). Any Sample Testing Results obtained by a Party which may have safety implications with respect to the Combination or a Compound will be immediately shared with the other Party. [\*] If either Party chooses not to conduct or determines that it is unable to conduct one or more of the Sample tests set forth in Schedule I, the Parties shall consult with each other, and if there is no legal or Third Party contractual restriction on the other Party conducting such tests, the other Party shall have the right to conduct such tests, in which case the data from such Sample Testing shall be owned by such other Party and shall be deemed to be such Party's Confidential Information.

**3.8** Ownership and Use of Clinical Data. All Clinical Data, including raw data and results, generated under this Agreement shall be jointly owned by BioLineRx and Merck. Merck hereby assigns to BioLineRx an undivided one-half interest in, to and under the Clinical Data. BioLineRx hereby assigns to Merck an undivided one-half interest in, to and under the Clinical Data. If such assignment cannot or does not occur, including in circumstances where such assignment is precluded by law, the Party with the obligation to assign hereby grants the other Party a non-exclusive license, with the right to grant sublicenses and to assign its license rights to the Clinical Data to any Person, in each case without the consent of the granting Party and without any accounting to such Party; provided that each such sublicensee and assignee is bound in writing to comply with the terms of this Agreement that are relevant to use and exploitation of such Clinical Data. BioLineRx shall maintain the Clinical Data in its internal database; provided, however, that at all times during the Term BioLineRx shall grant Merck access to all Clinical Data and any portions of BioLineRx's database that include Clinical Data. Notwithstanding the foregoing, and subject to the remaining provisions of this Section 3.8, [\*] provided, however, that the foregoing shall not limit or restrict either Party's ability to use the Clinical Data as may be necessary to comply with Applicable Law or as may be necessary to comply with its internal policies and procedures with respect to pharmacovigilance and adverse event reporting. For the avoidance of doubt, BioLineRx shall be free to use/share (including publish) data and results from the Study, including Clinical Data, which are solely related to the single-agent use of the BioLineRx Compound and are not related to the Combination, and which have been generated during the treatment period in which the BioLineRx Compound is used in monotherapy. Neither Party shall disclose the Clinical Data to a Third Party except to the extent that such Clinical Data has been published as provided in Section 12.2 [\*].

**3.9** Regulatory Submission. It is understood and acknowledged by the Parties that positive Clinical Data could be used to obtain label changes for the Compounds. In such event, the Parties will enter into good faith negotiations to determine a regulatory submission strategy for the Compounds [\*].

**3.10** Joint Development Committee. The Parties shall form a joint development committee (the “**Joint Development Committee**” or “**JDC**”), made up of an equal number of representatives of Merck and BioLineRx, which shall have responsibility of coordinating all regulatory and other activities under, and pursuant to, this Agreement. Each Party shall designate a project manager (the “**Project Manager**”) who shall be responsible for implementing and coordinating activities, and facilitating the exchange of information between the Parties, with respect to the Study. Other JDC members will be agreed by both Parties. The JDC shall meet as soon as practicable after the Effective Date and then no less than twice yearly, and more often as reasonably considered necessary at the request of either Party, to provide an update on the progress of the Study. The JDC may meet in person or by means of teleconference, Internet conference, videoconference or other similar communications equipment. Prior to any such meeting, the BioLineRx Project Manager shall provide an update in writing to the Merck Project Manager, which update shall contain information about the overall progress of the Study, recruitment status, interim analysis (if results available), final analysis and other information relevant to the conduct of the Study. In addition to a Project Manager, each Party shall designate an alliance manager (the “**Alliance Manager**”), who shall endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information, and shall serve as the primary point of contact for any issues arising under this Agreement. The Alliance Managers shall have the right to attend all JDC meetings and may bring to the attention of the JDC any matters or issues either of them reasonably believes should be discussed, and shall have such other responsibilities as the Parties may mutually agree in writing. In the event that an issue arises and the Alliance Managers cannot or do not, after good faith efforts, reach agreement on such issue, the issue shall be elevated to the Head of Clinical Oncology for Merck and the Vice President of Medical Affairs or Business Development for BioLineRx.

**3.11** Final Study Report. BioLineRx shall provide Merck with (i) an electronic draft of the final Study report, for Merck to provide comments to BioLineRx within [\*] days of receipt of the draft of the final Study report and (ii) a final version of the final Study report (the “**Final Study Report**”) promptly following Study Completion. BioLineRx shall consider in good faith any comments provided by Merck on the draft of the final Study report and shall not include any statements relating to the Merck Compound [\*]. “**Study Completion**” shall occur upon database lock of the Study results.

**3.12** [\*]

**3.13** [\*]

**3.14** Amendment to Agreement; Study Option. Upon Study Completion (or at any earlier point agreed upon by the Parties), either Party shall have the option to propose amending this Agreement and the Related Agreements for the purpose of including a Phase III registration study for the Combination [\*]

4 Protocol and Related Documents.

4.1 *Protocol.* A summary of the initial Protocol will be finalized and agreed upon by the Parties within [\*] days after the Effective Date, using the most recent draft discussed between the Parties attached hereto as Appendix A. BioLineRx shall provide a draft of the Protocol (and any subsequent revisions thereof) to Merck for Merck's review and comment, consistent with the remaining provisions of this Section 4.1.

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

a) BioLineRx shall have the final decision-making authority with respect to the contents of the Protocol, provided that any material changes to any draft of the Protocol (other than relating solely to the BioLineRx Compound) from the draft of the Protocol previously provided to Merck, any material changes (other than relating solely to the BioLineRx Compound) to the approved final Protocol, and [\*], shall require Merck's prior written consent. Any such proposed changes will be sent in writing to Merck's Project Manager and Merck's Alliance Manager. Merck will provide such consent, or a written explanation for why such consent is being withheld, within [\*] Business Days of receiving a copy of BioLineRx's requested changes.

b) [\*]

c) [\*]

4.2 *Informed Consent.* BioLineRx shall prepare the patient informed consent form for the Study (which shall include provisions regarding the use of Samples in Sample Testing) in consultation with Merck (it being understood and agreed that the portion of the informed consent form relating to the Sample Testing of the Merck Compound shall be provided to BioLineRx by Merck). Any proposed changes to such form that relate to the Merck Compound, including Sample Testing of the Merck Compound, shall be subject to Merck's review and written consent. Any such proposed changes will be sent in writing to Merck's Project Manager and Merck's Alliance Manager. Merck will provide such consent, or a written explanation for why such consent is being withheld, within [\*] Business Days of receiving a copy of BioLineRx's requested changes.

5 Adverse Event Reporting.

5.1 BioLineRx will be solely responsible for compliance with all Applicable Law pertaining to safety reporting for the Study and related activities. The Parties will use their reasonable efforts to execute a pharmacovigilance agreement ("**Pharmacovigilance Agreement**") within [\*] days of the Effective Date, and in any event prior to the initiation of clinical activities under the Study to ensure the exchange of relevant safety data within appropriate timeframes and in an appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety reviews. The Pharmacovigilance Agreement will include safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning any adverse experiences, pregnancy reports, and any other safety information arising from or related to the use of the Merck Compound and BioLineRx Compound in the Study, consistent with Applicable Law. Such guidelines and procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill, local and international regulatory reporting obligations to Government Authorities. BioLineRx will transmit to Merck serious adverse drug reactions ("**SADRs**") and serious adverse events ("**SAEs**") as follows:

5.1.1 For fatal and life-threatening SADRs, BioLineRx will send an early case notification to Merck within [\*], followed by a completely processed case (on a CIOMS-1 form) within [\*].

5.1.2 For all other SAEs, BioLineRx will send an early case notification to Merck within [\*] followed by a completely processed case (on a CIOMS-1 form) within [\*].

The early case notification will be marked as “Notification” and will contain the minimum criteria including an identifiable reporter, an identifiable patient, event term, and suspect therapy.

## **6** Term and Termination.

**6.1** Term. The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until the earlier of (i) delivery of the Final Study Report and (ii) Study Completion plus three (3) months, or until terminated by either Party pursuant to this Article 6 (the “**Term**”).

**6.2** Merck Termination Right for Safety or for OCS Non-Consent. Merck shall have the unilateral right to terminate this Agreement pursuant to Section 10.1.1. Additionally, in the event that Merck in good faith believes that the Merck Compound is being used in the Study in an unsafe manner and notifies BioLineRx in writing of the grounds for such belief, and if after receipt of such written notice, BioLineRx fails to promptly incorporate changes into the Protocol that are requested by Merck in writing to address such notified issue or to otherwise reasonably and in good faith address such notified issue, then Merck may immediately terminate this Agreement and the supply of the Merck Compound upon five (5) Business Days’ prior written notice to BioLineRx. During such five (5) Business Days period, BioLineRx shall have the right and opportunity to demonstrate that responsive Protocol changes have been incorporated.

**6.3** Material Breach. Either Party may terminate this Agreement if the other Party commits a material breach of this Agreement, and such material breach continues for thirty (30) days after receipt of written notice thereof from the non-breaching Party describing such breach and demanding its cure; provided that if such material breach cannot reasonably be cured within thirty (30) days, the breaching Party shall be given a reasonable period of time to cure such breach; provided further, that if such material breach is incapable of cure, then the notifying Party shall state such belief in its written breach notice, and if the breaching Party does not dispute such belief, the non-breaching Party may terminate this Agreement effective after the expiration of such thirty (30) day period.

**6.4** Mutual Termination Right for Patient Safety. If either Party determines in good faith, based on a review of the Clinical Data, Sample Testing Results or other Study-related Know-How or other information, that the Study may unreasonably affect patient safety, such Party shall promptly notify the other Party of such determination in writing. The Party receiving such notice may propose modifications to the Study to address the safety issue identified by the other Party and, if the notifying Party agrees, shall act to immediately implement such modifications; provided, however, that if the notifying Party, in its sole discretion, believes that there is imminent danger to patients, such Party need not wait for the other Party to propose modifications and may instead suspend the Study immediately upon written notice to such other Party. Furthermore, if the notifying Party, in its sole discretion, believes that any modifications proposed by the other Party will not resolve the patient safety issue, such Party may terminate this Agreement effective upon written notice to such other Party.



**6.5** Mutual Termination Right Due to Regulatory Action; Other Reasons. Either Party may terminate this Agreement upon five (5) Business Days' prior written notice to the other Party in the event that any Regulatory Authority takes any action, or raises any objection, that prevents the terminating Party from any further supply of its Compound for purposes of the Study. Additionally, either Party shall have the right to terminate this Agreement upon five (5) Business Days' prior written notice to the other Party in the event that it determines in its sole discretion to withdraw any applicable Regulatory Approval for its Compound or to discontinue development of its Compound, for medical, scientific or legal reasons.

**6.6** [Deleted]

**6.7** Return of Merck Compound. In the event that this Agreement is terminated, or in the event BioLineRx remains in possession (including through any Affiliate or Subcontractor) of Merck Compound at the time this Agreement expires, BioLineRx shall, at Merck's sole discretion, promptly either return or destroy all unused Merck Compound pursuant to Merck's instructions. If Merck requests that BioLineRx destroy the unused Merck Compound, BioLineRx shall provide written certification of such destruction. Notwithstanding anything to the contrary in the foregoing, if this Agreement is terminated (a) due to patient safety or regulatory issues, the Parties will share the costs incurred by BioLineRx for such return or destruction of the Merck Compound, or (b) due to an uncured material breach by a breaching Party, then the breaching Party shall be solely responsible for the costs incurred by BioLineRx for such return or destruction of the Merck Compound.

**6.8** Anti-Corruption. Either Party shall have the right to terminate this Agreement immediately upon written notice to the other Party, if such other Party fails to perform any of its obligations under Section 13.4 or breaches any representation or warranty contained in Section 13.4. The non-terminating Party shall have no claim against the terminating Party for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Section 6.8.

**6.9** Survival. The provisions of this Section 6.9 and Sections 3.4 through 3.9 (inclusive), 5.1, 6.6, 8.11, 12.2, 14.2, 14.3, and Articles 1, 9, 10, 11, 20, 21, 23, 24, 25 and 26 shall survive the expiration or termination of this Agreement.

**6.10** No Prejudice. Termination of this Agreement shall be without prejudice to any claim or right of action of either Party against the other Party for any prior breach of this Agreement.

**6.11** Confidential Information. Upon termination of this Agreement, each Party and its Affiliates shall promptly return to the Disclosing Party or destroy any Confidential Information of the Disclosing Party (other than Clinical Data, Sample Testing Results and Inventions, which may be used in accordance with this Agreement) furnished to the Receiving Party by the Disclosing Party, except that the Receiving Party shall have the right to retain one copy for record-keeping purposes. For clarity, any data or information (including Clinical Data) disclosed to a Receiving Party that relates to the single-agent use of the other Party's Compound shall be promptly returned to the other Party or destroyed in accordance with this Section 6.11.

**6.12** Merck's Manufacturing Costs. Provided the Parties do not otherwise dispute the circumstances of termination, in the event of termination by Merck pursuant to Section 6.2 or 6.3 above, Merck shall be entitled to reimbursement by BioLineRx for the Direct Manufacturing Costs and Indirect Manufacturing Costs (as defined herein) incurred by Merck for its Compound Delivered for the Study. "**Direct Manufacturing Costs**" shall be calculated consistent with Generally Accepted Accounting Principles ("**GAAP**") and include manufacturing fees; raw materials; direct labor; freight and duty, and factory overhead costs that can be directly attributed to the Compound, including but not limited to equipment maintenance and repair, supplies, ongoing stability program costs, other plant services, indirect labor and depreciation on direct capital assets. "**Indirect Manufacturing Costs**" shall be calculated consistent with GAAP and include allocations of indirect factory overhead and site support costs, including but not limited to utilities, quality, planning, engineering, maintenance, safety, site science and technology, and depreciation on indirect capital assets, procurement, warehousing, and corporate services. Allocations shall be based on each compound's utilization relative to a manufacturing site's total activity.

**6.13** BioLineRx's Study Costs; Unused Samples. Provided the Parties do not otherwise dispute the circumstances of termination, in the event of termination by BioLineRx pursuant to Section 6.3 above, BioLineRx shall be entitled to (a) reimbursement by Merck for the cost of replacing Merck Compound in the Study; and (b) require Merck to destroy or, at Merck's discretion, return to BioLineRx any unused Samples provided by BioLineRx to Merck.

The Parties agree that (i) Merck shall provide the Merck Compound for use in the Study, as described in Article 8 below; (ii) each Party will be responsible for its own internal costs and expenses to support the Study and the costs of any Sample Testing conducted by such Party in connection with the Study, and (iii) BioLineRx shall bear all other costs associated with the conduct of the Study, including that BioLineRx shall provide the BioLineRx Compound for use in the Study, as described in Article 8 below. For the avoidance of doubt, BioLineRx will not be required to reimburse Merck for any costs or expenses incurred by Merck or its Affiliates in connection with the Study and Merck will not be required to reimburse BioLineRx for any costs or expenses incurred by BioLineRx or its Affiliates in connection with the Study.

## **8** Supply and Use of the Compounds.

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

**8.2** Clinical Quality Agreement. Within [\*] days from the Effective Date of this Agreement, the Parties shall enter into a quality agreement that shall address and govern issues related to the quality of clinical Compounds to be supplied by the Parties for use in the Study (“**Clinical Quality Agreement**”). The Clinical Quality Agreement shall, among other things: (i) detail classification of any Compound found to have a Non-Conformance; (ii) include criteria for Manufacturer’s Release and related certificates and documentation; (iii) include criteria and timeframes for acceptance of Merck Compound; (iv) include procedures for the resolution of disputes regarding any Compounds found to have a Non-Conformance; and (v) include provisions governing the recall of Compounds.

**8.3** Minimum Shelf Life Requirements. Each Party shall use diligent and commercially reasonable efforts to supply its Compound hereunder with an adequate remaining shelf life at the time of Delivery to meet the Study requirements.

### **8.4** Provision of Compounds.

**8.4.1** Subject to Section 10.1.1, Merck will deliver the Merck Compound [\*] to BioLineRx’s, or its designee’s, location as specified by BioLineRx (“**Delivery**” with respect to such Merck Compound). Title and risk of loss for the Merck Compound shall transfer from Merck to BioLineRx at Delivery. All costs associated with the subsequent transportation, warehousing and distribution of Merck Compound shall be borne by [\*]. BioLineRx will, or will cause its designee to: (i) take delivery of the Merck Compound supplied hereunder; (ii) perform the acceptance procedures allocated to it under the Clinical Quality Agreement; (iii) subsequently label and pack the Merck Compound (in accordance with Section 8.5), and promptly ship the Merck Compound to the Study sites for use in the Study, in compliance with cGMP, GCP and other Applicable Law and the Clinical Quality Agreement; and (iv) provide, from time to time at the reasonable request of Merck, the following information: any applicable chain of custody forms, in-transport temperature recorder(s), records and receipt verification documentation, such other transport or storage documentation as may be reasonably requested by Merck, and usage and inventory reconciliation documentation related to the Merck Compound.

8.4.2 BioLineRx is solely responsible, at its own cost, for supplying (including all Manufacturing, acceptance and release testing) the BioLineRx Compound for the Study, and the subsequent handling, storage, transportation, warehousing and distribution of the BioLineRx Compound supplied hereunder for the Study. BioLineRx shall ensure that all such activities are conducted in compliance with cGMP, GCP and other Applicable Law and the Clinical Quality Agreement. For purposes of this Agreement, the “**Delivery**” of a given quantity of the BioLineRx Compound shall be deemed to occur when such quantity is packaged for shipment to a Study site.

**8.5** Labeling and Packaging; Use, Handling and Storage.

8.5.1 The Parties’ obligations with respect to the labeling and packaging of the Compounds are as set forth in the Clinical Quality Agreement. Notwithstanding the foregoing or anything to the contrary contained herein, Merck shall provide the Merck Compound to BioLineRx in the form of unlabeled vials, and BioLineRx shall be responsible for labeling, packaging and leafletting such Merck Compound in accordance with the terms and conditions of the Clinical Quality Agreement and otherwise in accordance with all Applicable Law, including cGMP, GCP, and health, safety and environmental protections.

8.5.2 BioLineRx shall (i) use the Merck Compound solely for purposes of performing the Study; (ii) not use the Merck Compound in any manner that is inconsistent with this Agreement or for any commercial purpose; and (iii) label, use, store, transport, handle and dispose of the Merck Compound in compliance with Applicable Law and the Clinical Quality Agreement, as well as all written instructions of Merck. BioLineRx shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the Merck Compound, and in particular shall not analyze the Merck Compound by physical, chemical or biochemical means, except as necessary to perform its obligations under the Clinical Quality Agreement.

**8.6** Product Specifications. A certificate of analysis prepared and delivered in accordance with the Clinical Quality Agreement shall accompany each shipment of the Merck Compound to BioLineRx. Upon request, BioLineRx shall provide Merck with a certificate of analysis covering each shipment of BioLineRx Compound used in the Study.

**8.7** Changes to Manufacturing. Each Party may make changes from time to time to its Compound or the Manufacturing Site; provided that such changes shall be in accordance with the Clinical Quality Agreement.

**8.8** Product Testing; Noncompliance.

8.8.1 After Manufacturer’s Release. After Manufacturer’s Release of the Merck Compound and concurrently with Delivery of the Compound to BioLineRx, Merck shall provide BioLineRx with such certificates and documentation as are described in the Clinical Quality Agreement (“**Disposition Package**”). BioLineRx shall, within the time defined in the Clinical Quality Agreement, perform (i) with respect to the Merck Compound, the acceptance (including testing) procedures allocated to it under the Clinical Quality Agreement, and (ii) with respect to the BioLineRx Compound, the testing and release procedures allocated to it under the Clinical Quality Agreement. BioLineRx shall be solely responsible for taking all steps necessary to determine that Merck Compound or BioLineRx Compound, as applicable, is suitable for release before making such Merck Compound or BioLineRx Compound, as applicable, available for human use, and Merck shall provide cooperation or assistance as reasonably requested by BioLineRx in connection with such determination with respect to the Merck Compound. BioLineRx shall be responsible for storage and maintenance of the Merck Compound until it is tested and/or released, which storage and maintenance shall be in compliance with (a) the Specifications for the Merck Compound, the Clinical Quality Agreement and Applicable Law, and (b) any specific storage and maintenance requirements as may be provided by Merck from time to time. BioLineRx shall be responsible for any failure of the Merck Compound to meet the Specifications to the extent caused by shipping, storage or handling conditions after Delivery to BioLineRx hereunder.

8.8.2 *Non-Conformance.*

a) In the event that either Party becomes aware that any Compound may have a Non-Conformance, despite testing and quality assurance activities (including any activities conducted by the Parties under Section 8.8.1), such Party shall immediately notify the other Party in accordance with the procedures of the Clinical Quality Agreement. The Parties shall investigate any Non-Conformance in accordance with Section 8.9 (*Investigations*) and any discrepancy between them shall be resolved in accordance with Section 8.8.3.

b) In the event that any proposed or actual shipment of the Merck Compound (or portion thereof) shall be agreed to have a Non-Conformance at the time of Delivery to BioLineRx, then unless otherwise agreed to by the Parties in writing, Merck shall replace such Merck Compound as is found to have a Non-Conformance (with respect to Merck Compound that has not yet been administered in the course of performing the Study) within [\*] calendar days, at Merck's sole expense. [\*]

c) BioLineRx shall be responsible for, and Merck shall have no obligations or liability with respect to, any BioLineRx Compound supplied hereunder that is found to have a Non-Conformance. BioLineRx shall replace any BioLineRx Compound for use in the Study as is found to have a Non-Conformance (with respect to BioLineRx Compound that has not yet been administered in the course of performing the Study).

8.8.3 *Resolution of Discrepancies.* Disagreements regarding any determination of Non-Conformance by BioLineRx shall be resolved in accordance with the provisions of the Clinical Quality Agreement.

8.9 *Investigations.* The process for investigations of any Non-Conformance shall be handled in accordance with the Clinical Quality Agreement.

8.10 *Shortage; Allocation.* In the event that a Party's Compound is in short supply as a result of a manufacturing disruption, manufacturing difficulties or other similar event such that a Party reasonably believes in good faith that it will not be able to fulfill its entire supply obligations hereunder with respect to its Compound, such Party will provide prompt written notice to the other Party thereof (including the shipments of Compound hereunder expected to be impacted and the quantity of its Compound that such Party reasonably determines it will be able to supply) and the Parties will promptly discuss such situation (including how the quantity of Compound that such Party is able to supply hereunder will be allocated within the Study). In such event, the Party experiencing such shortage shall (i) use its diligent and commercially reasonable efforts to remedy the situation giving rise to such shortage and to take action to minimize the impact of the shortage on the Study, and (ii) allocate to the other Party [\*]

**8.11** Records; Audit Rights. During the Term of this Agreement and [\*] years after the end of the Term, BioLineRx shall keep complete and accurate records pertaining to its use and disposition of Merck Compound (including its storage, shipping (cold chain) and chain of custody activities) and, upon written request of Merck, shall make such records open to review by Merck solely for the purpose of conducting investigations for the determination of Merck Compound safety and/or efficacy and BioLineRx's compliance with this Agreement with respect to the Merck Compound.

**8.12** Quality. Quality matters related to the Manufacture of the Compounds shall be governed by the terms of the Clinical Quality Agreement in addition to the relevant quality provisions of this Agreement.

**8.13** Quality Control. Each Party shall implement and perform operating procedures and controls for sampling, stability and other testing of its Compound, and for validation, documentation and release of its Compound and such other quality assurance and quality control procedures as are required by the Specifications, cGMPs and the Clinical Quality Agreement.

**8.14** Audits and Inspections. The Parties' audit and inspection rights related to this Agreement shall be governed by the terms of the Clinical Quality Agreement.

**8.15** Recalls. Recalls of the Compounds shall be governed by the terms of the Clinical Quality Agreement.

**8.16** VAT. It is understood and agreed between the Parties that any payments made under this Agreement are exclusive of any value added or similar tax ("VAT"), which shall be added thereon as applicable. Where VAT is properly charged by the supplying Party and added to a payment made under this Agreement, the Party making the payment will pay the amount of VAT only on receipt of a valid tax invoice from the supplying Party issued in accordance with the laws and regulations of the country in which the VAT is chargeable.

## **9** Confidentiality.

**9.1** Confidential Information. Subject to Section 13.4.8, BioLineRx and Merck agree to hold in confidence any Confidential Information provided by the other Party, and neither Party shall use Confidential Information of the other Party except for the performance of the Study and for the Permitted Use. The Receiving Party shall not, without the prior written permission of the Disclosing Party, disclose any Confidential Information of the Disclosing Party to any Third Party except to the extent disclosure (i) is required by Applicable Law; (ii) is pursuant to and in accordance with the terms of this Agreement; or (iii) is necessary for the conduct of the Study, and in each case ((i) through (iii)) provided that the Receiving Party shall provide reasonable advance written notice to the Disclosing Party before making such disclosure. For the avoidance of doubt, BioLineRx may, without Merck's consent, disclose Merck's Confidential Information to clinical trial sites and clinical trial investigators performing the Study, the data safety monitoring and advisory board relating to the Study, and Regulatory Authorities working with BioLineRx on the Study, in each case to the extent necessary for the performance of the Study and provided that such Persons (other than governmental entities) are bound by an obligation of confidentiality at least as stringent as the obligations contained herein.

9.2 Inventions. Notwithstanding the foregoing, (i) Inventions that constitute Confidential Information and are jointly owned by the Parties, shall constitute the Confidential Information of both Parties and each Party shall have the right to use and disclose such Confidential Information consistent with Articles 10, 11 and 12 and (ii) Inventions that constitute Confidential Information and are solely owned by one Party shall constitute the Confidential Information of that Party and each Party shall have the right to use and disclose such Confidential Information consistent with Articles 10, 11 and 12.

9.3 Personal Identifiable Data. All Confidential Information containing personal identifiable data shall be handled in accordance with all data protection and privacy laws, rules and regulations applicable to such data.

## 10 Intellectual Property.

### 10.1 Joint Ownership and Prosecution.

10.1.1 Subject to Section 10.2 and Section 10.3, all rights to all Inventions relating to, or covering, [\*] (each a “**Jointly Owned Invention**”) shall be negotiated in good faith in an additional agreement setting forth the rights of the Parties with respect to such Jointly Owned Invention (the “**Joint Rights Agreement**”), which Joint Rights Agreement shall be executed within [\*] days after the Effective Date, and shall contain the provisions set forth in Sections 10.1.2 and 10.1.3 of this Agreement. The Parties acknowledge that the Office of the Chief Scientist of the Ministry of Economy of the State of Israel (the “**OCS**”) must consent to the Joint Rights Agreement before such Agreement becomes effective. Promptly after the Effective Date, BioLineRx shall use its best efforts to obtain the consent of the OCS to the Joint Rights Agreement, having the terms set forth in Sections 10.1.2 and 10.1.3 below, and shall use its best efforts to seek to obtain such consent no later than [\*] after the Effective Date. BioLineRx shall be solely responsible for all costs and fees, or other compensation to the OCS or any other Third Party, required to secure such rights. The parties acknowledge that there is a possibility that the OCS may request changes in this Agreement and the Joint Rights Agreement as a result of its review of the Joint Rights Agreement. In such event, the Parties shall negotiate in good faith to agree on amendments to either or both of such agreements in accordance with the OCS request. [\*]

10.1.2 Subject to any changes that may be required in order to obtain the consent of the OCS to the Joint Rights Agreement as set forth in Section 10.1.1, such agreement will contain the following terms:

a. For Jointly Owned Inventions that are invented or created jointly by Merck or by Persons having an obligation to assign such rights to Merck, and by BioLineRx or by Persons having an obligation to assign such rights to BioLineRx, each Party shall have an undivided one-half interest in, to and under any such Jointly Owned Inventions. [\*]

b. [\*]

c. [\*]

d. If one Party brings any prosecution or enforcement action or proceeding against a Third Party with respect to any Joint Patent, the second Party agrees to be joined as a party plaintiff where necessary and to give the first Party reasonable assistance and authority to file and prosecute the suit. The costs and expenses of the (first) Party bringing suit under this subsection (d) shall be borne by such Party, and any damages or other monetary awards recovered shall be shared as follows: [\*]A settlement or consent judgment or other voluntary final disposition of a suit under this subsection (d) may not be entered into without the consent of the Party not bringing or controlling the suit.

10.1.3 Promptly following the receipt of the consent of OCS to the Joint Rights Agreement, patent representatives of each of the Parties shall meet (in person or by telephone) to discuss the patenting strategy for any Jointly Owned Inventions which may arise. In particular, the Parties shall discuss which Party will file a patent application (including any provisional, substitution, divisional, continuation, continuation in part, reissue, renewal, reexamination, extension, supplementary protection certificate and the like) in respect of any Jointly Owned Invention (each, a “**Joint Patent Application**”) and whether the Parties wish to appoint joint patent counsel. In any event, the Parties shall consult and reasonably cooperate with one another in the preparation, filing, prosecution (including prosecution strategy) and maintenance of such each Joint Patent Application and shall [\*]. In the event that one Party (the “**Filing Party**”) wishes to file a patent application for a Jointly Owned Invention and the other Party (the “**Non-Filing Party**”) does not want to file a patent application for such Jointly Owned Invention or does not want to file in a particular country, the Non-Filing Party shall execute such documents and perform such acts at the Filing Party’s reasonable expense as may be reasonably necessary to effect an assignment of such Jointly Owned Invention to the Filing Party (in such country or all countries, as applicable) in a timely manner to allow the Filing Party to file and prosecute such patent application. Likewise, if a Party (the “**Opting-out Party**”) wishes to discontinue the prosecution and maintenance (or sharing in the costs with respect thereto) of a Joint Patent Application (in one or more countries), the other Party, at its sole option (the “**Continuing Party**”), may continue such prosecution and maintenance. In such event, the Opting-out Party shall execute such documents and perform such acts at the Continuing Party’s [\*] to effect an assignment of such Joint Patent Application to the Continuing Party (in such country or all countries, as applicable) in a timely manner to allow the Continuing Party to prosecute and maintain such patent application. [\*]

10.1.4 Except as expressly provided in Section 10.1.3 and in furtherance and not in limitation of Section 9.1, each Party shall not file a patent application based on the other Party’s Confidential Information, and shall give no assistance to any Third Party for such application, without the other Party’s prior written authorization.

10.2 Inventions Owned by BioLineRx. Notwithstanding Section 10.1, the Parties agree that all rights to Inventions relating [\*], are the exclusive property of BioLineRx (“**BioLineRx Inventions**”). BioLineRx shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for any BioLineRx Invention. [\*]

10.3 Inventions Owned by Merck. Notwithstanding Section 10.1, the Parties agree that all rights to Inventions relating [\*], are the exclusive property of Merck (“**Merck Inventions**”). Merck shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for any Merck Invention. [\*]

10.4 [deleted]

11 Reprints; Rights of Cross-Reference.

Consistent with applicable copyright and other laws, each Party may use, refer to, and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences and/or symposia relating to the Study which disclose the name of a Party, provided such use does not constitute an endorsement of any commercial product or service by the other Party.

12 Publications; Press Releases.

12.1 Clinical Trial Registry. BioLineRx shall register the Study with the Clinical Trials Registry located at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and is committed to timely publication of the results following Study Completion, after taking appropriate action to secure intellectual property rights (if any) arising from the Study. The publication of the results of the Study will be in accordance with the Protocol.

12.2 Publication. BioLineRx, as sponsor of the Study, shall have the first right to publish the results of the Study. Upon Study completion or termination (as applicable), or earlier if mutually agreed by the Parties, and after BioLineRx has an opportunity for first publication of the Study results, each Party shall use reasonable efforts to publish or present scientific papers dealing with the Study in accordance with accepted scientific practice. The Parties agree that prior to submission of the results of the Study for publication or presentation or any other dissemination of results including oral dissemination, the publishing Party shall invite the other Party to comment on the content to be published or presented according to the following procedure:

12.2.1 At least [\*] days prior to submission for publication of any paper, letter or any other publication, or [\*] days prior to submission for presentation of any abstract, poster, talk or any other public presentation, the publishing Party shall provide to the other Party the full details of the proposed publication or presentation in an electronic version (cd-rom or email attachment). Upon written request from the other Party, the publishing Party will not submit data for publication/presentation for an additional [\*] days in order to allow for actions to be taken to preserve rights for patent protection.

12.2.2 The publishing Party shall give reasonable consideration to any request by the other Party made within the periods mentioned in Section 12.2.1 to modify the publication and the Parties shall work in good faith and in a timely manner to resolve any issue regarding the content for publication.

12.2.3 The publishing Party shall remove all Confidential Information of the other Party before finalizing the publication.

12.2.4 For clarity, nothing in this Section 12.2 restricts in any way the right of a Party to publish data or results relating to single agent use of its Compound.

12.3 Press Releases. On or immediately following the Effective Date, the Parties will issue a press release in the form attached hereto as Appendix C. [\*] Each Party agrees to identify the other Party and acknowledge such other Party's support of the Study in any press release and any other publication or presentation concerning the Study. [\*] For clarity, nothing in this Section 12.3 restricts in any way the right of a Party to publish data or results relating to single agent use of its Compound.

13 Representations and Warranties; Disclaimers.

13.1 [\*]



13.2 Compounds.

13.2.1 *BioLineRx Compound.* BioLineRx hereby represents and warrants to Merck that (i) BioLineRx has the full right, power and authority to grant all of the licenses granted to Merck under this Agreement, and (ii) BioLineRx Controls the BioLineRx Compound.

13.2.2 *Merck Compound.* Merck hereby represents and warrants to BioLineRx that (i) Merck has the full right, power and authority to grant all of the licenses granted to BioLineRx under this Agreement, and (ii) Merck Controls the Merck Compound.

13.3 *Results.* BioLineRx does not undertake that the Study shall lead to any particular result, nor is the success of the Study guaranteed. Merck does not undertake that the Study shall lead to any particular result, nor is the success of the Study guaranteed. Neither Party shall be liable for any use that the other Party may make of the Clinical Data nor for advice or information given in connection therewith.

13.4 Anti-Corruption

13.4.1 In performing their respective obligations hereunder, the Parties acknowledge that the corporate policies of BioLineRx and Merck and their respective Affiliates require that each Party's business be conducted within the letter and spirit of the law. By signing this Agreement, each Party agrees to conduct the business contemplated herein in a manner which is consistent with all Applicable Law, including the Stark Act, Anti-Kickback Statute, Sunshine Act, and the U.S. Foreign Corrupt Practices Act, good business ethics, and its ethics and other corporate policies and agrees to abide by the spirit of the other Party's guidelines for performance in accordance with its corporate policies, which may be provided by such other Party from time to time.

13.4.2 Specifically, each Party represents and warrants that it has not, and covenants that it, its Affiliates, and its and its Affiliates' directors, employees, officers, and anyone acting on its behalf, will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any action in furtherance of, any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it in obtaining or retaining business for it or the other Party, or in any way with the purpose or effect of public or commercial bribery.

13.4.3 Each Party shall not contact, or otherwise knowingly meet with, any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of the other Party, except where such meeting is consistent with the purpose and terms of this Agreement and in compliance with Applicable Law.

13.4.4 Each Party represents and warrants that it (i) is not excluded, debarred, suspended, proposed for suspension or debarment, in Violation or otherwise ineligible for government programs; and (ii) has not employed or subcontracted with any Person or Third Party for the performance of the Study who is excluded, debarred, suspended, proposed for suspension or debarment, or is in Violation or otherwise ineligible for government programs.

13.4.5 Each Party represents and warrants that except as disclosed to the other Party in writing prior to the Effective Date: (1) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; (2) it shall maintain arm's length relations with all Third Parties with which it deals for or on behalf of the other Party in performance of this Agreement; and (3) it has provided complete and accurate information and documentation to the other Party, the other Party's Affiliates and its and their personnel in the course of due diligence conducted by the other Party for this Agreement, including disclosure of any officers, employees, owners or Persons directly or indirectly retained by such Party in relation to the performance of this Agreement who are Government Officials or relatives of Government Officials. Each Party shall make all further disclosures as necessary to the other Party to ensure the information provided remains complete and accurate throughout the Term. Subject to the foregoing, each Party agrees that it shall not hire or retain any Government Official to assist in its performance of this Agreement, with the sole exception of conduct of or participation in clinical trials under this Agreement, provided that such hiring or retention shall be subject to the completion by the hiring or retaining Party of a satisfactory anti-corruption and bribery (*e.g.*, FCPA) due diligence review of such Government Official. Each Party further covenants that any future information and documentation submitted to the other Party as part of further due diligence or a certification shall be complete and accurate.

13.4.6 Each Party shall have the right during the Term, and for a period of two (2) years following termination of this Agreement, to conduct an investigation and audit of the other Party's activities, books and records, to the extent they relate to that other Party's performance under this Agreement, solely to verify compliance with the terms of this Section 13.4. Such other Party shall cooperate fully with such investigation or audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of the Party requesting such audit, but also reasonably acceptable to the audited Party.

13.4.7 Each Party shall use commercially reasonable efforts to ensure that all transactions under this Agreement are properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects. Each Party further represents, warrants and covenants that all books, records, invoices and other documents relating to payments and expenses under this Agreement are and shall be complete and accurate and reflect in reasonable detail the character and amount of transactions and expenditures. Each Party shall maintain a system of internal accounting controls reasonably designed to ensure that no off-the-books or similar funds or accounts will be maintained or used in connection with this Agreement.

13.4.8 Each Party agrees that in the event that the other Party believes in good faith that there has been a possible violation of any provision of Section 13.4, such other Party may make full disclosure of such belief and related information needed to support such belief at any time and for any reason to any competent government bodies and its agencies, and to whoever such Party determines in good faith has a legitimate need to know; provided, however, that the Party wishing to make the disclosure shall give the other Party at least five (5) days' written notice of such intention.

13.4.9 Each Party shall comply with its own ethical business practices policy and any corporate integrity agreement (if applicable) to which it is subject, and shall conduct its Study-related activities in accordance with Applicable Law. Each Party shall ensure that all of its employees involved in performing its obligations under this Agreement are made specifically aware of the compliance requirements under this Section 13.4. In addition, each Party shall ensure that all such employees participate in and complete mandatory compliance training to be conducted by each Party, including specific training on anti-bribery and corruption, prior to his/her performance of any obligations or activities under this Agreement. Each Party further shall certify its continuing compliance with the requirements under this Section 13.4 on a periodic basis during the Term in such form as may be reasonably specified by the other Party.

13.4.10 Each Party shall have the right to terminate this Agreement immediately upon the other Party's violation of this Section 13.4 in accordance with Section 6.8, provided that the other Party has been provided with written notice of the reasons for termination and has had an opportunity to promptly respond to such reasons.

13.5 DISCLAIMER. EXCEPT AS EXPRESSLY PROVIDED HEREIN, MERCK MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE MERCK COMPOUND, AND BIOLINERX MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE BIOLINERX COMPOUND.

14 Insurance; Indemnification; Limitation of Liability.

14.1 Insurance. Each Party warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Upon written request, a Party shall provide evidence of such insurance.

14.2 Indemnification.

14.2.1 Indemnification by BioLineRx. BioLineRx agrees to defend, indemnify and hold harmless Merck, its Affiliates, and its and their employees, directors, subcontractors and agents from and against any loss, damage, reasonable costs and expenses (including reasonable attorneys' fees and expenses) incurred in connection with any claim, proceeding, or investigation by a Third Party arising out [\*] (a "**Liability**"), to the extent such Liability [\*].

14.2.2 Indemnification by Merck. Merck agrees to defend, indemnify and hold harmless BioLineRx, its Affiliates, and its and their employees, directors, subcontractors and agents from and against any Liability to the extent such Liability [\*].

14.2.3 Procedure. The obligations of Merck and BioLineRx under this Section 14.2 are conditioned upon the delivery of written notice to Merck or BioLineRx, as the case might be, of any potential Liability within the other Party's indemnification obligation, within a reasonable time after such Party becomes aware of such potential Liability. The indemnifying Party will have the right to assume the defense of any suit or claim related to the Liability (using counsel reasonably satisfactory to the indemnified Party) if it has assumed responsibility for the suit or claim in writing; provided that the indemnified Party may assume the responsibility for such defense to the extent the indemnifying Party does not do so in a timely manner. The indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense. The Party controlling such defense (the "**Defending Party**") shall keep the other Party (the "**Other Party**") advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the Other Party with respect thereto. The Defending Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Other Party, which shall not be unreasonably withheld, conditioned or delayed. The Defending Party, but solely to the extent the Defending Party is also the indemnifying Party, shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Other Party from all liability with respect thereto or that imposes any liability or obligation on the Other Party without the prior written consent of the Other Party.

14.2.4 *Study Subjects.* BioLineRx shall not offer compensation on behalf of Merck to any Study subject or bind Merck to any indemnification obligations in favor of any Study subject. Likewise, Merck shall not offer compensation on behalf of BioLineRx to any Study subject or bind BioLineRx to any indemnification obligations in favor of any Study subject.

14.3 **LIMITATION OF LIABILITY.** IN NO EVENT SHALL EITHER PARTY (OR ANY OF ITS AFFILIATES OR SUBCONTRACTORS) BE LIABLE TO THE OTHER PARTY FOR, NOR SHALL ANY INDEMNIFIED PARTY HAVE THE RIGHT TO RECOVER, ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS OR DAMAGES FOR LOST OPPORTUNITIES), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF (X) THE MANUFACTURE OR USE OF ANY COMPOUND SUPPLIED HEREUNDER OR (Y) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT OR ANY REPRESENTATION, WARRANTY OR COVENANT CONTAINED IN OR MADE PURSUANT TO THIS AGREEMENT, EXCEPT THAT SUCH LIMITATION SHALL NOT APPLY TO DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY AN INDEMNIFYING PARTY FOR WHICH THE INDEMNIFIED PARTY IS ENTITLED TO INDEMNIFICATION HEREUNDER OR WITH RESPECT TO DAMAGES ARISING OUT OF OR RELATED TO A PARTY'S BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT TO USE, DISCLOSE, LICENSE, ASSIGN OR OTHERWISE TRANSFER CLINICAL DATA, CONFIDENTIAL INFORMATION, JOINTLY-OWNED INVENTIONS AND SAMPLE TESTING RESULTS ONLY FOR THE PERMITTED USE.

15 **Use of Name.**

Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement without the other Party's prior written consent.

16 **Force Majeure.**

If, in the performance of this Agreement, one of the Parties is prevented, hindered or delayed by reason of any cause beyond such Party's reasonable control (*e.g.*, war, riots, fire, strike, governmental laws), such Party shall be excused from performance to the extent that it is necessarily prevented, hindered or delayed ("**Force Majeure**"). The non-performing Party shall notify the other Party of such Force Majeure within [\*] after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance of the affected Party will be of no greater scope and no longer duration than is necessary and the non-performing Party shall use diligent and commercially reasonable efforts to remedy its inability to perform.

17 **Entire Agreement; Modification.**

The Parties agree to the full and complete performance of the mutual covenants contained in this Agreement. This Agreement, together with the Related Agreements, constitutes the sole, full and complete agreement by and between the Parties with respect to the subject matter of this Agreement, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement. No amendments, changes, additions, deletions or modifications to or of this Agreement shall be valid unless reduced to writing and signed by an authorized representative of each of the Parties hereto.

18 [\*]

19 Invalid Provision.

If any provision of this Agreement is held to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision. In lieu of the illegal, invalid or unenforceable provision, the Parties shall negotiate in good faith to agree upon a reasonable provision that is legal, valid and enforceable to carry out as nearly as practicable the original intention of the entire Agreement.

20 No Additional Obligations.

BioLineRx and Merck have no obligation to renew this Agreement or apply this Agreement to any clinical trial other than the Study. Neither Party is under any obligation to enter into another type of agreement at this time or in the future.

21 Governing Law

This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without reference to its conflicts of laws principles. The U.N. Convention on the Sale of Goods shall not apply to this Agreement.

22 Dispute Resolution.

22.1 Negotiation. The Parties shall attempt in good faith to settle all disputes arising out of or in connection with this Agreement in an amicable manner. Any dispute that is not an Excluded 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 resolved by the Parties within [\*] 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 (at Vice President level or above) designated by BioLineRx and a senior executive (at Vice President level or above) designated by Merck who are authorized to resolve such Dispute on behalf of their respective companies (“**Senior Executives**”). The Senior Executives will meet (or confer by telephone or video conference) within [\*] days after the end of the initial [\*] period referred to above, at a time and place acceptable to both Senior Executives. [\*]

[\*]

23 Notices.

All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by facsimile (and promptly confirmed by personal delivery or overnight courier), or sent by internationally-recognized overnight courier addressed as follows:

If to BioLineRx, to:

BioLineRx Ltd.  
Modi'in Technology Park  
2 HaMa'ayan Street  
Modi'in 7177871, Israel  
Attention: Chief Financial and Operating Officer

With a copy to:

General Counsel  
BioLineRx Ltd.  
Same address as above

If to Merck, to:

Merck Sharp & Dohme B.V.  
Waarderweg 39  
2031 BN Haarlem  
Netherlands  
Attention: Director  
Facsimile: [\*]

With a copy to:

Merck Sharp & Dohme Corp.  
One Merck Drive  
P.O Box 100  
Whitehouse Station, NJ 08889-0100  
Attention: Office of Secretary  
Facsimile No.: [\*]

24 Relationship of the Parties.

The relationship between the Parties is and shall be that of independent contractors, and does not and shall not constitute a partnership, joint venture, agency or fiduciary relationship. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or take any actions, which are binding on the other Party, except with the prior written consent of the other Party to do so. All Persons employed by a Party will be the employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

25 Counterparts and Due Execution.

This Agreement and any amendment may be executed in two (2) or more counterparts (including by way of facsimile or electronic transmission), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. When executed by the Parties, this Agreement shall constitute an original instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. For clarity, facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders, and the word “or” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including” as used herein shall be deemed to be followed by the phrase “without limitation” or like expression. The term “will” as used herein means shall. References to “Article,” “Section” or “Appendix” are references to the numbered sections of this Agreement and the appendices attached to this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, references to this “Agreement” shall include the appendices attached to this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

*[Remainder of page intentionally left blank.]*

**BioLineRx Ltd.**

By: \_\_\_\_\_

\_\_\_\_\_  
Name

\_\_\_\_\_  
Title

**Merck Sharp & Dohme B.V.**

By: \_\_\_\_\_

\_\_\_\_\_  
Name

\_\_\_\_\_  
Title

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DELIVERY SCHEDULE

[\*]

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**For Immediate Release**

DRAFT: January 8, 2016

**BioLineRx Announces Collaboration with MSD to  
investigate the combination of KEYTRUDA®  
(pembrolizumab) and BL-8040 in Pancreatic Cancer**

***BioLineRx management to hold conference call this morning  
at 10:00 am EST to further discuss this immunotherapy collaboration***

Tel Aviv, Israel - January xx, 2016 - BioLineRx Ltd. (NASDAQ/TASE: BLRX) today announced a collaboration with MSD, known as Merck in the US and Canada, to support a Phase 2 study investigating BioLineRx's BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with metastatic pancreatic cancer. The study is an open-label, multicenter, single-arm trial designed to evaluate the safety and efficacy of this combination in patients with metastatic pancreatic adenocarcinoma.

BL-8040, BioLineRx's lead oncology platform, is a CXCR4 antagonist that has been shown in several clinical trials to be a robust mobilizer of immune cells and to be effective at inducing direct tumor cell death. Additional findings in the field of immuno-oncology suggest that CXCR4 antagonists may be effective in inducing the migration of anti-tumor T cells into the tumor micro-environment. KEYTRUDA is a humanized monoclonal antibody that works by increasing the ability of the body's immune system to help detect and fight tumor cells. KEYTRUDA blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T- lymphocytes, which may affect both tumor cells and healthy cells. The Phase 2 study will evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T cells into the tumor and their reactivity.

"We are extremely happy to collaborate with MSD, a pioneer and world leader in cancer immunotherapy. This marks the entrance of BL-8040 into this exciting field, which is already transforming the lives of many cancer patients," stated Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "Because certain tumors exhibit only a modest response to existing immunotherapies, we are increasingly seeing clinical studies involving combinations of immuno-oncology agents with other classes of drugs. We are initiating this study with the hope that it will show that the combination of BL-8040 with KEYTRUDA has the potential to expand the benefit of immunotherapy to cancer types currently resistant to immuno-oncology treatments, such as pancreatic cancer, which represents a significant unmet medical need. If this potential can be realized, it will be an extremely important advance in the fight against cancer, as well as a seminal milestone for BioLineRx."

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“Today, there is a great opportunity and need to bring forward new scientific breakthroughs for the treatment of pancreatic cancer,” said Dr. Eric Rubin, vice president and therapeutic area head, oncology early-stage development, MSD Research Laboratories. “Evaluating the potential of combination therapies through strategic collaborations in difficult-to-treat tumor types continues to be an important part of our immuno-oncology clinical development program for KEYTRUDA.”

The agreement is between BioLineRx and MSD, through a subsidiary. Per the terms of the agreement, the trial will be sponsored and performed by BioLineRx. The study is planned to commence by mid-2016. Upon completion of the study, or at any earlier point, both parties will have the option to expand the collaboration to include a pivotal registration study. Additional details of the collaboration were not disclosed.

BioLineRx will hold a conference call to discuss the collaboration today, January xx, 2016, at 10:00 am EST. To access the conference call, please dial 1-888-281-1167 from the U.S. or +972-3-918-0610 internationally. The call will also be available via live webcast through BioLineRx’s website. A replay of the conference call will be available approximately two hours after completion of the live conference call. To access the replay, please dial 1-888-326-9310 from the U.S. or +972-3-925-5904 internationally. The replay will be available through January xx, 2016.

#### **About Pancreatic Cancer**

There are a number of types of pancreatic cancer. Based on available worldwide numbers, in 2012, pancreatic cancers of all types were the seventh most common cause of cancer deaths. According to the American Cancer Society, in 2015 nearly 50,000 were diagnosed with pancreatic cancer and an estimated 40,000 will die from the disease. The most common type of pancreatic cancer is pancreatic adenocarcinoma, which accounts for about 85 percent of cases. These adenocarcinomas start within the part of the pancreas that makes digestive enzymes. There are usually no symptoms in the early stages of the disease and symptoms that are specific enough to suggest the onset of pancreatic cancer typically do not develop until the disease has reached an advanced stage. The five-year survival rate of pancreatic adenocarcinoma is around 7 percent.

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**About BL-8040**

BL-8040 is a short peptide for the treatment of acute myeloid leukemia, solid tumors, and certain hematological indications. It functions as a high-affinity antagonist for CXCR4, a chemokine receptor that is directly involved in tumor progression, angiogenesis, metastasis and cell survival. CXCR4 is over-expressed in more than 70% of human cancers and its expression often correlates with disease severity. In a number of clinical and pre-clinical studies, BL-8040 has shown robust mobilization of cancer cells from the bone marrow, thereby sensitizing these cells to chemo- and bio-based anti-cancer therapy, as well as a direct anti-cancer effect by inducing apoptosis. In addition, BL-8040 has also demonstrated robust stem-cell mobilization, including the mobilization of colony-forming cells, and T, B and NK cells. BL-8040 was licensed by BioLineRx from Biokine Therapeutics and was previously developed under the name BKT-140.

**About BioLineRx**

BioLineRx is a 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 leading therapeutic candidates are: BL-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for relapsed/refractory AML, has recently initiated a Phase 2b study as an AML consolidation treatment, has recently initiated a Phase 1/2 study in hMDS and AA, and has successfully completed a Phase 1 study in stem cell mobilization; and BL-7010 for celiac disease, which has successfully completed a Phase 1/2 study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates.

For more information on BioLineRx, please visit [www.biolinerx.com](http://www.biolinerx.com) 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.

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Various statements in this release concerning future expectations 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 actual results, performance or achievements 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” sections of recent annual reports filed by the parties to this release. In addition, any forward-looking statements represent the parties’ views only as of the date of this release and should not be relied upon as representing their views as of any subsequent date. The parties do not assume any obligation to update any forward-looking statements unless required by law.

**Contact:**

PCG Advisory  
Vivian Cervantes  
Investor Relations  
212-554-5482  
[vivian@pcgadvisory.com](mailto:vivian@pcgadvisory.com)

or

Tsipi Haitovsky  
Public Relations  
+972-3-624-0871  
[tsipihai5@gmail.com](mailto:tsipihai5@gmail.com)

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Schedule I

DATA SHARING AND SAMPLE TESTING SCHEDULE

[\*]

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**SCHEDULE 2.4**

**Potential BioLineRx Subcontractors  
(in accordance with Section 2.4)**

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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.;
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: May 31, 2016

/s/ Kinneret Savitsky  
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: May 31, 2016

/s/ Philip Serlin

Philip Serlin

Chief Financial and Operating Officer