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

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# FORM 20-F/A

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(Mark One)

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

OR

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

For the fiscal year ended **December 31, 2014**

OR

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

OR

**o** 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)

**P.O. Box 45158**
**19 Hartum Street**
**Jerusalem 9777518, Israel**
(Address of principal executive offices)

**Philip Serlin**
**+972 (2) 548-9100**
**+972 (2) 548-9101 (facsimile)**
**phils@biolinerx.com**
**P.O. Box 45158**
**19 Hartum Street**
**Jerusalem 9777518, Israel**
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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Securities registered or to be registered pursuant to Section 12(b) of the Act:

| Title of each class | Name of each exchange on which registered |
|---|---|
| **American Depositary Shares, each representing 10 ordinary shares, par value NIS 0.01 per share** | **Nasdaq Capital Market** |
| **Ordinary shares, par value NIS 0.01 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 o No x

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

Yes o No x

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

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

Yes x No o

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

Yes o No o

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

Large accelerated filer o Accelerated filer o Non-accelerated filer x

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

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

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

o Item 17 o Item 18

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

Yes o No x

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

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

Yes o No o

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**EXPLANATORY NOTE**

This Amendment No. 1 amends our Annual Report on Form 20-F for the year ended December 31, 2014, as filed with the U.S. Securities and Exchange Commission on March 23, 2015 (the "Annual Report") and is being filed solely to correct a clerical error.

The entire Annual Report as amended is hereby filed.

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 initial filing date and time of our Annual Report.

**INTRODUCTION**

**Certain Definitions**

In this annual report, unless the context otherwise requires:

- references to "BioLineRx," "us," "we" and "our" refer to BioLineRx Ltd. (the "Registrant"), an Israeli company, and its consolidated subsidiaries;
- references to "ordinary shares," "our shares" and similar expressions refer to the Registrant's Ordinary Shares, NIS 0.01 nominal (par) value per share;
- references to "ADS" refer to the Registrant's American Depositary Shares;
- references to "dollars," "U.S. dollars" and "$" are to United States Dollars;
- references to "shekels" and "NIS" are to New Israeli Shekels, the Israeli currency;
- references to the "Companies Law" are to Israel's Companies Law, 5759-1999, as amended; and
- references to the "SEC" are to the United States Securities and Exchange Commission.

**Forward-Looking Statements**

Some of the statements under the sections entitled "Item 3. Key Information – Risk Factors," "Item 4. Information on the Company," and "Item 5. Operating and Financial Review and Prospects" and elsewhere in this Annual Report on Form 20-F constitute forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements, but these are not the only ways these statements are identified. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. In addition, the section of this Annual Report on Form 20-F entitled "Item 4. Information on the Company" contains information obtained from independent industry and other sources that we have not independently verified. You should not put undue reliance on any forward-looking statements. Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements. Readers are encouraged to consult the Company's filings made on Form 6-K, which are periodically filed with or furnished to the SEC.

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

- the initiation, timing, progress and results of our preclinical studies, clinical trials and other therapeutic candidate development efforts;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials;
- our receipt of regulatory approvals for our therapeutic candidates, and the timing of other regulatory filings and approvals;
- the clinical development, commercialization and market acceptance of our therapeutic candidates;
- our ability to establish and maintain corporate collaborations;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;
- the implementation of our business model and strategic plans for our business and therapeutic candidates;

- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- competitive companies, technologies and our industry; and
- statements as to the impact of the political and security situation in Israel on our business.

## PART I

### ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

### ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

### ITEM 3. KEY INFORMATION

#### A. Selected Financial Data

*The following table sets forth our selected consolidated financial data for the periods ended and as of the dates indicated. The following selected historical consolidated financial data for our company should be read in conjunction with "Item 5. Operational and Financial Review and Prospects" and other information provided elsewhere in this Annual Report on Form 20-F and our consolidated financial statements and related notes. The selected consolidated financial data in this section is not intended to replace the consolidated financial statements and is qualified in its entirety thereby.*

The selected consolidated statements of operations data for the years ended December 31, 2014, 2013 and 2012, and the selected consolidated balance sheet data as of December 31, 2014 and 2013, have been derived from our audited consolidated financial statements set forth elsewhere in this Annual Report on Form 20-F. The selected consolidated statements of operations data for the years ended December 31, 2011 and 2010, and the selected consolidated balance sheet data as of December 31, 2012, 2011 and 2010, have been derived from our audited consolidated financial statements not included in this Form 20-F.

Our consolidated financial statements included in this annual report were prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board, and reported in NIS.

| | Year Ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| **Consolidated Statements of Operations Data:**[1] | **2010** | **2011** | **2012** | **2013** | **2014** | **2014**[2] |
| | (in thousands, except share and per share data) | | | | | |
| | **NIS** | | | | | **U.S.$** |
| Revenues | 113,160 | – | – | – | – | – |
| Cost of revenues | (25,571) | – | – | – | – | – |
| Operating expenses: | | | | | | |
| Research and development expenses, net | (54,966) | (42,623) | (64,304) | (44,057) | (42,443) | (10,914) |
| Sales and marketing expenses | (4,609) | (3,308) | (3,227) | (4,101) | (5,685) | (1,462) |
| General and administrative expenses | (14,875) | (12,722) | (14,026) | (13,225) | (13,591) | (3,495) |
| Operating income (loss) | 13,139 | (58,653) | (81,557) | (61,383) | (61,719) | (15,871) |
| Non-operating income, net | – | – | 3,958 | 4,191 | 10,948 | 2,815 |
| Financial income | 3,056 | 12,730 | 8,819 | 2,600 | 12,754 | 3,280 |
| Financial expenses | (8,755) | (4,263) | (7,490) | (6,846) | (1,603) | (412) |
| Net income (loss) | 7,440 | (50,186) | (76,270) | (61,438) | (39,620) | (10,188) |
| Net earnings (loss) per ordinary share | 0.06 | (0.41) | (0.45) | (0.27) | (0.12) | (0.03) |
| Number of ordinary shares used in computing earnings (loss) per ordinary share | 123,512,098 | 123,587,030 | 169,404,730 | 224,885,157 | 324,338,834 | 324,338,834 |

| | As of December 31, | | | | | |
|---|---|---|---|---|---|---|
| **Consolidated Balance Sheet Data:** | **2010** | **2011** | **2012** | **2013** | **2014** | **2014**[2] |
| | (in thousands) | | | | | |
| | **NIS** | | | | | **U.S.$** |
| Cash and cash equivalents | 111,746 | 33,061 | 68,339 | 30,888 | 22,519 | 5,790 |
| Short-term bank deposits | 28,037 | 65,782 | 11,459 | 32,345 | 112,354 | 28,890 |
| Property, plant and equipment, net | 4,509 | 4,211 | 3,172 | 2,471 | 2,804 | 721 |
| Total assets | 154,613 | 111,660 | 90,808 | 69,469 | 140,827 | 36,211 |
| Total liabilities | 22,653 | 25,902 | 34,879 | 28,783 | 17,133 | 4,406 |
| Total shareholders' equity | 131,960 | 85,758 | 55,929 | 40,686 | 123,694 | 31,806 |

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

(2) Calculated using the exchange rate reported by the Bank of Israel for December 31, 2014 at the rate of one U.S. dollar per NIS 3.889.

We report our financial statements in NIS. No representation is made that the NIS amounts referred to in this Annual Report on Form 20-F could have been or could be converted into U.S. dollars at any particular rate or at all.

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

| | NIS per U.S. $ | | | |
|---|---|---|---|---|
| **Year Ended December 31,** | **High** | **Low** | **Average** | **Period End** |
| 2014 | 3.994 | 3.402 | 3.577 | 3.889 |
| 2013 | 3.791 | 3.504 | 3.611 | 3.471 |
| 2012 | 4.084 | 3.700 | 3.844 | 3.733 |
| 2011 | 3.821 | 3.363 | 3.578 | 3.821 |
| 2010 | 3.894 | 3.549 | 3.730 | 3.549 |

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

| | NIS per U.S. $ | | | |
|---|---|---|---|---|
| **Month** | **High** | **Low** | **Average** | **Period End** |
| March 2015 (through March 20, 2015) | 4.053 | 3.984 | 4.017 | 4.053 |
| February 2015 | 3.966 | 3.844 | 3.893 | 3.966 |
| January 2015 | 3.998 | 3.889 | 3.946 | 3.924 |
| December 2014 | 3.994 | 3.889 | 3.935 | 3.889 |
| November 2014 | 3.889 | 3.782 | 3.828 | 3.889 |
| October 2014 | 3.793 | 3.644 | 3.736 | 3.784 |
| September 2014 | 3.695 | 3.578 | 3.630 | 3.695 |

On March 20, 2015, the closing representative rate was $1.00 to NIS 4.053, as reported by the Bank of Israel.

**B. Capitalization and Indebtedness**

Not applicable.

**C. Reasons for the Offer and Use of Proceeds**

Not applicable.

**D. Risk Factors**

*You should carefully consider the risks we describe below, in addition to the other information set forth elsewhere in this Annual Report on Form 20-F, including our consolidated financial statements and the related notes beginning on page F-1, before deciding to invest in our ordinary shares and ADSs. These material risks could adversely impact our results of operations, possibly causing the trading price of our ordinary shares and ADSs to decline, and you could lose all or part of your investment.*

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

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

We are a clinical stage biopharmaceutical development company that was incorporated in 2003. Since our incorporation, we have been focused on research and development. Our most advanced therapeutic candidates are in clinical development. We, or our licensees, as applicable, will be required to conduct significant additional clinical trials before we or they can seek the regulatory approvals necessary to begin commercial sales of our therapeutic candidates. We have incurred losses since inception, principally as a result of research and development and general administrative expenses in support of our operations. We recorded net losses of approximately NIS 39.6 million in 2014, NIS 61.4 million in 2013 and NIS 76.3 million in 2012. As of December 31, 2014, we had an accumulated deficit of approximately NIS 545.4 million. We anticipate that we will incur significant additional losses as we continue to focus our resources on prioritizing, selecting and advancing our most promising therapeutic candidates. We may never be profitable and we may never achieve significant sustained revenues.

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

As of December 31, 2014, we held cash and short-term investments of approximately $34.7 million. In March 2015, we closed an underwritten public offering of our ADSs for gross proceeds of $28.8 million. We believe that our existing cash and investment balances and other sources of liquidity, not including potential milestone and royalty payments under our out-licensing agreements with Bellerophon BCM LLC, or Bellerophon, and with a subsidiary of Omega Pharma NV, or Omega Pharma, (see "Item 4. Information on the Company — Business Overview — Lead Therapeutic Candidates — BL-1040 and BL-5010), will be sufficient to meet our requirements into 2018. We have funded our operations primarily through public and private offerings of our securities and, until 2013, grants from the Office of the Chief Scientist of Israel's Ministry of the Economy, or the OCS. In addition, we have funded our operations through out-licensing arrangements with respect to our therapeutic candidates. The adequacy of our available funds to meet our operating and capital requirements will depend on many factors including: the number, breadth, progress and results of our research, product development and clinical programs; the costs and timing of obtaining regulatory approvals for any of our therapeutic candidates; the terms and conditions of in-licensing and out-licensing therapeutic candidates; and costs incurred in enforcing and defending our patent claims and other intellectual property rights.

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

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

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

To date, we have not marketed, distributed or sold an approved product. Currently, we have six clinical-stage therapeutic candidates in development: BL-1040 for the reduction or prevention of ventricular remodeling following an acute myocardial infarction, or AMI; BL-8040 for the treatment of acute myeloid leukemia, or AML, stem cell mobilization and other hematological indications; BL-7010 for the treatment of celiac disease; BL-5010 for the treatment of benign skin lesions; BL-7040 for the treatment of inflammatory bowel disease, or IBD; and BL-8020 for the treatment of the hepatitis C virus, or HCV, as well as other viral indications. Our therapeutic candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization of drugs and devices. We may not obtain marketing approval for any of our therapeutic candidates in a timely manner or at all. In connection with the clinical trials for BL-1040, BL-8040, BL-7010, BL-5010, BL-7040, BL-8020, and other therapeutic candidates that we are currently developing or may seek to develop in the future, either on our own or through out-licensing or co-development arrangements, we face the risk that:

- a therapeutic candidate or medical device may not prove safe or efficacious;
- the results with respect to any therapeutic candidate may not confirm the positive results from earlier preclinical studies or clinical trials;
- the results may not meet the level of statistical significance required by the U.S. Food and Drug Administration, or FDA, or other regulatory authorities; and

- the results will justify only limited and/or restrictive uses, including the inclusion of warnings and contraindications, which could significantly limit the marketability and profitability of the therapeutic candidate.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In 2009, we entered into an exclusive, royalty-bearing worldwide out-licensing arrangement with Bellerophon with respect to BL-1040, which we amended in 2015. Under the arrangement, Bellerophon is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or a product related thereto. In December 2014, we entered into an exclusive out-licensing arrangement with Omega Pharma for the rights to BL-5010 for over-the-counter, or OTC, indications in the territories of Europe, Australia and additional selected countries. Under the arrangement, Omega Pharma is obligated to use commercially reasonable best efforts to obtain regulatory approval in the licensed territory for at least two OTC indications and to commercialize BL-5010 for those two OTC indications. In addition, we have co-development collaborations with partners for BL-8020, BL-8030 and BL-9020 whereby such partners have development and commercialization rights in certain territories.

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

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

We employ a number of methods to identify therapeutic candidates that we believe are likely to achieve commercial success. In addition to our internal research and business developments efforts, we employ a rigorous screening system we developed. In addition, our Scientific Advisory Board and disease-specific third-party advisors evaluate each therapeutic candidate. However, there can be no assurance that our internal research efforts or our screening system will accurately or consistently select among various therapeutic candidates those that have the highest likelihood to achieve, and which ultimately achieve, commercial success. As a result, we may spend substantial resources developing therapeutic candidates that will not achieve commercial success and we may not advance those therapeutic candidates with the greatest potential for commercial success.

An important element of our strategy is maintaining relationships with universities, medical institutions and biotechnology companies in order to in-license potential therapeutic candidates. We may not be able to maintain relationships with these entities and they may elect not to enter into in-licensing agreements with us or to terminate existing agreements. Recently, a number of global pharmaceutical companies have set up operations in Israel, both with and without Israeli government funding, in order to identify and in-license new technologies. The presence of these global companies with significantly greater resources than we have may increase the competition with respect to the in-licensing of promising therapeutic candidates. We may not be able to acquire licenses on commercially reasonable terms, or at all. Failure to license or otherwise acquire necessary technologies could materially and adversely affect our business, financial condition and results of operations.

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

We depend on in-licensing agreements with third parties to maintain the intellectual property rights to our therapeutic candidates. Regarding the therapeutic candidates in clinical trials, we have in-licensed rights from B.G. Negev Technologies, the technology transfer company of Ben Gurion University, with respect to our BL-1040 therapeutic candidate; from Biokine Therapeutics Ltd., or Biokine, with respect to our BL-8040 therapeutic candidate; from Gestion Univalor, Limited Partnership, or Univalor, for our BL-7010 therapeutic candidate; from Innovative Pharmaceutical Concepts, Inc., or IPC, with respect to our BL-5010 therapeutic candidate; and from the Yissum Research Development Company of the Hebrew University of Jerusalem Ltd., or Yissum, with respect to our BL-7040 therapeutic candidate. See “Item 4. Information on the Company — Business Overview — Our Product Pipeline.” Our in-license agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these agreements. The royalty rates and revenue sharing payments vary from case to case but generally range from 22% to 29.5% of the consideration we receive from sublicensing the applicable therapeutic candidate. In some instances, we are required to pay a substantially lower percentage (generally less than 5%) if we elect to commercialize the subject therapeutic candidate independently. Due to the relatively advanced stage of development of the compound licensed from Biokine, our license agreement with Biokine provides for royalty payments of between 40-60% of the consideration we receive from sublicensing and between 10-12% of net sales, subject to certain limitations, should we independently sell products. The amount of the royalty for either direct sales or sublicensing is dependent on the aggregate amount of our investment in connection with the Biokine agreement, decreasing as the amount of our investment in the project increases. Based on the current and anticipated cumulative investment in the project made by us, we believe it is highly probable that the royalty payments to Biokine will be at the lowest end of the above ranges (i.e., 40% for sublicensing and 10% for direct sales). These in-license agreements last either throughout the life of the patents that are the subject of the agreements, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

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

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

Modifications to our therapeutic candidates, after they have been approved for marketing, if at all, or to any other pharmaceutical product or medical device that we may develop in the future, may require new regulatory clearance, or approvals, and, if necessitated by a problem with a marketed product, may result in the recall or suspension of marketing of the previously approved and marketed product until clearances or approvals of the modified product are obtained. The FDA requires pharmaceutical products and device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine in conformity with applicable regulations and guidelines that a modification may be implemented without pre-clearance by the FDA; however, the FDA can review a manufacturer’s decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. If the FDA requires new clearances or approvals of any pharmaceutical product or medical device for which we or our licensees receive marketing approval, if any, we or our licensees may be required to recall such product and to stop marketing the product as modified, which could require us or our licensees to redesign the product and will have a material adverse effect on our business, financial condition and results of operations. In these circumstances, we may be subject to significant enforcement actions.

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

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

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address the indications for which we are currently developing therapeutic candidates or for which we may develop therapeutic candidates in the future. Specifically, we are aware of several other companies who currently market and/or are in the process of developing products that address AMI, AML, celiac disease, skin lesions, IBD, and HCV and other viral indications.

There are no generally accepted products approved for structural support to prevent cardiac remodeling following an AMI. One group of product candidates that are currently in clinical development includes stem cell therapies to restore heart muscle cells following an AMI, with large Phase 3 trials expected to be completed in 2018 or 2019. We do not expect BL-1040 to compete with, or replace, current treatments for congestive heart failure following AMI, but instead believe it will become part of the treatment regimen used in conjunction with other therapies. In addition, because BL-1040 can be delivered by a minimally invasive percutaneous coronary intervention procedure, we do not believe it will directly compete with devices that are used to treat congestive heart failure, which are designed for administration during open heart surgery or by intra-cardiac injection involving a thoracotomy procedure. These include mesh restraining devices, for example HeartNet™; injectable biopolymers, for example Algisyl LVR™; and implantable electro stimulation devices, for example, CardioFit™. In addition, volume reduction surgery or cardiac assist devices, or pumps, are sometimes used to treat patients with congestive heart failure.

Approved treatments for AML currently include chemotherapy (Doxorubicin, Cyclophosphamide, Vincristine), radiation therapy and stem cell transplantation. In addition there are a number of potentially competitive compounds under development that act as CXCR4 inhibitors, including, among others, AMD 3100 (Mozobil), which is being developed by Genzyme and Sanofi; LY-2510924, which is being developed by Lilly; Ulocuplumab (MDX-1338; BMS-936564) developed by Medarex and Bristol Myaers Squibb; F-50067 developed by Pierre Fabre; burixafor developed by TaiGen Biotechnology Co; and POL-6326 developed by Polyphor Ltd; PTX-9908 developed by Chemokine Therapeutics Corp. In addition there are a number of potentially competitive compounds under development to treat AML including, among others, Dacogen (decitabine), which is being developed by Eisai and Johnson & Johnson; Vidaza (azacitidine), which is being developed by Celgene; Vosaroxin, which is being developed by Sunesis Pharmaceuticals; Midostaurin, which is being developed by Novartis; Quizartinib, which is being developed by Ambit; Volasertib, which is being developed by Boehringer Ingelheim; fludarabine, which is being developed by Sanofi; nintedanib and BI-836858, both of which are under development by Boehringer Ingelheim; dasatinib (Sprycel) developed under BMS; RG-6016 under development by Roche; OCV-501, under development by Otsuka Pharmaceutical; ibrutinib developed by Pharmacyclics, under license from Celera, and in collaboration with Janssen Biotech; CPI-613 developed by Cornerstone Pharmaceuticals; F-14512 developed by Pierre Fabre; SL-401 developed by Stemline Therapeutics; pacritinib developed by CTI BioPharma Corp; sonidegib developed by Novartis; venetoclax developed by AbbVie; lirilumab developed by Innate Pharma in collaboration with BMS; selinexor developed by Karyopharm Therapeutics; Ganetespib developed by Synta Pharmaceuticals; crenolanib, which is being developed by Arog Pharmaceuticals, under license from Pfizer; BVD-ERK developed by BioMed Valley Discoveries; tosedostat developed by CTI BioPharma; pidilizumab developed by Medivation, under license from CureTech; sorafenib (Nexavar) developed by Bayer; Bortezomib developed by Janssen and Takeda; Uprosertib developed by GSK; PLX-3397 developed by Plexxikon Inc.; Lenalidomide developed by Celgene; erlotinib developed by Roche Astellas and Chugai; Trametinib developed by GSK; Vorinostat developed by Merck and Co.; Selumetinib developed by Astra Zeneca; SGI-110 developed by Astex Pharmaceuticals;; OCV-501 developed by Otsuka Pharmaceuticals; Birinapant developed by Tetralogic Pharmaceuticals; Alvocidib developed by Tolero Pharmaceuticals Inc; Pracinostat developed by MEI Pharma; Rigosertib developed by Onconova Therapeutics , Baxter International and Symbio; Sapacitabine developed by Cyclacel Pharmaceuticals; and RP-323 under development by Rich Pharmaceuticals. Some of these treatments are currently developed for specific AML patient populations and lines of treatment (e.g., AC220 developed by Ambit Biosciences) and not for the entire AML population. Some of these treatments can be developed for administration to AML patients in combination with BL-8040.

Several compounds are currently under development for celiac disease including larazotide acetate (Alba Therapeutic Corp.), which inhibits the activity of Zonulin; and latiglutenase (Alvine Pharmaceuticals Inc.), which is a combination of gluten targeting proteases and endopeptidases. Celiac patients are prescribed a gluten-free diet to relieve their disease symptoms. Nevertheless the symptoms persist in most cases despite the patient's following a gluten-free diet. BL-7010, as well as the treatments specified above, is envisioned to be prescribed to patients who are on a gluten-free diet but still suffer from disease symptoms.

Skin lesions are generally removed using cryotherapy (liquid nitrogen), laser therapy, photodynamic therapy, electrodessication and curettage and several cream-based treatments. Picato (Leo Pharma) and Metvix® (Galderma Pharma) are cream-based treatments for skin lesions which have been approved in many countries.

IBD is often treated with currently marketed steroids, immunomodulators and immunomodulatory antibodies. Approved treatments for IBD currently include anti-TNFs, such as Remicade (infliximab, Janssen Biotech, Inc., a Johnson & Johnson company, Merck & Co. and Mitsubishi Tanabe Pharma), Humira (adalimumab, Abbott Laboratories and Eisai Co.), Cimzia (certolizumab, UCB, Inc.) and Simponi (golimumab, Janssen Biotech, Inc., Merck & Co. and Mitsubishi Tanabe Pharma), as well as antibodies inhibiting immune cell migration such as Tysabri (natalizumab, Biogen and Elan) and Vedolizumab (Takeda). In addition, there are generic brands of mesalazine, a 5-aminosalicylate, and the recently launched Budesonide MMX (Cosmo Pharmaceuticals, Ferring Pharmaceuticals and Santarus). The first biosimilar version of infliximab was approved for use in Europe in 2013. We are also aware of a number of potentially competitive compounds under development, including Xeljanz (tofacitinib, Pfizer Inc.), a Jak 1 inhibitor; Vedolizumab (Takeda, Millenium Pharmaceuticals), a MAdCAM inhibitor /integrin alpha-4/beta-7 antagonist; Ustekinomab (Johnson & Johnson), an anti-IL-12/IL23 mAb; JM-300 (Ajinomoto), an Integrin alpha-4/beta-7 antagonist; Etrolizumab a beta 7 targeting mAb developed by Roche; LP-02 developed by Lipid Therapeutics; and DIMS-0150 (Kappaproct) a TLR9-targeting oligo developed by InDex Pharmaceuticals.

HCV treatment consists of either a combination of interferon and ribavirin alone or together with a combination of direct anti-viral agents (DAAs) of several classes including NS3/4 protease inhibitors, NS5A inhibitors and NS5B inhibitors. Recently, treatment regimens that do not include interferon have been approved, and treatment regimens without ribavirin are at advanced stages of development. Approved anti-HCV treatments include Sovaldi (sofosbuvir) and Harvoni (a fixed combination of sofosbuvir and ledipasvir), both developed by Gilead Sciences; Viekira Pak (a fixed combination of paritaprevir/r + ombitasvir + dasabuvir ) developed by AbbVie; Olysio (simeprevir, Janssen Therapeutics and Medivir); Victrelis (boceprevir, Merck and Co); vaniprevir (developed by Merck and Co ); Incivek (telaprevir, Janssen Pharmaceuticals and Vertex Pharmaceuticals); asunaprevir and daclatasvir (developed by Bristol Myers Squibb). Compounds under development include elbasvir (Merck and Co.) and ACH-3102 (developed by Achillion). BL-8020's mechanism of action suggests that it could potentially be suitable for treatment of other viral infections, each of which has numerous competing treatments approved or in advanced stages of development.

An important element of our strategy for identifying future products is maintaining relationships with universities, medical institutions and biotechnology companies in order to in-license potential therapeutic candidates, and we compete with respect to this in-licensing with a number of global pharmaceutical companies, both with and without Israeli government funding. The presence of these global companies with significantly greater resources than we have may increase the competition with respect to the in-licensing of promising therapeutic candidates. Our failure to license or otherwise acquire necessary technologies could materially and adversely affect our business, financial condition and results of operations.

***We and our contract manufacturers are, and will be, subject to FDA and other comparable agency regulations.***

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

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

We currently have no sales, marketing or distribution capabilities and no experience in building a sales force or distribution capabilities. To be able to commercialize any of our therapeutic candidates upon approval, if at all, we must either develop internal sales, marketing and distribution capabilities, which will be expensive and time consuming, or enter into out-licensing arrangements with third parties to perform these services.

If we decide to market any of our other therapeutic candidates on our own, we must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. Factors that may inhibit our efforts to commercialize our products directly and without strategic partners include:

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

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

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

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

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

***We expect to rely upon third-party manufacturers to produce therapeutic supplies for phase 3 clinical trials, and commercialization, of our therapeutic candidates. If we manufacture any of our therapeutic candidates in the future, we will be required to incur significant costs and devote significant efforts to establish and maintain manufacturing capabilities.***

We currently have laboratories that are compliant with both current good manufacturing practices, or cGMP, and Good Laboratory Practices, or GLP, and allow us to manufacture drug products for our current clinical trials. If we decide to perform any phase 3 clinical trial, or commercialize, any therapeutic candidate on our own, we anticipate that we will rely on third parties to produce the therapeutic supplies. We have limited personnel with experience in drug or medical device manufacturing and we lack the resources and capabilities to manufacture any of our therapeutic candidates on a commercial scale. The manufacture of pharmaceutical products and medical devices requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products and medical devices often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields and quality control, including stability of the therapeutic candidate.

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

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

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

The failure of any of our contract manufacturers to maintain high manufacturing standards could result in injury or death of clinical trial participants or patients being treated with our products. Such failure could also result in product liability claims, product recalls, product seizures or withdrawals, delays or failures in testing or delivery, cost overruns or other problems, which would have a material adverse effect on our business, financial condition and results of operations.

**Risks Related to Our Industry**

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

Even if our therapeutic candidates are approved for commercialization, they may not become commercially viable products. For example, if we or our licensees receive regulatory approval to market a product, approval may be subject to limitations on the indicated uses or subject to labeling or marketing restrictions which could materially and adversely affect the marketability and profitability of the product. In addition, a new product may appear promising at an early stage of development or after clinical trials but never reach the market, or it may reach the market but not result in sufficient product sales, if any. A therapeutic candidate may not result in commercial success for various reasons, including:

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

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

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

In 2010, the U.S. Congress adopted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the PPACA), important legislation regarding health insurance which may have far-reaching consequences for most health care companies, including biopharmaceutical companies like us. Under the new legislation, substantial changes are going to be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage.

Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payors and government programs (Medicare, Medicaid and State Children’s Health Insurance Program), creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs and biopharmaceuticals, such as those we and our licensees are currently developing. If reimbursement for our approved products, if any, is substantially reduced in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

Extending medical benefits to those who currently lack coverage will likely result in substantial cost to the U.S. federal government, which may force significant changes to the healthcare system in the United States. Much of the funding for expanded healthcare coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of care.

Cost of care could be reduced by decreasing the level of reimbursement for medical services or products (including those biopharmaceuticals currently being developed by us or our licensees), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for, any product for which we receive marketing approval in the future could have a materially adverse effect on our financial performance.

The PPACA also requires the medical device industry to subsidize healthcare reform in the form of a 2.3% excise tax on U.S. sales of certain medical devices beginning January 1, 2013 and also includes new regulatory mandates and other measures designed to constrain medical costs, as well as stringent new reporting requirements of financial relationships between device manufacturers and physicians and hospitals.

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

Our revenues and profits will depend heavily upon the availability of adequate reimbursement for the use of our approved candidates, if any, from governmental or other third-party payors, both in the United States and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that the use of an approved product is:

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

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

Regardless of the impact of the PPACA on us, the U.S. government, other governments and commercial payors have shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could cause significant pressure on the pricing of healthcare products and services, including those biopharmaceuticals currently being developed by us or our licensees, in the United States and internationally, as well as the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors to contain or reduce healthcare costs may compromise our ability to set prices at commercially attractive levels for our products that we may develop, which in turn could adversely impact how much or under what circumstances healthcare providers will prescribe or administer our products, if approved. Changes in healthcare policy, such as the creation of broad limits for diagnostic products, could substantially diminish the sale of or inhibit the utilization of diagnostic tests, increase costs, divert management's attention and adversely affect our ability to generate revenues and achieve consistent profitability. This could materially and adversely impact our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our products, if approved.

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

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

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

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

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

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

**Risks Related to Intellectual Property**

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

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

We currently have in-licensing agreements relating to our lead therapeutic candidates under clinical development. In January 2005, we in-licensed the rights to BL-1040 under a license agreement with B.G. Negev Technologies. Under the BL-1040 license agreement, we are obligated to use commercially reasonable efforts to develop the licensed technology in accordance with a specified development plan, including meeting certain specified diligence goals. In September 2012, we in-licensed the rights to BL-8040 under a license agreement from Biokine. Under the BL-8040 license agreement, we are obligated to make commercially reasonable, good faith efforts to sublicense or commercialize BL-8040 for fair consideration. In February 2011, we in-licensed the rights to BL-7010 from Univalor. Under the BL-7010 license agreement, we are obligated to use commercially reasonable efforts to develop the licensed technology in accordance with a specified development plan, including meeting certain specified diligence goals. In November 2007, we in-licensed the rights to BL-5010 under a license agreement with IPC. Under the BL-5010 license agreement, we are obligated to use commercially reasonable efforts to develop the licensed technology in accordance with a specified development plan, including meeting certain specified diligence goals. In June 2011, we in-licensed the rights to BL-7040 under a license agreement from Yissum. Under the BL-7040 license agreement, we are responsible for, and are required to exert, reasonable commercial efforts to carry out the development, regulatory, manufacturing, and marketing work necessary to develop and commercialize products under the agreement in accordance with a specified development plan. In January 2012, we in-licensed the rights to BL-8020 under a license agreement from Panmed and Genoscience. Under the BL-8020 license agreement, we were obligated to use commercially reasonable efforts to develop and commercialize the licensed technology in accordance with a specified development plan. In January 2014, we entered into a collaboration agreement with the licensors of the compound whereby, in consideration for the payment of future royalties to us, we terminated the license agreement, the licensors agreed to take over development of the compound and we agreed to supply, at the licensors' request and for full payment, the drug product needed for a clinical trial to be administered by the licensors.

Each of the foregoing in-licensing agreements, or the obligation to pay royalties thereunder, will generally remain in effect until the expiration, under the applicable agreement, of all of the licensing, royalty and sublicense revenue obligations to the applicable licensors, determined on a product-by-product and country-by-country basis. We may terminate the BL-1040 in-licensing agreement by providing 60 days' prior written notice to B.G. Negev Technologies. We may terminate the BL-8040 in-licensing agreement upon 90 days' prior written notice to Biokine. We may terminate the BL-7010 in-licensing agreement, the BL-5010 in-licensing agreement or the BL-7040 in-licensing agreement upon 30 days' prior written notice to the respective licensor.

Any party to any of the foregoing in-licensing agreements may terminate the respective agreement for material breach by the other party if the breaching party is unable to cure the breach within an agreed upon period, generally 30 days to 90 days, after receiving written notice of the breach from the non-breaching party. Each of the foregoing in-licensing agreements provide that with respect to any termination for material breach, if the breach is not susceptible to cure within the stated period and the breaching party uses diligent, good faith efforts to cure such breach, the stated period will be extended by an additional 30 days. In addition, either party to one of the foregoing in-licensing agreements may terminate the agreement upon notice to the other upon the occurrence of certain bankruptcy events.

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

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

We try to protect our proprietary position by, among other things, filing U.S., European, Israeli and other patent applications related to our proprietary products, technologies, inventions and improvements that may be important to the continuing development of our therapeutic candidates. As of December 31, 2014 we owned or exclusively licensed for uses within our field of business 18 patent families that, collectively, contain 54 issued patents, three allowed patent applications and over 40 pending patent applications relating to our clinical candidates. We are also pursuing patent protection for other drug candidates in our pipeline.

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

Patent rights are territorial; thus, the patent protection we do have will only extend to those countries in which we have issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the United States and Israel. For example, the patent laws of China and India are relatively new and are not as developed as are older, more established patent laws of other countries. Competitors may successfully challenge our patents, produce similar drugs or products that do not infringe our patents, or produce drugs in countries where we have not applied for patent protection or that do not respect our patents. Furthermore, it is not possible to know the scope of claims that will be allowed in published applications and it is also not possible to know which claims of granted patents, if any, will be deemed enforceable in a court of law.

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

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

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

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

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

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

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

Our license agreements with our licensees, including Bellerophon, Omega Pharma and our other co-development partners, contain, and any contract that we enter into with licensees in the future will likely contain, indemnity provisions that obligate us to indemnify the licensee against any losses arising from infringement of third party intellectual property rights. In addition, our in-license agreements contain provisions that obligate us to indemnify the licensors against any damages arising from the development, manufacture and use of products developed on the basis of the in-licensed intellectual property.

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

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

In July 2014 and October 2014, Bellerophon was notified by the European Patent Office that Notices of Opposition to two European patents that Bellerophon licensed from us, one of which covers the BCM intended commercial product described above, have been filed with the European Patent Office. A Notice of Opposition initiates a process during which the European Patent Office can decide to reconsider an issued patent and modify or revoke some or all of the patent claims. As our licensee, Bellerophon has the right to respond to the Notices of Opposition before the European Patent Office makes a decision whether or not any or all of the patent claims are to be modified or revoked. Bellerophon filed a response to the first patent opposition in December 2014 and intends to file a response in the near future for the second patent opposition as Bellerophon and BioLineRx believe the two issued patents were properly examined and appropriately granted by the European Patent Office. Furthermore, Bellerophon and BioLineRx believe the arguments made in the Notices of Opposition misstate the facts and lack scientific merit.

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

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

**Risks Related to our Ordinary Shares and ADSs**

***We may be a passive foreign investment company, or PFIC, for U.S. federal income tax purposes in 2015 or in any subsequent year. There may be negative tax consequences for U.S. taxpayers that are holders of our ordinary shares or our ADSs.***

We will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (i) at least 75% of our gross income is "passive income" or (ii) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account. We believe that we were a PFIC during certain prior years and, although we have not determined whether we will be a PFIC in 2015, or in any subsequent year, our operating results for any such years may cause us to be a PFIC. If we are a PFIC in 2015, or any subsequent year, and a U.S. shareholder does not make an election to treat us as a "qualified electing fund," or QEF, or make a "mark-to-market" election, then "excess distributions" to a U.S. shareholder, and any gain realized on the sale or other disposition of our ordinary shares or ADSs will be subject to special rules. Under these rules: (i) the excess distribution or gain would be allocated ratably over the U.S. shareholder's holding period for the ordinary shares (or ADSs, as the case may be); (ii) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (iii) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, if the U.S. Internal Revenue Service, or the IRS, determines that we are a PFIC for a year with respect to which we have determined that we were not a PFIC, it may be too late for a U.S. shareholder to make a timely QEF or mark-to-market election. U.S. shareholders who hold our ordinary shares or ADSs during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to exceptions for U.S. shareholders who made a timely QEF or mark-to-market election. A U.S. shareholder can make a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. A QEF election generally may not be revoked without the consent of the IRS. Upon request, we will annually furnish U.S. shareholders with information needed in order to complete IRS Form 8621 (which form would be required to be filed with the IRS on an annual basis by the U.S. shareholder) and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC.

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

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

- announcements of technological innovations or new products by us or others;
- announcements by us of significant acquisitions, strategic partnerships, in-licensing, out-licensing, joint ventures or capital commitments;
- expiration or terminations of licenses, research contracts or other collaboration agreements;
- public concern as to the safety of drugs we, our licensees or others develop;
- general market conditions;
- the volatility of market prices for shares of biotechnology companies generally;
- success of research and development projects;
- departure of key personnel;
- developments concerning intellectual property rights or regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our ordinary shares or ADSs are covered by analysts;
- statements about the Company made in the financial media or by bloggers on the Internet;
- changes in government regulations or patent decisions;
- developments by our licensees; and
- general market conditions and other factors, including factors unrelated to our operating performance.

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

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

Our ordinary shares are traded on the TASE and our ADSs are listed on the Nasdaq Capital Market. Trading in our securities on these markets takes place in different currencies (dollars on the Nasdaq Capital Market and NIS on the TASE), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Israel). The trading prices of our securities on these two markets may differ due to these factors, the factors listed above, or other factors. Any decrease in the price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

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

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

As a result of previous financings, we have warrants outstanding for the purchase of approximately 4,200,000 ADSs at an average exercise price of $3.71 per ADS. In addition we have stock options granted to directors, employees and consultants for the purchase of approximately 32,500,000 Ordinary Shares with an average exercise price of $0.25 per Ordinary Share (equivalent to 3,250,000 ADSs with an average exercise price of approximately $2.45 per ADS).

In May 2014, we entered into a purchase agreement with Lincoln Park Capital Fund, LLC, or LPC, for the sale, from time to time, of up to $20 million of our ADSs to LPC. During the 36-month term of this purchase agreement, we control the timing and amount of any sales to LPC, if and when we decide, in accordance with the agreement. LPC has no right to require us to sell any ADSs to LPC, but LPC is obligated to make purchases as we direct, subject to certain conditions. The purchase price related to any sales to LPC is based on the prevailing market prices of our ADSs immediately preceding the notice of sale to LPC, without any fixed discount. The agreement may be terminated by us at any time, at our sole discretion, without any cost or penalty. As of the date of this annual report, we have not yet sold any ADSs to LPC under the purchase agreement.

The issuance of any additional ordinary shares, any additional ADSs, or any securities that are exercisable for or convertible into our ordinary shares or ADSs, may have an adverse effect on the market price of our ordinary shares and ADSs and will have a dilutive effect on our shareholders.

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

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

- the failure to obtain regulatory approval or achieve commercial success of our therapeutic candidates, including BL-1040, BL-8040, BL-7010, BL-5010, BL-7040 and BL-8020;
- our success in effecting out-licensing arrangements with third-parties;
- our success in establishing other out-licensing or co-development arrangements;
- the success of our licensees in selling products that utilize our technologies;
- the results of our preclinical studies and clinical trials for our earlier stage therapeutic candidates, and any decisions to initiate clinical trials if supported by the preclinical results;
- the costs, timing and outcome of regulatory review of our therapeutic candidates that progress to clinical trials;
- the costs of establishing or acquiring specialty sales, marketing and distribution capabilities, if any of our therapeutic candidates are approved, and we decide to commercialize them ourselves;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our issued patents and defending intellectual property-related claims;
- the extent to which we acquire or invest in businesses, products or technologies and other strategic relationships; and
- the costs of financing unanticipated working capital requirements and responding to competitive pressures.

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

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

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of those otherwise required under the Marketplace Rules of the Nasdaq for domestic issuers. For instance, we may follow home country practice in Israel with regard to, among other things, composition of the Board of Directors, director nomination procedure, composition of the compensation committee, approval of compensation of officers, and quorum at shareholders' meetings. In addition, we will follow our home country law, instead of the Marketplace Rules of the Nasdaq, which require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the company and certain acquisitions of the stock or assets of another company. Following our home country governance practices as opposed to the requirements that would otherwise apply to a United States company listed on the Nasdaq may provide less protection than is accorded to investors under the Marketplace Rules of the Nasdaq applicable to domestic issuers. See "Item 16G — Corporate Governance — Nasdaq Listing Rules and Home Country Practices."

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

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

Section 404 of the Sarbanes-Oxley Act requires companies subject to the reporting requirements of the U.S. securities laws to do a comprehensive evaluation of its and its subsidiaries' internal controls over financial reporting. To comply with this statute, we are required to document and test our internal control procedures, and our management is required to assess and issue a report concerning our internal controls over financial reporting. In addition, our independent registered public accounting firm may be required to issue an opinion on management's assessment of those matters.

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

**Risks Related to our Operations in Israel**

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

Our headquarters, all of our operations and some of our suppliers and third party contractors are located in central Israel and our key employees, officers and most of our directors are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could adversely affect our operations and results of operations and could make it more difficult for us to raise capital. During the summer of 2006, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party; during the winter of 2008-2009 and the autumn of 2012, Israel was engaged in armed conflicts with Hamas, a militia group and political party operating in the Gaza Strip; and during the summer of 2014, another escalation in violence among Israel, Hamas and other groups took place. This escalation became known as "Operation Protective Edge." These conflicts involved missile strikes against civilian targets in various parts of Israel, as well as civil insurrection of Palestinians in the West Bank in some cases, and negatively affected business conditions in Israel. In addition, Israel faces threats from more distant neighbors, in particular Iran. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, and various rebel militia groups in Syria. Recent political uprisings and social unrest in various countries in the Middle East and North Africa are affecting the political stability of those countries. The year 2014 saw the rise of an Islamic fundamentalist group known as ISIS. Following swift operations, ISIS gained control of large areas in the Middle East, including in Iraq and Syria, which have contributed to the turmoil experienced in these areas. As a result, the United States armed forces have recently engaged in limited operations against ISIS. This instability may lead to deterioration of the political relationships that exist between Israel and these countries, and has raised concerns regarding security in the region and the potential for armed conflict. These situations may escalate in the future to more violent events which may affect Israel and us. Among other things, this instability may affect the global economy and marketplace through changes in oil and gas prices. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations. For example, any major escalation in hostilities in the region could result in a portion of our employees being called up to perform military duty for an extended period of time. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in the agreements.

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

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

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

Many of our male employees in Israel, including members of our senior management, are obligated to perform one month, and in some cases more, of annual military reserve duty until they reach the age of 40 (or older, for officers or reservists with certain occupations) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists, and recently some of our employees have been called up in connection with armed conflicts. It is possible that there will be military reserve duty call-ups in the future. Our operations could be disrupted by the absence of a significant number of our employees or of one or more of our key employees. Such disruption could materially adversely affect our business, financial condition and results of operations.

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

Our reporting and functional currency is the NIS, and we pay a substantial portion of our expenses in NIS. The revenues from our out-licensing and co-development arrangements are payable in U.S. dollars and euros and we expect our revenues from future licensing arrangements to be denominated in U.S. dollars or in euros. As a result, we are exposed to the currency fluctuation risks relating to the recording of our revenues in NIS. For example, if the NIS strengthens against either the U.S. dollar or the euro, our reported revenues in NIS may be lower than anticipated. The Israeli rate of inflation has generally not offset or compounded the effects caused by fluctuations between the NIS and the U.S. dollar or the euro. From time to time, we engage in currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of the currencies mentioned above in relation to the NIS. These measures, however, may not adequately protect us from material adverse effects. Effective January 1, 2015, our reporting and functional currency will be the dollar, which we expect will reduce, to some extent, our exposure to the currency fluctuation risks mentioned above.

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

Our research and development efforts, including the operation of a biotechnology incubator which we terminated at the end of 2013, have been financed, in part, through grants and loans that we have received from the OCS. Of our 10 current development projects, two were approved for funding by the OCS: BL-1040 and BL-7040. In addition, before we in-licensed BL-8040, Biokine had received funding for the project from the OCS, and as a condition to OCS consent to our in-licensing of BL-8040, we were required to agree to abide by any obligations resulting from such funding. We therefore must comply with the requirements of the Israeli Law for the Encouragement of Industrial Research and Development, 1984, and related regulations, or the Research Law with respect to these projects. Through December 31, 2014, we have received approximately NIS 76.1 million ($19.6 million) in funding from the OCS, of which approximately NIS 53.7 million ($13.8 million) was funding provided to our biotechnology incubator, which we undertook to repay from proceeds received from the sale of products developed under the incubator project. Under the terms of the biotechnology incubator, we had recorded a first-degree floating lien on all assets of the incubator against the repayment of funding received by the incubator for the projects developed under it. As previously described, we terminated the incubator at the end of 2013, and recorded the projects as having been terminated for repayment purposes. Through December 31, 2014, we have paid the OCS approximately NIS 24.3 million ($6.2 million) in royalties under our approved programs. As of December 31, 2014, we have a contingent obligation to the OCS (other than for BL-8040 – see below) in the total amount of NIS 13.2 million ($3.4 million) under all of our approved programs, of which NIS 12.5 million ($3.2 million) are attributed to projects recorded by the Company as terminated for repayment purposes (as a result of the actual termination of the license agreements with the relevant licensors) but which still require a formal termination process with the OCS. In connection with the in-licensing of BL-8040 from Biokine, and as a condition to OCS consent to the transaction, we agreed to abide by any obligations resulting from funds previously received by Biokine from the OCS. The contingent liability to the OCS assumed by us relating to this transaction amounts to NIS 10.6 million ($2.7 million) as of December 31, 2014. We have a full right of offset for amounts payable to the OCS from payments that we may owe to Biokine in the future. Therefore, the likelihood of any payment obligation to the OCS with regard to the Biokine transaction is remote. When know-how, technology or products are developed using OCS grants, the terms of these grants and the Research Law restrict the transfer of that know-how (as well as know-how that is derived from funded know-how) and the development or manufacture of those products out of Israel without the prior approval of the OCS. Therefore, the discretionary approval of an OCS committee will be required for any transfer to third parties of our therapeutic candidates developed with OCS funding, for the purpose of the commercialization of our product candidates. We received approval in 2009 for the out-licensing of BL-1040 to Bellerophon; however, the out-licensing of BL-7040 and BL-8040 to any party outside of Israel will be subject to the prior approval of the OCS. There is no assurance that we will receive the required approvals should we wish to transfer this technology or development out of Israel in the future. Furthermore, the OCS committee may impose certain conditions on any arrangement under which we transfer technology or development out of Israel. Transfers of know-how from OCS funded programs, including our biotechnology incubator, even if approved by the OCS, may be subject to restrictions set forth in the Research Law, and may include payments to the OCS, as described more fully under “Item 4. Information on the Company — Business Overview — Government Regulation and Funding — Israeli Government Programs — Office of the Chief Scientist.”

The transfer abroad of the manufacturing of any OCS-supported product or technology is also subject to various conditions, including the payment of increased royalties equal to, in the aggregate, up to 300% of the total grant amounts received in connection with the product or technology, plus interest, depending on the portion of total manufacturing that is performed outside of Israel. Payment of the increased royalties would constitute the repayment amount required with respect to the OCS grants received for the development of the products or technology for which the manufacturing is performed outside of Israel. In addition, any decrease in the percentage of manufacture performed in Israel of any product or technology, as originally declared in the application to the OCS with respect to the product or technology, may require us to notify, or to obtain the approval of, the OCS, and may result in increased royalty payments to the OCS of up to 300% of the total grant amounts received in connection with the product or technology, plus interest, depending on the portion of total manufacturing that is performed outside of Israel. In addition, the OCS has the discretion to permit overseas manufacture in excess of the declared percentage (deviations of up to 10% do not require consent, but the OCS must be notified). Consent is contingent upon payment of additional royalties, at rates and subject to ceilings set out in the relevant regulations, up to three times the amount of the grants. Furthermore, the transfer of OCS-supported know-how, and the transfer of OCS-supported manufacturing or manufacturing rights of products, technologies or know-how inside or outside of Israel is subject to payment of transfer fees. Maximal transfer fees with respect to the transfer of know-how are as follows: up to three times the original grant received plus accrued interest as of the date of transfer, when the OCS Research Committee is satisfied that the core research and development activity will remain in Israel, and up to six times the value of the original grant in the case of liquidation of activities in Israel. Therefore, if aspects of our technologies are deemed to have been developed with OCS funding, the discretionary approval of an OCS committee would be required for any transfer to third parties inside or outside of Israel of know how or manufacturing or manufacturing rights related to those aspects of such technologies. These restrictions may impair our ability to sell our technology assets or to outsource or transfer development or manufacturing activities with respect to any product or technology. These restrictions continue to apply even after we have repaid any grants, in whole or in part, unless otherwise agreed by the designated OCS committee.

We cannot be certain that any approval of the OCS will be obtained on terms that are acceptable to us, or at all. Furthermore, if we undertake a transaction involving the transfer to a non-Israeli entity of technology developed with OCS funding pursuant to a merger or similar transaction, the consideration available to our shareholders may be reduced by the amounts we are required to pay to the OCS. If we fail to comply with the conditions imposed by the OCS, including the payment of royalties with respect to grants received, we may be required to refund any payments previously received, together with interest and penalties, and may be subject to criminal penalties. See "Item 4. Information on the Company — Business Overview — Government Regulation and Funding — Israeli Government Programs — Office of the Chief Scientist."

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

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, a majority of each class of securities of the target company must approve a merger. Moreover, a full tender offer can only be completed if the acquirer receives the approval of at least 95% of the issued share capital (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved the tender offer, except that if the total votes to reject the tender offer represent less than 2% of the company's issued and outstanding share capital, in the aggregate, approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer), and the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, claim that the consideration for the acquisition of the shares did not reflect their fair market value and petition the court to alter the consideration for the acquisition accordingly (unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights, and the acquirer or the company published all required information with respect to the tender offer prior to the date indicated for response to the tender offer).

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

These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders.

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

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

We are incorporated in Israel. All of our executive officers and the majority of our directors reside outside of the United States, and all of our assets and most of the assets of our executive officers and directors are located outside of the United States. Therefore, a judgment obtained against us or any of our executive officers and directors in the United States, including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It also may be difficult for you to effect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel.

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

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

## ITEM 4. INFORMATION ON THE COMPANY

### A. History and Development of the Company

Our legal and commercial name is BioLineRx Ltd. We are a company limited by shares organized under the laws of the State of Israel. Our principal executive offices are located at 19 Hartum Street, Jerusalem 9777518, Israel, and our telephone number is +972 (2) 548-9100.

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

Our capital expenditures for the years ended December 31, 2012, 2013 and 2014 were $0.2 million, $0.1 million and $0.2 million, respectively. Our current capital expenditures involve acquisitions of laboratory equipment, computers and communications equipment. We expect to incur additional capital expenditures in 2015 for leasehold improvements associated with the lease of our new premises. See " — Property, Plant and Equipment."

**B. Business Overview**

We are a clinical stage biopharmaceutical development company dedicated to identifying, in-licensing and developing therapeutic candidates that have advantages over currently available therapies or that address unmet medical needs. Our current development pipeline consists of six clinical-stage therapeutic candidates: BL-1040, a novel polymer solution for use in the prevention of ventricular remodeling following an acute myocardial infarction, or AMI; BL-8040, a novel peptide for the treatment of acute myeloid leukemia (AML), stem cell mobilization and other hematological indications; BL-7010, a novel co-polymer for the treatment of celiac disease; BL-5010, a customized, proprietary, pen-like applicator containing a novel, acidic, aqueous solution, which is being developed in Europe as a medical device for the non-surgical removal of benign skin lesions; BL-7040, an oligonucleotide for the treatment of inflammatory bowel disease, or IBD; and BL-8020, an orally available treatment for the hepatitis C virus, or HCV, and other viral indications, with a unique mechanism of action involving the inhibition of virus-induced autophagy in host cells. In addition, we have four therapeutic candidates in the preclinical stages of development. We generate our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. None of our therapeutic candidates have been approved for marketing and, to date, there have been no commercial sales of any of our therapeutic candidates. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies. We also evaluate, on a case-by-case basis, co-development and similar arrangements and the commercialization of our therapeutic candidates independently.

In December 2014, we entered into a strategic collaboration with Novartis Pharma AG, or Novartis, for the co-development of selected Israeli-sourced novel drug candidates. Under the agreement, we intend, in collaboration with Novartis, to co-develop a number of pre-clinical and early clinical therapeutic projects through clinical proof-of-concept for potential future licensing by Novartis.

Our first therapeutic candidate, BL-1040 (now called “Bioabsorbable Cardiac Matrix,” or BCM), is a medical device, injected in patients following an AMI, intended for prevention of ventricular remodeling and subsequent congestive heart failure. Ventricular remodeling is the structural alteration of the damaged heart muscle that occurs following an acute heart attack. Once this damage occurs, the weakened heart muscle forces the rest of the heart to compensate. Under this extra workload, the heart muscle dilates, the walls of the heart thin, and the heart further remodels, thereby causing another cycle of dilation and overcompensation. The extra workload to the heart causes further structural damage and can lead to congestive heart failure. BL-1040 is a liquid polymer which is delivered in a bolus injection via the coronary artery during catheterization and flows into the damaged heart muscle, creating a scaffold within injured cardiac muscle designed to enhance cardiac mechanical strength during the healing period and prevent pathological ventricular dilation. BL-1040 remains in the infarct zone for a few months and is excreted through the kidneys. The data from our preclinical trials in various animal models indicate that, by supporting the damaged heart tissue, BL-1040 preserves the normal functioning of the heart, and the data from our clinical trials indicate that BL-1040 should be safe. After consultation by our out-licensing partner, Bellerophon BCM LLC, or Bellerophon, with the FDA, BL-1040 is being developed as a class III medical device under the FDA’s pre-marketing approval, or PMA, regulatory pathway. In December 2011, Bellerophon commenced PRESERVATION 1, a CE Mark registration clinical trial of BL-1040. PRESERVATION 1 aims to evaluate the safety and effectiveness of BL-1040 for prevention of ventricular remodeling when administered following AMI. The trial is a placebo-controlled, randomized, double-blind, multi-country and multi-center trial. BL-1040 is being administered to subjects who had successful percutaneous coronary intervention with stent placement after ST-segment elevation myocardial infarction (STEMI). Enrollment for this trial was completed in December 2014, with 303 AMI patients having been recruited and treated. There are almost 90 sites activated worldwide for this trial, 16 of which are in the United States. Bellerophon expects to report top line results from the study, which includes a six-month follow-up period, in mid-2015. If the results of this trial are positive, Bellerophon expects it would form the basis for an application for CE marking in the European Union, potentially in the first half of 2016. In addition, again assuming positive results of the trial, Bellerophon expects it would conduct a second, larger clinical trial, beginning in the first half of 2016, to support approval in the United States through the premarket approval, or PMA, pathway, and furthermore intends to consider testing BL-1040 in an expanded population, including patients with moderate STEMIs, and for deployment of BL-1040 during the primary percutaneous coronary intervention procedure, eliminating the need for a second invasive procedure. Bellerophon currently intends to begin this trial in the second half of 2015.

In 2009, we entered into an out-licensing arrangement with Bellerophon (formerly known as “Ikaria Development Subsidiary One LLC”) with regard to BL-1040, which we amended in January 2015. Under this arrangement, Bellerophon is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or a product related thereto. To date, we have received $17.0 million from Bellerophon, and we are entitled to receive up to an additional $265.5 million from Bellerophon upon achievement of certain development, regulatory, and commercial milestones. In addition, we are entitled to receive from Bellerophon royalties from net sales of any product developed under the arrangement. Pursuant to the January 2015 amendment, a certain milestone and related payments have been adjusted, but the total potential milestone payments to be paid to us under the license agreement remain the same. We believe that Bellerophon has financial resources sufficient to meet its contractual obligations under its agreement with us.

We are obligated to pay 28% of all net consideration received under this arrangement to B.G. Negev Technologies and Applications Ltd., or B.G. Negev Technologies, the party from which we in-licensed BL-1040 in 2004. We have agreed to pay Ramot at Tel Aviv University Ltd., or Ramot, a portion of the payments we make to B.G. Negev Technologies in connection with the in-license arrangement to satisfy contractual obligations between B.G. Negev Technologies and Ramot with respect to certain intellectual property rights to the licensed technology. We have also agreed to indemnify Ramot and certain of its related parties in connection with our use of the technology we in-licensed from B.G. Negev Technologies.

Our second clinical-stage therapeutic candidate, BL-8040, is a novel, short peptide that functions as a high-affinity antagonist for CXCR4, which we intend to develop for AML, stem cell mobilization and other hematological indications. CXCR4 is a chemokine receptor that is directly involved in tumor progression, angiogenesis (growth of new blood vessels in the tumor), metastasis (spread of tumor to other organs) and cell survival. CXCR4 is over-expressed in more than 70% of human cancers and its over-expression often correlates with poor prognosis. BL-8040 mobilizes cancer cells from the bone marrow and may therefore sensitize these cells to chemo- and bio-based anti-cancer therapy. In addition, BL-8040 has demonstrated a direct anti-cancer effect by inducing apoptosis (cell death). Multiple pre-clinical studies have shown the safety and efficacy of BL-8040. These studies have shown that BL-8040 is efficient, both alone and in combination with chemotherapy, in reducing malignant bone marrow cells and stimulating their cell death. BL-8040 also mobilizes stem cells from the bone marrow to the peripheral blood, enabling their collection for subsequent autologous or allogeneic transplantation in cancer patients. In September 2013, the FDA granted an Orphan Drug Designation to BL-8040 as a therapeutic for the treatment of AML; and in January 2014, the FDA granted an Orphan Drug Designation to BL-8040 as a treatment for stem cell mobilization.

In June 2013, we commenced a Phase 2 trial for BL-8040 for the treatment of AML. The study is currently being conducted at four sites in the United States, including MD Anderson Cancer Center in Houston, Memorial Sloan-Kettering Cancer Center in New York, Northwestern University Hospital in Chicago, and Mayo Clinic in Jacksonville, as well as at five well-known sites in Israel. The study is a multicenter, open-label study under an Investigational New Drug, or IND, approval from the FDA, designed to evaluate the safety and efficacy profile of repeated escalating doses of BL-8040 in adult subjects with relapsed/refractory AML. Early results of this trial showed that BL-8040, as a stand-alone therapy and in combination with high-dose Cytarabine (Ara-C), is safe at all doses tested to date, and triggers substantial mobilization of cancer cells from the bone marrow to the peripheral blood, thereby increasing the vulnerability of the cells to chemotherapy treatment. In addition, signs of robust apoptosis of cancer cells were observed following administration of higher doses tested. At the annual ASH conference in December 2014, we presented data which showed substantial mobilization of AML cancer cells from the bone marrow to the peripheral blood and robust apoptosis of these cells, as well as an excellent safety and tolerability profile. The dose-escalation stage of the study is expected to be completed in early 2015, while the full study results from both the dose-escalation and dose-expansion stages of the study are expected in the second half of 2015.

Targeting a second AML treatment line, BL-8040 is scheduled to commence a Phase 2b trial, as a consolidation treatment for AML patients who have responded to standard induction treatment, in the first half of 2015. The trial will be conducted in collaboration with the German Study Alliance Leukemia Group. The trial aims to improve the response of AML patients to the second stage of AML treatment, termed consolidation therapy, by eliminating the minimal residual disease left in the bone marrow after the first stage of the standard treatment regimen, called induction therapy. We recently announced the filing of the regulatory submissions required to commence the trial.

In addition, BL-8040 is scheduled to commence a Phase 1/2 trial in the first half of 2015 for the treatment of a third population of AML patients, those with the FLT3-ITD mutation. The Phase 1/2 trial, which will be conducted in collaboration with the MD Anderson Cancer Center, is aimed at improving the response of FLT3-ITD mutated AML patients to treatment with sorafenib (a FLT3 inhibitor). This trial follows the presentation at several conferences during 2014 of positive preclinical results of BL-8040 as a treatment for AML patients with FLT3 mutations.

In September 2014, we announced the dosing of the first patient in a Phase 1 trial for another indication of BL-8040, as a novel treatment for the mobilization of stem cells from the bone marrow to the peripheral blood circulation, where they can be harvested for transplant supporting the treatment of hematological indications. The study is being conducted at the Hadassah Medical Center in Jerusalem. Part 1 of the study is a randomized, double-blind, placebo-controlled dose escalation study exploring the safety and tolerability of escalating repeated doses of BL-8040 in healthy volunteers. In January 2015, we announced that all healthy volunteers had completed the treatment phase of the study. Following initial analysis of the data, the optimal safe and efficacious dose of BL-8040 was selected to be used as a stand-alone therapy in the second part of the study. Part 2 is an open-label study designed to assess BL-8040's stem cell mobilization capacity, as well as the yield of cells collected by apheresis. The top line results of both parts of this study are expected by the end of the first quarter of 2015.

We are also planning to conduct a Phase 1/2 trial, again in collaboration with the MD Anderson Cancer Center, for a fifth indication of BL-8040 as a treatment for hypoplastic myelodysplastic syndrome, or hMDS, and aplastic anemia, or AA. The study will be open label and designed to evaluate the safety, tolerability and efficacy of the combination of BL-8040 with immunosuppressive therapies (hATG, cyclosporine and prednisone). We plan to commence the trial in the first half of 2015.

Our third clinical-stage therapeutic candidate, BL-7010, is a novel, non-absorbable, orally available, high-molecular-weight co-polymer intended for the treatment of celiac disease. It has a high affinity for gliadins, the immunogenic proteins present in gluten that cause an immune response in patients with celiac disease. BL-7010 effectively masks gliadins from enzymatic degradation and prevents the formation and absorption of immunogenic peptides that trigger the immune system. BL-7010 is excreted with gliadin from the digestive tract, preventing the absorption of gliadin peptides. This significantly reduces the immune response triggered by gluten. The safety and efficacy of BL-7010 were demonstrated in pre-clinical and clinical studies.

In December 2013, we commenced a Phase 1/2 trial for BL-7010 at Tampere Hospital in Finland, a leading site for celiac research. The trial was a two-part (single and repeated administration), double-blind, placebo-controlled, dose escalation study of BL-7010 in up to 40 well-controlled celiac patients. The primary objective of the study was to assess the safety of single and repeated ascending doses of BL-7010. Secondary objectives included an assessment of the systemic exposure, if any, of BL-7010 in the study patients. In November 2014, we reported the final results of the study. Those results confirmed that BL-7010 is safe and well tolerated in both single and repeated-dose administrations. Based on these results, we selected the dosing regimen of one gram, three times per day, of BL-7010 as the optimal repeated dose for the upcoming efficacy study, which is expected to commence in the second half of 2015. In addition, pharmacokinetic analyses revealed no systemic exposure of BL-7010 in plasma and urine samples from all patients at all doses and time points tested, both in the single- and repeated-dose regimens. Based on previous communications with a Notified Body in the European Union, we believe the lack of systemic exposure will likely support a medical-device classification in Europe for BL-7010, which would significantly accelerate its development in Europe.

Our fourth clinical-stage therapeutic candidate, BL-5010, is a novel medical device containing a novel, acidic, aqueous solution for the non-surgical removal of benign skin lesions. It offers an alternative to painful, invasive and expensive removal treatments including cryotherapy, laser treatment and surgery. Since the treatment is non-invasive, it poses minimal infection risk and eliminates the need for anesthesia, antiseptic precautions and bandaging. The pre-filled device controls and standardizes the volume of solution applied to a lesion, ensuring accurate administration directly on the lesion and preventing both accidental exposure of the healthy surrounding tissue and unintentional dripping. It has an ergonomic design, making it easy to handle, and it will be childproofed. The product has completed a phase 1/2 pilot clinical study for the removal of a skin lesion known as seborrheic keratosis, or SK, which showed excellent efficacy and cosmetic results, and has received confirmation in Europe for the regulatory pathway classification as a Class 2a medical device.

Our original development plan for BL-5010 consisted of clinical testing for the treatment of SK. However, during discussions in recent years with potential partners for the development and commercialization of BL-5010, we learned that they had more interest in the possibilities of BL-5010 for over-the-counter, or OTC, indications. In December 2014, we entered into an exclusive out-licensing arrangement with Omega Pharma for the rights to BL-5010 for OTC indications in the territories of Europe, Australia and additional selected countries. We will retain the non-OTC rights to BL-5010 in Omega Pharma's territories as well as all rights to BL-5010 in the United States and the rest of the world. Under our out-licensing arrangement with Omega Pharma, Omega Pharma is obligated to use commercially reasonable best efforts to obtain regulatory approval in the licensed territory for at least two OTC indications and to commercialize BL-5010 for those two OTC indications. In addition, Omega Pharma will sponsor and manufacture BL-5010 in the relevant regions. Omega Pharma will pay us an agreed amount for each unit sold, and we will be entitled to certain commercial milestone payments. In addition, we will have full access to all clinical and research and development data generated during the performance of the development plan and may use these data in order to develop or license the product in other territories and fields of use where we retain the rights. We expect that the first OTC products will enter the market in 2016. As a result of this out-licensing arrangement, as well as the previous discussions with other potential partners for this product, the development activities for BL-5010 are currently focused on OTC indications. However, we may decide to continue development of BL-5010 for non-OTC indications, including, but not limited to, SK

We are required to pay a portion, within the standard range of sublicense receipt consideration paid to our licensors, of the revenues we receive from our arrangement with Omega Pharma, to Innovative Pharmaceutical Concepts, Inc. or IPC, the party from which we in-licensed BL-5010 in 2007.

Our fifth clinical-stage therapeutic candidate, BL-7040, is an oligonucleotide being developed for the treatment of inflammatory bowel disease (IBD). The compound had already been the subject of phase 1 safety and pharmacokinetics studies and a phase 2a study examining the efficacy of the compound for the treatment of myasthenia gravis, an autoimmune, neurodegenerative disease. BL-7040 showed a high level of safety and efficacy in those trials. The compound was also found to target the innate inflammatory pathway and, therefore, we decided to develop the compound for the treatment of IBD and other inflammatory diseases.

In April 2013, we announced positive results from a phase 2a proof-of-concept study to evaluate the effectiveness of BL-7040 for the treatment of IBD at five sites in Israel. The study showed that BL-7040 is safe and effective in treating ulcerative colitis, a form of IBD. Sixteen of the 22 patients who were enrolled in the clinical trial completed the full five-week course of treatment and two-week follow-up. The primary clinical endpoint in the study – a 3-point and 30% reduction in the Mayo score between baseline and completion of treatment – was achieved. Fifty percent of patients (8 patients) met the primary endpoint, while the remaining 8 patients demonstrated a stable clinical condition or minor improvement.

In November 2013, we announced additional results from this study showing significant improvement of disease measurements in biopsies taken from IBD patients treated with BL-7040. The histological and biochemical analyses of inflammation indicators reinforced the initial positive results of the study described above. During the third quarter of 2014, we conducted a pharmacokinetic study which indicated that BL-7040 reaches the target organ (the colon) and appears to have a local, as opposed to systemic, effect. We are currently discussing this therapeutic candidate with a number of potential co-development partners, as well as planning the next stages of development.

Our sixth clinical-stage therapeutic candidate, BL-8020, is an orally available treatment for the hepatitis C virus, or HCV, and other viral indications, with a unique mechanism of action involving the inhibition of virus-induced autophagy in host cells. In April 2013, we commenced a phase 1/2 clinical trial to evaluate the safety, tolerability and effectiveness of BL-8020 at two sites in France. In January 2014, we entered into a collaboration agreement with the licensors of the compound whereby, in consideration for the payment of future royalties to us, we terminated the license agreement, the licensors agreed to take over development of the compound and we agreed to supply, at the licensors' request and for full payment, the drug product needed for a clinical trial to be administered by the licensors. In August 2014, the licensors decided to terminate the ongoing phase 1/2 trial in HCV due to a very slow recruitment rate, and are now determining the next steps in the clinical development plan of the compound, including an assessment regarding potential additional viral indications for development.

As part of our business strategy, we continue to actively source, rigorously evaluate and in-license selected therapeutic candidates. We establish and maintain close relationships with research institutes, academic institutions and biotechnology companies in Israel, including, in some instances, a formal right of first offer for therapeutic compounds in their portfolios. More recently, we have extended our sourcing activities to other countries. Before in-licensing, each therapeutic candidate must pass through our thorough screening process. Our Scientific Advisory Board and disease-specific third-party advisors are active in evaluating each therapeutic candidate. Our approach is consistent with our objective of proceeding only with therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. To date, we have screened over 2,000 compounds, presented more than 70 candidates to our Scientific Advisory Board for consideration, initiated development of 45 therapeutic candidates and terminated 35 feasibility programs.

**Our Strategy**

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

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

Using this approach, we have successfully advanced six therapeutic candidates into clinical development. Specific elements of our current strategy include the following:

- **Support the successful development and commercialization of therapeutic candidates that have already been partnered.** We currently have five programs at various stages of development in our pipeline that have already been partnered.
- **Commercialize additional therapeutic candidates through out-licensing or co-development arrangements or, where appropriate, by ourselves.** We intend to commercialize many of our other products through out-licensing or co-development arrangements with third parties who may perform any or all of the following tasks: completing development, securing regulatory approvals, manufacturing and/or marketing. If appropriate, we may also enter into co-development and similar arrangements with respect to any therapeutic candidate with third parties or commercialize a therapeutic candidate ourselves.
- **Design development programs that reach critical decisions quickly.** At each step of our screening process for therapeutic candidates, a candidate is subjected to rigorous feasibility testing and potential advancement or termination. We believe our feasibility approach reduces costs and increases the probability of commercial success by eliminating less promising candidates quickly before advancing them into more costly preclinical and clinical programs.
- **Use our expertise and proven screening methodology to evaluate in-licensing opportunities.** In order to review and select among various candidates efficiently and effectively, we employ a rigorous screening system we developed. Our Scientific Advisory Board and disease-specific third-party advisors evaluate each candidate. We intend to in-license a sufficient number of therapeutic candidates to allow us to move a new therapeutic candidate into clinical development every 12 to 24 months.
- **Leverage and expand our relationships with research institutes, academic institutions and biotechnology companies, including the specific strategic relationships that we have developed with Israeli research and academic institutions, to identify and in-license promising therapeutic candidates.** To date, we have successfully in-licensed compounds from many major Israeli universities, as well as from many Israeli hospitals, technology incubators and biotechnology companies. We continue to maintain close contacts with university technology transfer offices, research and development authorities, university faculty, and many biotechnology companies to actively seek out early stage compounds. In addition, we actively source and evaluate non-Israeli compounds.
- **Seek to co-develop certain pre-clinical and early clinical therapeutic projects through clinical proof-of-concept by means of our multi-year strategic collaboration agreement with Novartis**. Pursuant to an agreement entered into in December 2014, Novartis will evaluate jointly with us both clinical and pre-clinical stage projects presented by us via a Joint Steering Committee, which will determine which projects to advance further in development and on what terms. Projects at or reaching the clinical stage will be eligible for selection by Novartis. Upon selection of a project, Novartis will pay us an option fee of $5 million, as well as fund 50% of the anticipated remaining development costs associated with establishing clinical proof-of-concept, in the form of an additional equity investment in BioLineRx. The companies intend to develop up to three programs pursuant to this collaboration. Under the terms of the agreement, Novartis acquired 5,000,000 of our ADSs in a private transaction at a price of $2.00 per ADS, for a total equity investment of $10 million, and agreed to certain standstill provisions.

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**Our Product Pipeline**

The table below summarizes our current pipeline of therapeutic candidates, including the target indications and status of each candidate and our development partners:


**Lead Therapeutic Candidates**

***BL-1040***

BL-1040 is a medical device, injected to patients following AMI, intended for prevention of ventricular remodeling and subsequent congestive heart failure. AMIs result from an occlusion in the coronary artery and affect the left ventricle of the heart, or the LV. Patients with severe injury to the LV may be at risk for developing harmful changes in the size, shape and function of the LV, or ventricular remodeling, that may lead to congestive heart failure, or CHF. In the clinical trial, BL-1040 is deployed via the coronary artery and settles into the damaged heart muscle. BL-1040 is a liquid polymer which is delivered in a bolus injection via the coronary artery during catheterization and flows into the damaged heart muscle, creating a scaffold within injured cardiac muscle designed to enhance cardiac mechanical strength during the healing period and prevent pathological ventricular dilation. BL-1040 remains in the infarct zone for a few months and is excreted through the kidneys. After discussions between Bellerophon and the FDA, BL-1040 is being developed as a class III medical device, specifically under the PMA pathway in the United States. There can be no assurance, however, that the FDA or comparable foreign agencies will not determine that BL-1040 needs to be assessed as a drug instead of a medical device.

BL-1040 is being developed to treat patients that suffered an AMI and are at a high risk to develop significant ventricular remodeling. Data from long-term third party studies suggest that the five-year post-AMI rate of congestive heart failure or death is approximately 35% to 40%. Prevention of ventricular remodeling may prevent transition to CHF and/or improve patient survival over the long term.

We believe that BL-1040 is a novel, safe and non-surgical treatment for patients who suffered heart attacks and are at risk for ventricular remodeling and CHF. We believe that the transformation of BL-1040 into a gel is a result of the polymer chains' interaction with elevated levels of calcium ions present at the injury site. As the heart heals, there is a natural decrease in the calcium concentration causing the BL-1040 gel to transform back to liquid form and then be excreted naturally from the body within a few months after injection. The data from our preclinical studies indicate that treatment with BL-1040 helps preserve the normal functioning of the heart.

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

*Acute Myocardial Infarction and Ventricular Remodeling.* AMI is a leading cause of mortality and morbidity among both men and women. According to the publication entitled "Morbidity and Mortality: 2012 Chart Book on Cardiovascular, Lung and Blood Diseases," made available by the National Heart, Lung and Blood Institute of the U.S. National Institutes of Health, the annual occurrence of AMI cases in the United Stated is estimated at 1,255,000. AMI is caused by a severe narrowing of coronary arteries, known as atherosclerotic occlusion, often exacerbated by the formation of clots. The narrowing and/or blockage in the coronary artery disrupts the blood supply to cardiac tissue, resulting in extensive cell death that constitutes the AMI. As a result, the affected region of the heart muscle is generally replaced by scar tissue over a six-to eight-week period. This damage can lead to ventricular remodeling, the structural alteration of the damaged heart muscle. When damage occurs, the weakened heart muscle forces the rest of the heart to compensate. Under this extra workload, the heart muscle dilates, the walls of the heart thin, and the heart further remodels, thereby causing another cycle of dilation and overcompensation. The extra workload to the heart causes further structural damage and can lead to CHF. There are a number of different approaches to prevent ventricular remodeling that have been, or currently are, the subject of preclinical and clinical trials. Certain medications, including ACE inhibitors and beta-blockers have been shown to reduce ventricular remodeling. Despite the wide use of these medications, data from long-term third party studies suggest that the five-year post-AMI rate of congestive heart failure or death is approximately 35% to 40% and a subsequent reduction in ejection fraction, or the fraction of blood pumped out of a ventricle with each heartbeat.

*Development and Commercialization Arrangement.* In 2009, we entered into a licensing arrangement with Bellerophon, pursuant to which we granted Bellerophon an exclusive, worldwide license to develop, manufacture and commercialize BL-1040 for use in the prevention, mitigation and treatment of injury to the myocardial tissue of the heart.

Bellerophon is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or a product related thereto. We were responsible for the costs of the completed phase 1/2 trial. Bellerophon is responsible for the costs associated with conducting all other development and regulatory activities of BL-1040, including those costs relating to the completion of its clinical development, the conduct and funding of its commercialization and the prosecution and maintenance of patents. We have received $17.0 million from Bellerophon and we are entitled to receive up to an additional $265.5 million from Bellerophon upon achievement of certain development, regulatory, and commercial milestones. In addition, we are entitled to receive from Bellerophon royalties from net sales of any product developed under the agreement ranging from 11% to 15%, depending on net sales levels achieved by Bellerophon, and its affiliates and sublicensees. However, if Bellerophon is required to obtain a license from a third party in order to exercise its rights under the agreement with Bellerophon, the royalty we receive on net sales may be less than 11%.

*Clinical and Preclinical Results.* We commenced a pilot phase 1/2 multi-center open label study of BL-1040 in March 2009. The study was designed to assess the safety and feasibility of BL-1040 in patients following an AMI. The trial was conducted at nine sites in Germany and Belgium and was completed in January 2010. In the trial, 27 patients were successfully treated with BL-1040 with no device-related clinically significant complications including arrhythmia, further elevations in cardiac enzymes or occlusions. In February 2010, we received the final assessment of the Independent Safety Monitoring Board, or ISMB. The ISMB's conclusions, relating to the 27 patients who participated in the study and completed a six-month follow-up period, indicated no safety signals and that it would be appropriate to continue clinical development of the device. The FDA must approve an investigational drug exemption (IDE) for BL-1040 before human clinical trials of BL-1040 can be conducted in the United States.

After consultation by Bellerophon with the FDA, BL-1040 is being developed as a class III medical device under the FDA's pre-marketing approval, or PMA, regulatory pathway. In December 2011, Bellerophon commenced PRESERVATION 1, a CE Mark registration clinical trial of BL-1040 (BCM), outside of the United States. The purpose of PRESERVATION 1 is to evaluate the safety and effectiveness of BL-1040 (BCM) for prevention of ventricular remodeling when administered following AMI. The trial is a placebo-controlled, randomized, double-blind, multi-country and multi-center trial with an estimated enrollment of approximately 300 patients. BL-1040 is being administered to subjects who had successful percutaneous coronary intervention with stent placement after STEMI. The primary endpoint is change in the anatomical measurement of left ventricular end-diastolic volume index by echocardiography measured six months after device deployment. Secondary endpoints include the measurement of functional capacity of change in six-minute walk distance and the measurement of patient reported outcome as recorded on the quality of life tool of Kansas City Cardiomyopathy Questionnaire. Enrollment for this trial was completed in December 2014, with 303 AMI patients having been recruited. There are almost 90 sites activated worldwide for this trial, 16 of which are in the United States. Bellerophon expects to report top line results from the study, which includes a six-month follow-up period, in mid-2015. If the results of this trial are positive, Bellerophon expects it would form the basis for an application for CE marking in the European Union, potentially in the first half of 2016. Assuming positive results, Bellerophon further intends to commence a pivotal pre-market approval trial in the first half of 2016, which will be designed to support registration in the United States. Bellerophon expects that once initiated, the trial will take approximately two to three years to complete. In addition, if the PRESERVATION I trial demonstrates that BL-1040 is well tolerated and has a clinical benefit in severe STEMIs when deployed in a second percutaneous coronary intervention procedure, Bellerophon intends to consider testing BL-1040 in an expanded population, including patients with moderate STEMIs, and for deployment of BL-1040 during the primary percutaneous coronary intervention procedure, eliminating the need for a second invasive procedure. Bellerophon currently intends to begin this trial in the second half of 2015.

Prior to initiating the pilot phase 1/2 study, we evaluated BL-1040 in preclinical safety, biocompatibility, and efficacy studies. We interpreted the safety and biocompatibility studies to demonstrate that the anticipated human dosages are not expected to produce significant local or systemic toxicity. Preclinical efficacy studies in rat, dog and pig models of AMI showed that BL-1040 administered immediately following an AMI and up to seven days after the AMI may provide long-term protection to the heart tissue by preventing progressive LV dilation.

***BL-8040***

BL-8040 is a novel, short peptide that functions as a high-affinity antagonist for CXCR4, which we intend to develop for AML, stem cell mobilization and other hematological indications. CXCR4 is 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 over-expression often correlates with poor prognosis. We in-licensed BL-8040 from Biokine in September 2012.

*Acute Myeloid Leukemia (AML)*. AML is a cancer of the myeloid line of blood cells, characterized by the rapid growth of abnormal, immature white blood cells that accumulate in the bone marrow and interfere with the production of normal blood cells. Approximately 250,000 adults throughout the world are diagnosed annually with AML. Despite considerable efforts in the development of therapy for AML, prognosis for the disease is very poor and less than 25% of patients survive five years after disease onset. Current treatments for AML include conventional chemotherapy, radiation therapy and stem cell transplantation.

*Stem Cell Mobilization*. High-dose chemotherapy followed by stem cell transplantation has become an established treatment modality for a variety of hematologic malignancies, including multiple myeloma, as well as various forms of lymphoma and leukemia. Stem cells are mobilized from the bone marrow using granulocyte colony-stimulating factor, or G-CSF, harvested from the peripheral blood by apheresis, and infused to the patient after chemotherapy. This type of treatment often replaces the use of traditional bone marrow harvesting, because the stem cells are easier to collect and the treatment allows for a quicker recovery time and fewer complications.

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

*Preclinical Results.* In vitro and in vivo data show that BL-8040 binds CXCR4 at the low nanomolar range (1-2.5nM) and occupies it for prolonged periods of time (>24h). These studies have shown that BL-8040 mobilizes cancer cells from the bone marrow and may therefore sensitize these cells to chemo- and bio-based anti-cancer therapy. In addition, BL-8040 directly induces apoptosis of cancer cells. BL-8040 was efficient, both alone and in combination with chemotherapy, in reducing malignant bone marrow malignant cells and stimulating their cell death.

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

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

*Clinical Trials.*

In a Phase 1/2, open-label, dose escalation, safety and efficacy clinical trial in 18 multiple myeloma patients, BL-8040 demonstrated an excellent safety profile at all doses tested and was highly effective in combination with G-CSF, in the mobilization of hematopoietic stem cells and white blood cells from the bone marrow to the peripheral blood.

In June 2013, we commenced a Phase 2 trial for BL-8040 for the treatment of AML. The study is being conducted at four sites in the United States, including MD Anderson Cancer Center in Houston, Memorial Sloan-Kettering Cancer Center in New York, Northwestern University Hospital in Chicago, and Mayo Clinic in Jacksonville, as well as at five well-known sites in Israel. The study is a multicenter, open-label study under an IND, designed to evaluate the safety and efficacy profile of repeated escalating doses of BL-8040 in adult subjects with relapsed/refractory AML. As of the date of this report, 19 patients have been enrolled in the study, out of a total expected enrollment of up to 70 patients. The primary endpoints of the study are the safety and tolerability of the drug. Secondary endpoints include the pharmacokinetic profile of the drug and an efficacy evaluation, indicated by the extent of mobilization of cancer cells from the bone marrow to the peripheral blood, the level of cancer cell death (apoptosis) and clinical responses. The study is also designed in a way that will enable the investigators to evaluate the capabilities of BL-8040 in mobilizing cancer cells from the bone marrow to the peripheral blood, and in inducing their cell death. The study is comprised of two parts – the current dose escalation phase and a subsequent expansion phase at the highest tolerated dose found during the escalation phase. During the dose escalation phase, trial participants are recruited in cohorts of three patients at a time, and the dose is increased for each subsequent cohort depending on the safety and tolerability results of the previous cohort. The dose-escalation stage of the study is expected to be completed in the first half of 2015, while the full study results from both the dose-escalation and dose-expansion stages of the study are expected in the second half of 2015.

Early results of this trial showed that BL-8040, as a stand-alone therapy and in combination with high-dose Cytarabine (Ara-C), is safe at all doses tested to date, and triggers substantial mobilization of cancer cells from the bone marrow to the peripheral blood, thereby increasing the vulnerability of the cells to chemotherapy treatment. In addition, signs of robust apoptosis of cancer cells were observed following administration of higher doses tested.

At the annual ASH conference in December 2014, we presented data from the trial showing that even at the highest dose reached at that time (1.25 mg/kg), there were no dose-limiting toxicity events or serious adverse events, nor early discontinuations attributable to BL-8040. Furthermore, we presented data showing that BL-8040 triggered substantial mobilization of AML cancer cells from the bone marrow to the peripheral blood, with a median 6-fold increase of AML cells in the blood. This mobilization is crucial for exposing a higher ratio of AML cells to accompanying chemotherapy such as Ara-C. Additional results from the trial show that after only two days of BL-8040 monotherapy, there was a median decrease of approximately 70% in the amount of AML cells in the bone marrow, while the levels of normal progenitor cells remained stable. Furthermore, BL-8040 as a monotherapy showed a 3.5-fold increase in cell death (apoptosis) of AML cells, both in the bone marrow and in peripheral blood samples.

Targeting a second AML treatment line, BL-8040 is scheduled to commence a Phase 2b trial, as a consolidation treatment for AML patients who have responded to standard induction treatment, in the first half of 2015. The trial will be conducted in collaboration with the German Study Alliance Leukemia Group. The trial aims to improve the response of AML patients to the second stage of AML treatment, termed consolidation therapy, by eliminating the minimal residual disease left in the bone marrow after the first stage of the standard treatment regimen, called induction therapy. The trial is a double-blind, placebo-controlled, randomized, multicenter study with repeated administrations and multiple treatment cycles. It is planned to be carried out at approximately 25 sites in Germany with a total expected enrollment of approximately 200 patients. The primary endpoint of the study is relapse free survival rates at 18 months after randomization; the toxicity, safety and tolerability of BL-8040 in combination with high dosages of Ara-C as part of the consolidation treatment; minimum residual disease at the time of enrollment and during the follow-up period; and overall survival as an open label extension. We recently announced the filing of the regulatory submissions required to commence the trial.

BL-8040 is scheduled to commence a Phase 1/2 trial for the treatment of a third population of AML patients, those with the FLT3-ITD mutation, in the first half of 2015. AML patients with the FLT3-ITD mutation exhibit poor response and high relapse rates to chemotherapy, and only transient response rates to FLT3 inhibitors. Preclinical data (presented at several conferences during 2014) show that by inhibiting the CXCR4 receptor, BL-8040 enhances the effect of FLT3 inhibition in killing FLT3-mutated leukemic cells. The Phase 1/2 trial, which will be conducted in collaboration with the MD Anderson Cancer Center, is aimed at improving the response of FLT3-ITD mutated AML patients to treatment with sorafenib (a FLT3 inhibitor). Patients testing positive for the FLT3-ITD mutation will receive several treatment cycles of BL-8040 and sorafenib in combination. The safety of the combination treatment, as well as the response rate to the treatment and the duration of the response will be evaluated. This trial follows the presentation of positive preclinical results of BL-8040 as a treatment for AML patients with FLT3 mutations at several conferences during 2014.

In September 2014, we announced the dosing of the first patient in a Phase 1 trial for a fourth indication of BL-8040 as a novel treatment for the mobilization of stem cells from the bone marrow to the peripheral blood circulation, where they can be harvested for transplant supporting the treatment of hematological indications. The study is being conducted at the Hadassah Medical Center in Jerusalem. The trial is divided into two parts. Part 1 is a randomized, double-blind, placebo-controlled dose escalation study exploring the safety and tolerability of escalating repeated doses of BL-8040 in healthy volunteers. Secondary objectives include assessment of the efficacy of BL-8040 in mobilizing stem cells as a stand-alone therapy, as well as monitoring the pharmacokinetic profile of the drug. In January 2015 we announced that all healthy volunteers had completed the treatment phase of the study. Following analysis of the initial data, the optimal safe and efficacious dose of BL-8040 was selected to be used as a stand-alone therapy in the second part of the study. Part 2 is an open-label study designed to assess BL-8040's stem cell mobilization capacity, as well as the yield of cells collected by leukapheresis. Secondary endpoints of the study include evaluation of the viability and biological activity of cells mobilized by BL-8040 and collected by leukapheresis. The top line results of both parts of this study are expected by the end of the first quarter of 2015.

A fifth clinical development program planned for BL-8040 designates the drug for the treatment of hypoplastic myelodysplastic syndrome, or hMDS and aplastic anemia, or AA. hMDS is a subtype of myelodysplastic syndrome, a collection of myeloid malignancies characterized by one or more peripheral blood cytopenias (deficiency in the number of blood cells). AA is a disease in which the bone marrow and the blood stem cells that reside in the marrow are depleted, resulting in a deficiency of all three blood cell types: red blood cells, white blood cells, and platelets. Treatment for these bone-marrow failure conditions consists of immunosuppressive therapy with hATG and cyclosporine; however, a sizable fraction of patients do not respond to this therapy. Preclinical data suggest that BL-8040 promotes stem cell proliferation and differentiation thereby allowing recovery of hematopoiesis (formation and development of blood cells). The data show that treatment of mice with BL-8040 contributes to bone marrow regeneration, and increases the number of progenitor cells and the mature components of the blood and immune systems. We are planning to commence a Phase 1/2 trial in the first half of 2015, in collaboration with the MD Anderson Cancer Center, to assess the addition of BL-8040 to the standard immunosuppressive therapy in patients with hMDS or AA.

***BL-7010***

BL-7010 is a novel, non-absorbable, orally available, high-molecular-weight co-polymer intended for the treatment of celiac disease. It has a high affinity for gliadins, the immunogenic proteins present in gluten that cause an immune response in patients with celiac disease. BL-7010 effectively masks gliadins from enzymatic degradation and prevents the formation of immunogenic peptides that trigger the immune system. BL-7010 is excreted with gliadin from the digestive tract, preventing the formation and absorption of gliadin peptides. This significantly reduces the immune response triggered by gluten. We in-licensed the exclusive, worldwide rights to develop, market and sell BL-7010 from Valorisation-Recherche, Limited Partnership, or Univalor in February 2011.

*Celiac Disease.* Celiac disease is a chronic, autoimmune, inflammatory disease of the small intestine characterized by damage to the lining of the small intestine and typically leads to dyspepsia, malabsorption and a variety of other symptoms. It occurs in genetically predisposed individuals and is caused by an immunological reaction to gluten, found in wheat, barley and rye. Estimates suggest that 1% of the world's population is affected by celiac disease, and prevalence is expected to increase dramatically with improved diagnosis and awareness of the disease. There are currently no treatments approved for celiac disease and the only treatment option is a life-long, strict, gluten-free diet, which is difficult to maintain both due to food contamination with gluten, as well as eating habits in a social setting. Estimates suggest that approximately 30% of patients on a gluten-free diet are still symptomatic to some extent.

*Preclinical Results.* BL-7010 was evaluated in preclinical safety and efficacy studies. Safety data available include a 6-week rat toxicity study and a biocompatibility package of studies. BL-7010 was found to be well tolerated in the rat toxicity study conducted at a dose range of 500 mg/kg to 3,000 mg/kg body weight/day by oral gavage. In addition, BL-7010 was found to have no mutagenic activity, to have no local irritation effect in the gastrointestinal tract and is not considered to be a sensitizer.

BL-7010 was evaluated in well-validated murine models of celiac disease (transgenic mice carrying the human DQ8 gene, sensitized to gluten). It was found that BL-7010 significantly reduced the damage to the small intestine and the immune response triggered by gluten or gliadin.

In preclinical pharmacokinetics studies, it was found that BL-7010 is not absorbed systemically and is excreted in the feces, hence presenting a very good safety profile. It was also found that BL-7010 interacts specifically with gliadin, and does not interact with tested vitamins and selected drugs. This high specificity suggests that BL-7010 will not have an effect on the absorption of nutrients and on the digestive process.

*Clinical Trial.*

In December 2013, we commenced a Phase 1/2 trial for BL-7010 at Tampere Hospital in Finland, a leading site for celiac research. The study was a two-part (single and repeated), double-blind, placebo-controlled, dose escalation study of BL-7010 in up to 40 patients. The primary objective of the study was to assess the safety of single and repeated ascending doses of BL-7010 in well-controlled celiac patients. Secondary objectives included an assessment of the systemic exposure, if any, of BL-7010 in the study patients. The study was conducted based on a device pre-clinical submission package under an approval from the Finnish National Supervisory Authority for Welfare and Health (Valvira).

During the single-administration part of the study, six dose levels of BL-7010 were evaluated compared to placebo in a 6+2 standard design, with six patients on BL-7010 and two patients on placebo. This escalation stage reached the highest planned dose with no serious or dose-limiting adverse events. All planned doses were safe and well-tolerated with all patients completing this part of the study. During the second, repeated-administration part of the study, each patient received either 3 grams of BL-7010 or placebo for 14 days, three times per day, in the same 6+2 standard design. BL-7010 was well-tolerated over 14 days of treatment, with only one patient not completing the 14-day treatment period. Gastrointestinal-related adverse events (primarily diarrhea) were reported in six out of eight patients, though none were considered serious or dose-limiting and were also observed in one of the two patients on placebo. In light of these findings, and based on pre-clinical studies where the efficacious dose is predicted to be lower than the dose tested in the repeated administration stage of the study, we filed an amendment to further investigate lower repeated doses of BL-7010 in this study in order to select the optimal dose for the upcoming efficacy study.

In November 2014, we reported the final results of the study, including the results of the additional cohort tested. The final results of the study fully confirmed the positive unblinded results previously reported in July, and showed a substantially reduced level of gastrointestinal-related adverse events. Based on these results, we selected the dosing regimen of one gram, three times per day, of BL-7010 as the optimal repeated dose for the upcoming efficacy study. We expect to commence the efficacy study in the second half of 2015.

In addition, pharmacokinetic analyses revealed no systemic exposure of BL-7010 in plasma and urine samples from all patients at all doses and time points tested, both in the single- and repeated-dose regimens. Based on previous communications with a Notified Body in the European Union, we believe the lack of systemic exposure will likely support a medical-device classification in Europe for BL-7010, which would significantly accelerate its development in Europe.

**Other Clinical Therapeutic Candidates**

***BL-5010***

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

*Development and Clinical History*. We originally developed BL-5010 for the treatment of skin lesions such as seborrheic keratosis, or SK, and actinic keratosis. Clinically diagnosed skin lesions, or a growth or patch of skin that does not resemble the area surrounding it, are very common and often constitute a cosmetic and functional annoyance. Moles and warts are other examples of skin lesions. In 2009 and 2010 we conducted a successful phase 1/2 clinical trial in 60 patients with SK in Germany and the Netherlands to assess the safety and efficacy of BL-5010 in completely removing the lesion and to assess the cosmetic outcome of the novel treatment. A pivotal, CE Mark registration trial for BL-5010P had been planned for 2014. However, during discussions in recent years with potential partners for the development and commercialization of BL-5010, we learned that they had more interest in the possibilities of BL-5010 for OTC indications than in its use by physicians for SK and other lesions. In December 2014, we entered into the out-licensing arrangement with Omega Pharma described below and the development activities for BL-5010 will be restricted for the time being to OTC indications.

*Development and Commercialization Arrangement.* In December 2014, we entered into an exclusive out-licensing arrangement with Omega Pharma for the rights to BL-5010 for over-the-counter, or OTC, indications in the territory of Europe, Australia and additional selected countries. We will retain the rights to BL-5010 in the United States and the rest of the world. Under our out-licensing arrangement with Omega Pharma, Omega Pharma is obligated to use commercially reasonable best efforts to obtain regulatory approval in the licensed territory for at least two OTC indications and to commercialize BL-5010 for those two OTC indications. In addition, Omega Pharma will sponsor and manufacture BL-5010 in the relevant regions. Omega Pharma will pay us an agreed amount for each unit sold, and we will be entitled to certain commercial milestone payments. In addition, we will have full access to all clinical and research and development data generated during the performance of the development plan and may use these data in order to develop or license the product in other territories and fields of use where we retain the rights. We expect that the first OTC products will enter the market in 2016. As a result of this out-licensing arrangement, as well as the previous discussions with other potential partners for this product, the development activities for BL-5010 are currently focused on OTC indications. However, we may decide to continue development of BL-5010 for non-OTC indications, including, but not limited to, SK.

***BL-7040***

BL-7040 is a novel oligonucleotide which we are developing for the treatment of IBD. It is an orally-available, synthetic oligonucleotide consisting of a sequence of nucleic acids, the building blocks of genetic material such as DNA, with unique dual activity. It has a specific agonist effect on a receptor involved in the immune system and inflammatory reactions called Toll-Like Receptor 9 (TLR-9). It also acts as a specific suppressor of acetylcholinesterase, a key enzyme involved in neurological pathways.

We in-licensed the exclusive, worldwide rights to develop, and/or sell BL-7040 from Yissum in June 2011. Yissum had previously out-licensed the compound to Ester Neurosciences who performed phase 1 safety and pharmacokinetics studies and a phase 2a study examining the efficacy of the compound for the treatment of myasthenia gravis, an autoimmune, neurodegenerative disease. The compound was also found to target the innate inflammatory pathway and, therefore, we decided to develop the compound for the treatment of IBD and other inflammatory diseases.

*Inflammatory Bowel Disease.* IBD, including Crohn's disease and ulcerative colitis, is a chronic inflammatory gastrointestinal disease characterized by chronic inflammatory conditions, abdominal pain, intestinal hemorrhaging, reduced nutritional uptake, bloating and alteration of bowel habits. According to Datamonitor, in 2009 there were estimated to be 890,000 people with Crohn's disease, over half of them in the United States, and there are estimated to be 1.4 million cases of ulcerative colitis in the seven major markets. There are several specific treatment options available to treat IBD and many of the treatments are either insufficiently effective, very expensive or have serious side effects. IBD is a chronic autoimmune disease and none of the available treatments brings about a full cure. It is expected that through his/her lifetime an IBD patient will go through several rounds of treatment with an increased level of intensity and associated risk. Deferring treatment with corticosteroids, immunomodulators and surgery as much as possible is a primary treatment goal for physicians treating IBD. Approved treatments include steroids, which treat inflammation, and immunomodulators, which have an effect on the immune system. Many patients are referred to surgical treatment due to lack of efficacy by pharmacological agents. Biologics, which are therapeutics that are created by biologic processes rather than chemical synthesis, especially anti-TNFs (tumor necrosis factor - a protein actively involved in the inflammatory process), have become critical induction and maintenance agents. Remicade (infliximab), a treatment marketed by Janssen Biotech, Inc., a Johnson & Johnson company, Merck & Co. and Mitsubishi Tanabe Pharma, is the first approved anti-TNF for the treatment of IBD and is considered the gold standard of treatment. However, it is administered by IV, has a black box warning for serious infections and cancer and, like other biologics, is very expensive. Another approved treatment for IBD is Humira (adalimumab), which is self-administered by sub-cutaneous injection, giving it an advantage over treatments with other forms of administration. Humira is marketed by Abbot Laboratories and Eisai Co. Sales of existing drugs to treat IBD are estimated by Datamonitor to be $3.5 billion annually in the seven major markets. In 2013, the first biosimilar infliximab molecule gained regulatory approval in Europe.

*Clinical and Preclinical Results.* In March 2012, we commenced a phase 2a proof-of-concept study of BL-7040 to evaluate the effectiveness of BL-7040 for the treatment of IBD. Our phase 2a trial was an open-label study to evaluate the efficacy, pharmacodynamics, safety and tolerability of oral BL-7040 in 22 patients with moderately active ulcerative colitis, a type of IBD. Patients were treated for up to five weeks with BL-7040: 12mg/day for up to three weeks followed by 40mg/day for two additional weeks. The clinical trial was carried out at five sites in Israel: Sourasky Medical Center (Ichilov Hospital) in Tel Aviv; Hadassah Medical Center in Jerusalem; Shaare Zedek Medical Center in Jerusalem; Rambam Medical Center in Haifa; and Soroka Medical Center in Beer Sheva.

In April 2013, we announced positive results from this study. Sixteen of the 22 patients who were enrolled in the clinical trial completed the full five-week course of treatment and two-week follow-up. The primary clinical endpoint in the study – a 3-point and 30% reduction in the Mayo score between baseline and completion of treatment – was achieved. Fifty percent of patients (8 patients) met the primary endpoint, while the remaining 8 patients demonstrated a stable clinical condition or minor improvement. Fifty-six percent of patients (9 patients) demonstrated decreases of at least 1 point in the rectal-bleeding sub-score and 69% (11 patients) had rectal-bleeding sub-scores of ≤1 (in 6 of the 11 patients, no rectal bleeding was seen at all). Fifty percent of the patients completing study treatment also met certain secondary endpoints, such as a partial Mayo score reduction and mucosal healing evaluated by endoscopy sub-score measurements. The results of these additional secondary endpoints were not conclusive, although certain positive trends were noted. BL-7040 was highly safe and well tolerated by the study participants, with a very low incidence of drug related, mild-to-moderate adverse events (AEs), as well as one serious adverse event (SAE) not related to the treatment. Both patients and investigators were very satisfied with the safety and tolerability profile of the treatment and, in particular, emphasized the ease of oral administration.

In November 2013, we announced additional results from this study showing significant improvement of disease measurements in biopsies taken from IBD patients treated with BL-7040. The histological and biochemical analyses of inflammation indicators reinforced the initial positive results of the study described above.

In order to perform the histological and biochemical analyses, biopsies were taken from trial participants before and after treatment. Biopsies from each time point were collected and randomly assigned to either a histological evaluation or to an assessment for levels of cytokines, considered as pro-inflammatory bio-markers. All analyses were performed in a blinded manner.

The histological results show that neutrophil levels were significantly reduced (p=0.002) in patients treated with BL-7040. Neutrophils are the major cellular participant in acute inflammation, and their presence in the colon mucosa is believed to play a key role in causing tissue damage and clinical symptoms in IBD patients. Neutrophil levels are known to decrease when a patient's clinical condition improves. In this respect, all patients whose neutrophil levels were reduced also showed a clinical improvement as assessed by their Mayo score, the gold standard for assessing ulcerative colitis therapy.

An additional measure of disease severity is the level of the pro-inflammatory cytokine, interleukin 6 (IL-6). IL-6 is the predominant cytokine found in inflamed areas in ulcerative colitis patients, and its concentration correlates with the Mayo endoscopic score for disease severity. IL-6 levels were also significantly reduced (p=0.046) in patients treated with BL-7040, and most patients with reduced cytokine levels showed clinical improvement.

During the third quarter of 2014, we conducted a pharmacokinetic study in mice which indicated that BL-7040 reaches the target organ (the colon) and appears to have a local, as opposed to systemic, effect. These findings support our understanding of the mechanism of action of BL-7040. We are currently discussing this therapeutic candidate with a number of potential co-development partners, as well as planning the next stages of development.

The phase 2a study conducted by Ester Neurosciences was a multi-national, multi-center, cross-over, double-blind study to compare the efficacy of three doses of BL-7040 (10, 20 and 40 mg). A total of 31 patients with a clinical diagnosis of Myasthenia Gravis (MG) according to the MG Foundation of America (MGFA) classification were enrolled in the study. The efficacy of the three doses of BL-7040 given orally once daily for one week was evaluated using changes in the Quantitative Myasthenia Gravis Test (QMG), a grading system used in the comparative analysis of therapeutic interventions for MG, between baseline and end of treatment. The improvements observed in patients at the end of each week for each dose level of BL-7040 were clinically and statistically significant compared to the baseline for that week. All three doses resulted in an improvement in the severity of the MG symptoms and appear superior to Mestinon, the current first line treatment for MG, with no adverse events reported.

The phase 1b study conducted by Ester Neurosciences was an open label study to evaluate the safety and efficacy of escalating doses of BL-7040 administered orally to patients with MG. A total of 16 patients participated in the study. During the first day of treatment, each patient received 10 mcg/kg, 50 mcg/kg and 150 mcg/kg. During days two through four, patients received a daily dose of 500 mcg/kg. All of the patients completed the treatment and no major adverse events related to the study drug were reported.

Prior to initiating the clinical trials, BL-7040 was evaluated in preclinical safety and efficacy studies. Safety data available includes: acute single dose in mice, single and repeated dose in rats, repeated dose in monkeys by oral and IV administration, genetic toxicity and safety pharmacology studies. BL-7040 was found to have no mutagenic or clastogenic potential. BL-7040 was also found to have no toxic effects in any of the studies conducted at a dose range of 150mg/kg to 1,000mg/kg body weight/day by oral gavage or 500 mcg/kg-200 mg/kg body weight/day by IV administration in rodents and monkeys.

BL-7040 was evaluated in a well-validated murine model of IBD (TNBS (2,4,6-trinitrobenzenesulfonic acid)-induced IBD). It was found that BL-7040's therapeutic effect was similar to dexamethasone, a common routine steroidal treatment for human colitis. BL-7040 induced a statistically significantly decrease in the severity of the colitis (a decrease of about 80%). Other studies have demonstrated the specific agonistic effect of BL-7040 on TLR-9.

***BL-8020***

BL-8020 is a proprietary fixed-dose combination treatment composed of Ribavirin and Hydroxychloroquine, or HCQ. Efficacy results in replicon assays, as well as in ex-vivo infected human liver samples, showed a time and dose-dependent inhibitory effect of BL-8020 on HCV replication and infectivity. In addition, a synergistic effect with other anti-HCV agents was observed in these models. This effect on other therapies is likely to increase their potency and reduce the numerous adverse effects often associated with these drugs by reducing their effective doses. BL-8020 targets the infected host cells and inhibits HCV induced autophagy in the host. This unique mechanism of action differentiates BL-8020 from other currently used anti-HCV agents in its potential pan genotypic activity and high genetic barrier to resistance (low susceptibility for drug-resistant mutations to be developed by the virus). BL-8020 may also have an effect on other viral indications, such as dengue fever, and may be developed for such indications in the future.

*Hepatitis C*. Hepatitis C infection is a blood-borne infection of the liver caused by the hepatitis C virus (HCV) which becomes chronic in about 85% of cases. According to a 2011 report from Decision Resources, about 180 million people worldwide are chronically infected with HCV. In addition, HCV infection is the leading cause of liver transplantation and is a risk factor for liver cancer. The global hepatitis market was estimated at $6 billion in 2011 and is forecasted to grow to $20 billion by the end of the decade.

*Preclinical Results*. BL-8020's safety and efficacy have been demonstrated in a number of pre-clinical studies. These studies have shown that BL-8020 has a synergistic effect with other anti-HCV agents that is likely to increase their potency and reduce the numerous adverse effects often associated with these drugs by enabling utilization of lower dosages.

*Clinical Trial*. In April 2013, we commenced a Phase 1/2 trial for BL-8020 at two sites in France. The study was an open-label trial to evaluate the efficacy, safety and tolerability of BL-8020 in patients infected with HCV. In January 2014, we entered into a collaboration agreement with the licensors of the compound whereby, in consideration for the payment of future royalties to us, we terminated the license agreement, the licensors agreed to take over development of the compound and we agreed to supply, at the licensors' request and for full payment, the drug product needed for a clinical trial to be administered by the licensors. In August 2014, the licensors decided to terminate the ongoing phase 1/2 trial in HCV due to a very slow recruitment rate, and are now determining the next steps in the clinical development plan of the compound, including an assessment regarding potential additional viral indications for development. See "— In-Licensing Agreements — BL-8020."

**Termination of BL-1020.** BL-1020 was an orally administered antipsychotic for the treatment of schizophrenia. We in-licensed the worldwide, exclusive rights to research, develop and commercialize BL-1020 from Bar Ilan Research and Development and Ramot. In June 2011, we commenced the phase 2/3 CLARITY clinical trial with respect to BL-1020. The CLARITY trial was designed to be a randomized, double-blind trial to examine both acute (6 weeks) and long-term (24 weeks) cognitive and antipsychotic efficacy, safety and tolerability of BL-1020 on patients with acute schizophrenia.

In March 2013, we announced the discontinuation of the Phase 2/3 CLARITY trial of BL-1020 after the results from an interim analysis indicated that the trial would not meet the pre-specified primary efficacy endpoint. The interim analysis included data on 230 subjects, of which 168 were evaluable for analysis on the primary (six-week) cognitive endpoint. The analysis indicated insufficient efficacy of BL-1020, in comparison to Risperidone, relative to the cognitive primary and secondary (12-week and 24-week) endpoints. We then performed a complete analysis of the un-blinded study data on all enrolled patients in order to ascertain whether there could be potential for the product. No such potential was determined, and therefore in March 2014, the project was terminated.

**Therapeutic Candidates in Preclinical Development**

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

| Therapeutic Candidate | Description | Indication | Status | In-Licensing Source |
|---|---|---|---|---|
| BL-8030 | Small molecule | Hepatitis C | Preclinical studies; in collaboration with CTTQ for China and Hong Kong | Genoscience and RFS Pharma |
| BL-9010 | Bi-specific antibody | Severe allergies/asthma | Preclinical studies | Yissum and University of Genoa, Italy |
| BL-9020 | Monoclonal antibody | Type 1 Diabetes | Preclinical studies and optimization of antibody; in collaboration with JHL Biotech for China and Southeast Asia | Yissum, B.G. Negev Technologies and Hadasit Ltd. |
| BL-1110 | Small molecule | Neuropathic pain | Preclinical studies | University of Colorado |

**Product Development Approach**

We seek to develop a pipeline of promising therapeutic candidates that exhibit distinct advantages over currently available therapies or address unmet medical needs. Our resources are focused on advancing our therapeutic candidates through development and toward commercialization. Our current drug development pipeline consists of 10 therapeutic candidates.

We have established relationships with various universities, academic and research institutions and biotechnology companies that permit us to identify and select compounds at a very early stage of development. Initially, we focused on Israeli institutions as the primary source of our therapeutic candidates. In Israel, we established close relationships with the Technion – Israel Institute of Technology, or Technion, Ben Gurion University of the Negev, Hebrew University of Jerusalem, Tel Aviv University, Bar Ilan University and the Weizmann Institute. More recently, we have begun to source therapeutic candidate opportunities worldwide. Although our focus since inception has been on identifying development stage therapeutic candidates, we have begun evaluating pre-clinical and clinical candidates in order to introduce therapeutic candidates with a greater potential for clinical success to our pipeline.

Once we identify a candidate, it enters our internal evaluation system and undergoes our rigorous selection process. We employ internal research efforts to evaluate candidates. We evaluate each compound's potential for success by looking at the candidate's efficacy, safety, total estimated development costs, technological novelty, patent status, market potential and approvability. Following evaluation and diligence, each therapeutic candidate is evaluated by our Scientific Advisory Board and by disease-specific advisors for external scientific review. Following a Scientific Advisory Board meeting, the compound is referred to more advanced feasibility testing. At each step of the process, a therapeutic candidate is subjected to critical evaluation and potential termination. Our approach is consistent with our objective of proceeding only with therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. To date, we have screened over 2,000 compounds, presented more than 70 candidates to our Scientific Advisory Board for consideration, initiated development of 45 therapeutic candidates and terminated 35 feasibility programs.

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

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

**Investment and Collaboration Agreement with Novartis**

In December 2014, we entered into a multi-year strategic collaboration agreement with Novartis designed to facilitate development and commercialization of Israeli-sourced drug candidates. Novartis will evaluate projects identified and presented by us for co-development and potential future licensing under the collaboration. The companies intend to co-develop a number of pre-clinical and early clinical therapeutic projects through clinical proof-of-concept. As part of the agreement, Novartis made an initial equity investment in BioLineRx of $10 million, representing 12.8% of our then current shares outstanding. See “Item 10. Additional Information — Material Contracts — Investment and Collaboration Agreement with Novartis.”

**Out-Licensing Agreement with Bellerophon**

In 2009, we entered into a licensing arrangement with Bellerophon, pursuant to which we granted Bellerophon an exclusive, worldwide license to develop, manufacture and commercialize BL-1040 for use in the prevention, mitigation and treatment of injury to the myocardial tissue of the heart. Bellerophon is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or a product related thereto. We were responsible for the costs of the completed phase 1/2 studies. Bellerophon is responsible for the costs associated with conducting all other development and regulatory activities of BL-1040, including those costs relating to the completion of its clinical development, the conduct and funding of its commercialization and the prosecution and maintenance of patents.

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

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

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

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

During 2014, we had discussions with Bellerophon relating to its performance under our license agreement with it. We believed that Bellerophon had breached the license agreement in several ways, and we also disagreed with Bellerophon about the timing of a $12.5 million milestone payment that Bellerophon would owe to us in the future based upon progress in the BL-1040 clinical development program. In January 2015, we reached an agreement with Bellerophon to amend the BL-1040 license agreement, thereby resolving the prior disputes and providing for a release of all our claims against Bellerophon. The amendment has also changed a certain milestone and related payments, but the total potential milestone payments to be paid to us under the license agreement remain the same.

**Out-Licensing Agreement with Omega Pharma**

In December 2014, we entered into an exclusive out-licensing arrangement with Omega Pharma for the rights to BL-5010 for over-the-counter, or OTC, indications in the territory of Europe, Australia and additional selected countries (collectively, the "Territory"). We will retain the rights to BL-5010 in the United States and the rest of the world. Omega Pharma is obligated to make all necessary efforts to launch a licensed product commercially in the Territory in 2016, including having secured sufficient licensed product supply to support such commercial launch. In addition, Omega Pharma is obligated to use commercially reasonable best efforts to obtain regulatory approval in the Territory for at least two OTC indications and to commercialize BL-5010 for those two OTC indications.

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

Omega Pharma is obligated to pay us an agreed amount for each unit sold, and we will be entitled to certain commercial milestone payments. We must pay a portion of all net consideration we receive from Omega Pharma, within our standard range of sublicense receipt consideration, to IPC, the company from which we initially in-licensed the development rights to BL-5010. See "— In-Licensing Agreements — BL-5010."

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

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

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

**Other Out-licensing/Collaboration Agreements**

***CTTQ***

In June 2013, we signed an out-licensing agreement with Jiangsu Chia-tai Tianqing Pharmaceutical Co., Ltd., or CTTQ, the leading Chinese pharmaceutical company in the liver disease therapeutic area, granting CTTQ exclusive rights to develop, manufacture and commercialize BL-8030, an orally available treatment for HCV, in China and Hong Kong, or the CTTQ Territory. We have retained the right to develop and commercialize BL-8030 in other parts of the world. Both parties are obligated to carry out in collaboration their allotted activities regarding the development of BL-8030 (including full access to data generated by the other party), and CTTQ is obligated to use commercially reasonable efforts to commercialize BL-8030 in the CTTQ Territory. CTTQ is responsible for the costs associated with development and regulatory activities of BL-8030 in its territory, including those costs relating to the completion of the clinical development of BL-8030, the conduct and funding of commercialization and the prosecution and maintenance of patents.

CTTQ paid us a small upfront license fee and is obligated to pay us future development, regulatory and commercialization milestones, for a total potential deal value of approximately $30 million. In addition, we have the right to receive high single-digit royalties on future sales of the drug. We must pay a portion of all net consideration we receive from CTTQ to RFS Pharma, LLC and Genoscience, the companies from which we initially in-licensed the development rights to BL-8030.

CTTQ has the right to sublicense BL-8030 in the CTTQ Territory in arm's-length transactions consistent with the terms and conditions of the license agreement.

Our agreement with CTTQ expires upon the cessation of all commercialization of BL-8030 in the CTTQ Territory. Either party may terminate the agreement by providing 30 days' written notice of a material breach of the agreement by the other party if the breaching party does not cure the breach during that time. In addition, CTTQ may terminate the agreement (a) without cause upon 90 days' prior written notice (subject, in certain cases, to payment of compensation to us) and (b) upon 30 days' prior written notice in the event of any significant adverse clinical events or other adverse toxicity, safety or efficacy data relating to a product.

***JHL***

In January 2014, we signed a collaboration agreement with JHL Biotech, or JHL, a biopharmaceutical company that develops, manufactures, and commercializes biologic medicines, pursuant to which we will collaborate with JHL in the development and commercialization of BL-9020, a novel monoclonal antibody for the treatment of Type 1 diabetes. JHL will be responsible for all process development and manufacturing of BL-9020 during its pre-clinical and clinical development stages, and we will be responsible for all pre-clinical development of BL-9020. Responsibility for clinical development of BL-9020 will be shared by the parties on a regional basis. Under the terms of the agreement, JHL will have global manufacturing rights to BL-9020, along with development and commercialization rights in China and Southeast Asia, or the JHL Territory, and we will have development and commercialization rights in the rest of the world. In all development and manufacturing of BL-9020, JHL will adhere to FDA guidelines and regulations. Each party will have rights to all development and regulatory data generated under the agreement in order to commercialize BL-9020 in its respective territory.

Each party will be entitled to single-digit royalties on the sale of BL-9020 in the other party's respective territory. We must pay 16% of all net consideration we receive from JHL to Yissum, B.G. Negev Technologies and Hadasit Medical Research Services and Development Ltd., the companies from which we initially in-licensed the development rights to BL-9020. See "— In-Licensing Agreements — BL-9020." In addition, we are required to pay 12% of all net consideration we receive as a result of the out-licensing of BL-8030, including without limitation the net consideration we receive from JHL, to a party that is assisting us in the initial development of BL-8030.

JHL has the right to sublicense BL-9020 in the JHL Territory in arm's-length transactions consistent with the terms and conditions of the license agreement.

Our agreement with JHL expires upon the later of the date on which JHL reasonably expects no additional sales of product in the JHL Territory or the date on which on which we reasonably expect that we will no longer receive additional sublicensing consideration or net sales. Either party may terminate the agreement by providing either 30 or 60 days' written notice (depending on which provision of the agreement has been breached) of a material breach of the agreement by the other party if the breaching party does not cure the breach during that time.

**In-Licensing Agreements**

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

The scope of payments we are required to make under our in-licensing agreements is comprised of various components that are paid commensurate with the progressive development and commercialization of our drug products.

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

- **Revenue sharing payments**. These are payments to be made to licensors with respect to revenue we receive from sub-licensing to third parties for further development and commercialization of our drug products. These payments are generally fixed at a percentage of the total revenues we earn from these sublicenses.

- **Milestone payments**. These payments are generally linked to the successful achievement of milestones in the development and approval of drugs, such phases 1, 2 and 3 of clinical trials and approvals of new drug applications, or NDAs.

- **Royalty payments**. To the extent we elect to complete the development, licensing and marketing of a therapeutic candidate, we are generally required to pay our licensors royalties on the sales of the end drug product. These royalty payments are generally based on the net revenue from these sales. In certain instances, the rate of the royalty payments decrease upon the expiration of the drug's underlying patent and its transition into a generic drug. Certain of our agreements provide that if a licensed drug product is developed and sold through a different corporate entity, the licensors may elect to receive shares in such company instead of a portion of the royalties.

- **Additional payments**. In addition to the above payments, certain of our in-license agreements provide for a one-time or periodic payment that is not linked to milestones. Periodic payments may be paid until the commercialization of the product, either by direct sales or sublicenses to third parties. Other agreements provide for the continuation of these payments even following the commercialization of the licensed drug product.

The royalty and revenue sharing rates we agree to pay in our in-licensing agreements vary from case to case but in most cases range from 22% to 29.5% of the consideration we receive from sublicensing the applicable therapeutic candidate. We are required to pay a substantially lower percentage, generally less than 5%, if we elect to commercialize the subject therapeutic candidate independently. In addition, milestone payments are not generally payable if revenue-sharing from an out-licensing transaction is greater than any relevant payments due under our in-licensing agreements.

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

***BL-1040***

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

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

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

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

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

***BL-8040***

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

There were no upfront payments due under the agreement. We are obligated to pay a monthly development fee for certain development services that Biokine has committed to provide to us under the agreement, as follows:

- during the initial 12-month period following execution of the agreement; $100,000 per month;

- after the initial 12-month period and continuing until the earlier of (i) completion of the clinical trials contemplated under the agreement or (ii) grant of a sublicense, as follows: $65,000 per month for the following 12 months, $60,000 per month for the next six months and $50,000 per month thereafter until the earlier of the completion of the two clinical trials contemplated by the parties or the grant of a sublicense pursuant to the agreement..

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

The agreement contemplates two non-comparative clinical trials studying the effects of BL-8040 in two indications. If both clinical trials contemplated under the agreement are completed within a given period, we are obligated to pay Biokine a bonus of $250,000. This is the sole milestone payment due under the agreement.

Should we independently develop manufacture and sell products (excluding sublicensing) containing the licensed technology, we are obligated to make royalty payments of between 10-12% of net sales, subject to certain limitations.

The agreement also grants us the right to grant sublicenses for the licensed technology. In such event, we are required to pay Biokine a royalty payment of between 40-60% of the amounts we receive as consideration in connection with any sublicensing, development, manufacture, marketing, distribution or sale of the licensed technology. The amount of the royalty for either direct sales or sublicensing is dependent on the aggregate amount of our investment in connection with the agreement, decreasing as the amount of our investment in the project increases. Based on the current and anticipated cumulative investment in the project made by us, we believe it is highly probable that the royalty payments to Biokine will be at the lowest end of the above ranges (i.e., 40% for sublicensing and 10% for direct sales).

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

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

We have the first right to prepare, file, prosecute and maintain any patent applications and patents, in respect of the licensed technology and any part thereof, at our expense, provided that we are required to consult with Biokine regarding patent prosecution and patent maintenance. In addition, we have the right to take action in the prosecution, prevention, or termination of any patent infringement of the Licensed Technology. We are responsible for all the expenses of any patent infringement suit that we bring, including any expenses incurred by Biokine in connection with such suits, with such expenses reimbursable from any sums recovered in such suit or in the settlement thereof for. After such reimbursement, if any funds remain, both we and Biokine are each entitled to a certain percentage of any remaining sums.

The agreement will remain in full effect until the expiration of all of our royalty and sublicense revenue obligations to Biokine, determined on a product-by-product and country-by-country basis. We may terminate the agreement for any reason on 90 days' prior written notice to Biokine. Either party may terminate the agreement for a material breach by the other party if the breaching party is unable to cure the breach within 30 days after receiving written notice of the breach from the non-breaching party. With respect to any termination for a material breach, if the breach is not susceptible to cure within the stated period and the breaching party uses diligent, good faith efforts to cure such breach, the stated period will be extended by an additional 30 days. In addition, either party may terminate the agreement upon the occurrence of certain bankruptcy events.

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

***BL-7010***

In February 2011, we in-licensed the rights to BL-7010 under a license agreement with Univalor, the technology transfer office for the University of Montreal. Under the agreement, Univalor granted us an exclusive, worldwide, sublicensable license to research, have researched, develop, have developed, manufacture, have manufactured, use, market, distribute, offer for sale, sell, have sold, export and import products that comprise, contain or incorporate a certain invention relating to polymeric binders for celiac disease and/or provide services relating thereto. Notwithstanding the exclusive license, the University of Montreal retained the right to use the licensed invention and patents for academic (i.e., non-commercial) research and teaching purposes. Under the agreement, we are required to use commercially reasonable efforts to carry out the development work necessary to develop products under the agreement in accordance with a specified development plan.

According to the terms of the agreement, we reimbursed Univalor for a portion of all past documented patents costs relating to the registration and maintenance of the licensed patents. On execution of the agreement, we paid Univalor a non-refundable license issue fee. On each anniversary of the execution of the agreement, we have paid an annual, non-refundable license maintenance fee and will continue to pay such annual maintenance fee until such time as we become obligated to pay minimum annual royalties after the first commercial sale made by us, our affiliates or our sublicensees. If we manufacture and/or sell in any way products under the license, we are obligated to pay Univalor low, single-digit royalties which vary in amount depending on whether sales are made in a country where there is a licensed patent. The minimum annual royalties are fully creditable against actual royalties due. The agreement obligates us to pay milestone payments on the occurrence of each of the following: enrollment of the first patient in the first Phase I clinical trial relating to the licensed products; enrollment of the first patient in the first Phase II clinical trial relating to the products; enrollment of the first patient in the first Phase III clinical trial relating to the products; the first filing of a new drug application (NDA) or equivalent for the products; and receipt of a first regulatory approval from any relevant registration authority (e.g. FDA, TPD or EMEA) for the products. If we grant sublicenses of our rights under the license, we are required to pay Univalor a portion of the consideration we receive in connection with the grant of a sublicense or option to obtain a sublicense, subject to certain criteria. Royalties are payable under the agreement beginning with the first commercial sale of a product under the agreement and expiring on the expiration of the last valid patent claim in or covered by any patent application related to any of the licensed invention, the licensed patents, the improvements made therein, or any other patent pertaining to such invention or improvements, whichever expires last.

Either we or Univalor may terminate the agreement immediately upon written notice to the other relating to bankruptcy and insolvency matters, and upon 60 days' written notice of a material breach if such breach is not cured. Notwithstanding the foregoing, a party is entitled to an extra 30 days to cure a breach if the breach is not capable of cure during the stated period if the breaching party uses diligent good faith efforts to cure the breach. Termination of the agreement will result in the termination of the license and, accordingly, the licensed invention and all rights included therein will revert to Univalor. All sublicenses under the agreement are required to provide that, upon termination of the license the sublicense shall terminate; provided that as long as the sublicensee is not in breach of the sublicense agreement at such time to the extent that we would have the right to terminate the sublicense, Univalor will be required to act in one of the two following ways: either (a) take over the sublicense; or (b) enter into a new agreement with the sublicensee on substantially the same terms as those contained in the existing sublicense agreement.

We have the first right to prepare, file, prosecute and maintain any patent applications and patents in respect of the licensed invention and any part thereof, at our expense, subject to certain conditions. We are required to make all the reasonable efforts necessary to obtain and maintain patent protection of the licensed technology in at least the following countries: Canada, the United States, France, Italy and Belgium. We have the right, but not the obligation, to take action in the prosecution, prevention or termination of any infringement of patents licensed under the agreement. We are responsible for the expenses of any patent infringement suit that we bring, including the expenses incurred by Univalor in connection with such suits. We are entitled to reimbursement from any awards or settlements recovered in such suit or in the settlement thereof for all costs and expenses involved in the prosecution of any such suit. If we elect not to pursue any action in connection with infringement, Univalor may elect to do so. In such event, Univalor will be responsible for the expenses of any patent infringement suit that it brings, including the expenses incurred by Univalor in connection with such suits and be entitled to reimbursement from any awards or settlements recovered in such suit or in the settlement thereof for all costs and expenses involved in the prosecution of any such suit.

***BL-5010***

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

The license agreement remains in effect until the expiration of all of our license, royalty and sublicense revenue obligations to IPC, determined on a product-by-product and country-by-country basis, unless we terminate the license agreement earlier. We may terminate the license agreement for any reason on 30 days' prior written notice. We may also terminate the license agreement upon 60 days' prior written notice to IPC for scientific, regulatory or medical reasons which, as determined by our Scientific Advisory Board, would prevent us from continuing the development of the licensed technology pursuant to the development plan. Either party may terminate the agreement for material breach if the breach is not cured within 30 days after written notice from the non-breaching party. If the breach is not susceptible to cure within the stated period and the breaching party uses diligent, good faith efforts to cure such breach, the stated period will be extended by an additional 30 days. In addition, either party may terminate the agreement upon the occurrence of certain bankruptcy events.

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

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

***BL-7040***

In June 2011, we in-licensed the rights to BL-7040 under a license agreement with Yissum. Under the agreement, Yissum granted us an exclusive, worldwide, sublicensable license to develop, have developed, manufacture, have manufactured, use, market, distribute, export, import and/or sell products and/or processes that comprise, contain or incorporate certain technology relating to a novel oligonucleotide. Notwithstanding the exclusive license, Yissum and the Hebrew University of Jerusalem retained the right to make non-commercial, academic use of the technology at the Hebrew University, including academic research sponsored by third parties that does not conflict or interfere with the license. In addition, Yissum may grant licenses to third party academic or research institutions for non-commercial, academic research and teaching purposes provided that any results from such efforts shall be the sole property of Yissum and exclusively licensed to us under the agreement. Under the license agreement, we are responsible for, and are required to exert, reasonable commercial efforts to carry out the development, regulatory, manufacturing and marketing work necessary to develop and commercialize products under the agreement in accordance with a specified development plan.

Upon execution of the agreement, we were obligated to make a $30,000 initial payment to Yissum for all previous documented expenses and costs directly incurred by Yissum relating to the registration and maintenance of the licensed patents. We are obligated under the agreement to pay license fees as follows: $150,000 upon completion of the dosing of the last patient to be enrolled in the first phase II clinical trial with respect to a product under the agreement; and $450,000 upon enrollment of the first patient in a phase III clinical trial of a product under the agreement. We are obligated to make a 4.5% royalty payment on net sales of products, subject to certain limitations, if we manufacture and sell products developed under the agreement on our own. These royalties are reduced to 2% with respect to sales in any country after the expiration in such country of the last to expire patent with a valid claim. If we grant sublicenses of our rights in the licensed technology, we are required to pay Yissum a payment of either 28% or 29.5% of the consideration we receive in connection with the grant of a sublicense or option to obtain a sublicense, subject to certain criteria. In any event, however, the consideration that we are required to actually pay to Yissum as a result of royalties or other sales related consideration that we receive from sublicenses shall not be less than 3.5% of the net sales which form the basis for computation of the royalties paid to us by such sublicensees. In addition, if we sublicense or assign the rights to the licensed technology and/or development results under the agreement to a company-owned entity established for the sole purpose of commercializing and developing the licensed technology and the development results, Yissum may elect to receive 12.5% of the entity's ordinary shares and reduced royalties and sublicense fees equal to 1.875% and 12.5%, respectively.

In addition, we are required, upon the completion of the development of any product under the agreement, to use commercially reasonable efforts to maximize net sales of the product on a regular and consistent basis.

Royalties are payable under the agreement beginning upon the first commercial sale of a product under the agreement and expiring on a country-by-country basis on the occurrence of the later of (a) the expiration in such country of the last-to-expire patent with a valid claim and (b) the elapse of 15 years from the date of the first commercial sale of a product under the agreement in the country. Either we or Yissum may terminate the agreement immediately upon written notice to the other relating to bankruptcy and insolvency matters, upon 60 days' written notice of a material breach if such breach is not cured, and upon 90 days with notice of a non-material breach, is such breach is not cured. Notwithstanding the foregoing, a party is entitled to an extra 30 days to cure a breach if the breach is not capable of cure during the stated period if the breaching party uses diligent good faith efforts to cure the breach. In addition, Yissum may terminate the agreement (a) immediately if an attachment is made over our assets and/or execution proceedings are taken against us and are not set aside within 60 days of the date of attachment or proceedings, as applicable and (b) if we fail to pay, in full, the research fee under a related sponsored research agreement upon 30 days' notice, subject to certain exceptions. We may terminate the license agreement for any reason on 30 days' prior written notice to Yissum.

Termination of the agreement will result in the termination of the license and, accordingly, the licensed technology and all rights included therein will revert to Yissum. All sublicenses under the agreement are required to provide that, upon termination of the license, in whole or in part, that is, with respect to any country, the sublicense shall terminate; provided that as long as the sublicensee is not in breach of the sublicense agreement at such time to the extent that we would have the right to terminate the sublicense, Yissum will be required to act in one of the two following ways: either (a) enter into a new agreement with the sublicensee upon substantially the same terms as the sublicense as long as the terms are amended such that Yissum is not subject to any obligation or liability which are not included in, or in greater scope than, Yissum's obligations or liabilities under the license agreement; or (b) require the sublicensee to enter into a new license agreement on substantially the same terms and conditions as those contained in the license agreement.

We have the first right to prepare, file, prosecute and maintain any patent applications and patents in respect of the licensed technology and any part thereof, at our expense, subject to certain conditions. We are required to file each licensed patent application at least in the United States, Europe and Japan. We are also required to take action, in reasonable commercial circumstances and after consultation with patent counsel, in the prosecution, prevention or termination of any infringement of patents licensed under the agreement. We are responsible for the expenses of any patent infringement suit that we bring, including the expenses incurred by Yissum in connection with such suits. We are entitled to reimbursement from any awards or settlements recovered in such suit or in the settlement thereof for all costs and expenses involved in the prosecution of any such suit. If we elect not to pursue any action in connection with infringement and Yissum in good faith disagrees with us that it is in the mutual best interest of both parties not to pursue any such action, then, at our election, we may either allow Yissum to pursue such actions, at Yissum's expense, or pay Yissum the royalties that Yissum would otherwise receive from us attributable to lost sales resulting from such alleged infringement.

***BL-8020***

In January 2012, we in-licensed the rights to BL-8020 under a license agreement with Panmed and Genoscience. Under the agreement, the licensors granted us an exclusive, worldwide, sublicensable license to research, have researched, develop, have developed, manufacture, have manufactured, use, market, distribute, offer for sale, sell, have sold, export and import certain technology relating to the use of HCQ for the treatment of HCV. Under the license agreement, we are obligated to use commercially reasonable efforts to develop the licensed technology in accordance with a specified development plan. In accordance with this obligation, in April 2013, we commenced a Phase 1/2 trial for BL-8020 in France. Due to a number of considerations, including the potential for other viral indications, as well as a re-prioritization of our pipeline, and after consultation with the licensors, we agreed with them that as of April 1, 2014, the license agreement would be terminated and that we would enter into a collaboration agreement whereby, among other things, the licensors agreed to take over development of the drug in consideration for 28% of future sublicense receipts by the licensors, and we agreed to supply, at the licensors' request and in consideration for full payment, the drug needed for a clinical trial to be administered by the licensors. In August 2014, the licensors decided to terminate the ongoing phase 1/2 trial in HCV due to a very slow recruitment rate, and are now determining the next steps in the clinical development plan of the compound, including an assessment regarding potential additional viral indications for development.

**Intellectual Property**

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

***Patents***

As of March 20, 2015, we owned or exclusively licensed for uses within our field of business 18 patent families that collectively contain over 55 issued patents, five allowed patent applications and over 40 pending patent applications relating to the five clinical candidates listed below. We are also pursuing patent protection for other drug candidates in our pipeline. Patents related to our therapeutic candidates may provide future competitive advantages by providing exclusivity related to the composition of matter, formulation, and method of administration of the applicable compounds and could materially improve the value of our therapeutic candidates. The patent positions for our five therapeutic candidates are described below and include both issued patents and pending patent applications we exclusively license. We vigorously defend our intellectual property to preserve our rights and gain the benefit of our investment.

- With respect to BL-1040, we have an exclusive license to a patent family directed to the BL-1040 composition and methods of its use for the treatment of myocardial infarction. Patents of this family have been granted or received notice of allowance in the United States, India, China, Australia, Mexico, Israel, Europe, Japan, Canada and South Korea. The U.S. composition of matter patent will expire in 2029, plus any applicable patent term extension, and the U.S. method of treatment patent will expire in 2024. A broad method of manufacturing patent is issued and expires in 2025. In July 2014 and October 2014, Bellerophon was notified by the European Patent Office that Notices of Opposition to two European patents that Bellerophon licensed from us, one of which covers the BCM intended commercial product described above, have been filed with the European Patent Office. A Notice of Opposition initiates a process during which the European Patent Office can decide to reconsider an issued patent and modify or revoke some or all of the patent claims. As our licensee, Bellerophon has the right to respond to the Notices of Opposition before the European Patent Office makes a decision whether or not any or all of the patent claims are to be modified or revoked. Bellerophon filed a response to the first patent opposition in December 2014 and intends to file a response in the near future for the second patent opposition as Bellerophon and BioLineRx believe the two issued patents were properly examined and appropriately granted by the European Patent Office. Furthermore, Bellerophon and BioLineRx believe the arguments made in the Notices of Opposition misstate the facts and lack scientific merit.

- With respect to BL-8040, we have an exclusive license to two patent families that cover the molecule that is the active ingredient of our proprietary drug. Patents and patent applications of these families have been granted or are pending in the United States, Europe, Japan and Canada. The patents and any patents to issue in the future based on pending patent applications in these families will expire in 2023 (in the United States) and 2021 (in other countries) , plus any applicable patent term extension. In addition, we have an exclusive license to seven other patent families pending worldwide directed to the use of BL-8040 for the treatment of certain types of cancer and other indications. Furthermore, we have Orphan Drug status for both AML and stem cell mobilization, as well as exclusivity protection afforded to BL-8040 as a new chemical entity, or NCE.

- With respect to BL-7010, we have an exclusive license to a patent family directed to the BL-7010 composition and its use for the treatment of celiac disease. Patents and patent applications of this family have been granted or are pending in the United States, Israel, Europe, Japan, Canada, Brazil, China, India, Mexico, Russia and Australia. The issued patents and any patents to issue in the future based on pending patent applications in this family will expire in October 2026, with a possibility of up to five years of patent-term extension.

- With respect to BL-5010, we have an exclusive license to a patent family directed to the BL-5010 composition and its use for the removal and preservation of skin lesions. Patents and patent applications corresponding to the international patent application have been granted or are pending in the United States, Israel and Europe. The issued patents and any patents to issue in the future based on pending patent applications in these families will expire at the end of 2021. In addition, we have an exclusive license to an international patent application directed to a novel applicator uniquely configured for applying the BL-5010 composition to targeted skin tissue safely and effectively. Patents to issue in the future based on this international patent application will expire in 2034.

- With respect to BL-7040, we have an exclusive license to a patent family that covers the molecule that is the active ingredient of our proprietary drug. Patents and patent applications corresponding to the international patent application have been granted or are pending in the United States, Israel, Europe, Japan, Canada, New Zealand and India. The patents and any patents to issue in the future based on pending patent applications in this family will expire in 2021, plus any applicable patent term extension. We also have an exclusive license to a patent family claiming the use of BL-7040 for the treatment of inflammatory diseases such as IBD. Patents and patent applications corresponding to the international patent application are pending in the United States, Europe and Japan. The patents and any patents to issue in the future based on pending patent applications in this family will expire in 2023. In addition, we have exclusivity protection afforded to BL-7040 as an NCE.

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

***Trade Secrets***

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

**Scientific Advisory Board**

Our Scientific Advisory Board, which consists of a number of leading scientists and physicians, plays an active role in the evaluation of in-licensing opportunities, the development of our pipeline, and in the rejection of in-licensing opportunities that do not meet our licensing criteria. We also seek advice from our Scientific Advisory Board on scientific and medical matters generally. Our Scientific Advisory Board meets approximately every 3-4 months to, among other things:

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

The following table sets forth information for our Scientific Advisory Board members.

| Name | Position/Institutional Affiliation |
|---|---|
| J. Aaron Ciechanover, M.D., Ph.D. | Professor Ciechanover is a Distinguished University Professor in the Faculty of Medicine of the Technion. He is a recipient of many prizes, among them the Nobel Prize in Chemistry (2004), the Israel Prize in Biological Research (2003) and the Albert Lasker Award for Basic Medical research (2000). He is a member of numerous learned societies, among them the Israeli Academy of Sciences and Humanities, the National Academy of Sciences (United States) and its Institute of Medicine (Foreign Member). |
| Aliza Eshkol, Ph.D. | Dr. Eshkol is an independent scientific advisor for pharmaceutical development. She retired as Vice President for Scientific Affairs, Serono International SA, Geneva, Switzerland. Dr. Eshkol is a member of several national and international professional societies. |
| Gianni Gromo, M.D., Ph.D. | Dr. Gromo is the founder of Gromo Consulting, whose focus is primarily on R&D strategies for discovering new medicines, as well as a partner at Versant Ventures, a leading global health care venture capital firm. Until November 2012, Dr. Gromo headed various R&D units at F. Hoffmann-La Roche Ltd., mainly in the areas of metabolic, renal and vascular diseases. His last position at the company was as head of the R&D organization in China. |

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| David Ladkani, M.D. | Dr. Ladkani has held roles of increasing responsibility in R&D, business development and medical affairs at senior levels for 35 years at Teva. His most recent position at Teva has been Vice President Research, Scientific Affairs. Dr. Ladkani is the recipient of the Rothschild Award for innovation and is widely published in the field of multiple sclerosis treatments. |
| Yaakov Naparstek, M.D. | Professor Naparstek is a specialist in Internal Medicine, Rheumatology and Clinical Immunology and a senior physician in the Hadassah Medical Organization. His main research interests are in the field of autoimmunity, systemic lupus erythematosus, autoimmune arthritis and inflammatory bowel diseases. |
| Moshe Phillip, M.D. | Professor Phillip is the Chairman of our Scientific Advisory Board and has been a member since 2004. From 2004 through December 2013, Prof. Phillip was our Vice President of Medical Affairs and Senior Clinical Advisor. Prof. Phillip is the Director of the Institute for Endocrinology and Diabetes of the Israel National Center for Childhood Diabetes at Schneider Children's Medical Center of Israel and the Vice Dean for Research and Development at the Sackler School of Medical Education at Tel Aviv University. |
| Itamar Shalit, M.D. | Professor Shalit is Associate Professor in Pediatrics, Sackler Faculty of Medicine, Tel-Aviv University. In addition, he was the founder, a consultant and a board member of NasVax Ltd., an Israeli biotechnology company. Currently, he is a board member of Mor Institute for Medical Information; a board member of Migal – Galilee Research Institute; CEO of The Galilee Bio-Medical Research Administration; a delegate of the Israeli Ministry of Health to the European SAB of Infect-Era; a director of Biocancell Ltd.; and a SAB member of Integra Holdings Ltd. |
| Yosef Yarden, Ph.D. | Professor Yarden is the head of the Signal Transduction and Growth Factors Laboratory of the Weizmann Institute of Science. He is a member of the Israel Academy of Sciences and Humanities and Past President of the Federation of the Israel Societies of Experimental Biology (FISEB). Among his many awards, in the last four years he received the Susan G. Komen for the Cure® Brinker Award for Scientific Distinction in Basic Research, and the Ernst W. Bertner Memorial Award of the MD Anderson Cancer Center. |

**Manufacturing**

Our laboratories, which are located in our headquarters in Jerusalem, Israel, are compliant with both current good manufacturing practices, or cGMP, and Good Laboratory Practices, or GLP, and allow us to manufacture drug products for our current clinical trials. The suppliers of the drug substances used for our current clinical trials have the necessary approvals as well. See "— Property, Plant and Equipment." If we decide to perform any phase 3 clinical trial with respect to, or commercialize, any therapeutic candidate on our own, we anticipate that we will rely on third parties to produce the therapeutic supplies. We have limited personnel with experience in drug or medical device manufacturing and we lack the resources and capabilities to manufacture any of our therapeutic candidates on a commercial scale.

Under our out-licensing agreement with Bellerophon with regard to BL-1040, we have the option to manufacture at least 20% of BL-1040 products pursuant to the terms of a supply agreement to be negotiated in good faith with Bellerophon. See "— Out-Licensing Agreement with Bellerophon." There can be no assurance that our therapeutic candidates, if approved, can be manufactured in sufficient commercial quantities, in compliance with regulatory requirements and at an acceptable cost. Under our collaboration agreement with Panmed and Genoscience with regard to BL-8020, we have agreed to supply, at the licensors' request, the drug needed for a clinical trial to be administered by the licensors, subject to the parties agreeing to commercially reasonable supply terms. We and our contract manufacturers are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products or medical devices. We and our contract manufacturers must ensure that all of the processes, methods and equipment are compliant with cGMP, for drugs or QSR for devices on an ongoing basis, mandated by the FDA and other regulatory authorities, and conduct extensive audits of vendors, contract laboratories and suppliers.

**Contract Research Organizations**

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

**Competition**

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

***BL-1040***

There are no generally accepted products approved for structural support to prevent cardiac remodeling following an AMI. One group of product candidates that are currently in clinical development includes stem cell therapies to restore heart muscle cells following an AMI, with large Phase 3 trials expected to be completed in 2018 or 2019. We do not expect BL-1040 to compete with, or replace, current treatments for congestive heart failure following AMI, but instead believe it will become part of the treatment regimen used in conjunction with other therapies. In addition, because BL-1040 can be delivered by a minimally invasive percutaneous coronary intervention procedure, we do not believe it will directly compete with devices that are used to treat congestive heart failure, which are designed for administration during open heart surgery or by intra-cardiac injection involving a thoracotomy procedure. These include mesh restraining devices, for example HeartNet™; injectable biopolymers, for example Algisyl LVR™; and implantable electro stimulation devices, for example, CardioFit™. In addition, volume reduction surgery or cardiac assist devices, or pumps, are sometimes used to treat patients with congestive heart failure.

***BL-8040***

If approved, BL-8040 will compete with currently approved treatments for AML that include chemotherapy (Doxorubicin, Cyclophosphamide, Vincristine), radiation therapy and stem cell transplantation. In addition there are a number of potentially competitive compounds under development that act as CXCR4 inhibitors, including, among others, AMD 3100 (Mozobil), which is being developed by Genzyme and Sanofi; LY-2510924, which is being developed by Lilly; Ulocuplumab (MDX-1338; BMS-936564) developed by Medarex and Bristol Myaers Squibb; F-50067 developed by Pierre Fabre; burixafor developed by TaiGen Biotechnology Co; and POL-6326 developed by Polyphor Ltd; PTX-9908 developed by Chemokine Therapeutics Corp. In addition there are a number of potentially competitive compounds under development to treat AML including, among others, Dacogen (decitabine), which is being developed by Eisai and Johnson & Johnson; Vidaza (azacitidine), which is being developed by Celgene; Vosaroxin, which is being developed by Sunesis Pharmaceuticals; Midostaurin, which is being developed by Novartis; Quizartinib, which is being developed by Ambit; Volasertib, which is being developed by Boehringer Ingelheim; fludarabine, which is being developed by Sanofi; nintedanib and BI-836858, both of which are under development by Boehringer Ingelheim; dasatinib (Sprycel) developed under BMS; RG-6016 under development by Roche; OCV-501, under development by Otsuka Pharmaceutical; ibrutinib developed by Pharmacyclics, under license from Celera, and in collaboration with Janssen Biotech; CPI-613 developed by Cornerstone Pharmaceuticals; F-14512 developed by Pierre Fabre; SL-401 developed by Stemline Therapeutics; pacritinib developed by CTI BioPharma Corp; sonidegib developed by Novartis; venetoclax developed by AbbVie; lirilumab developed by Innate Pharma in collaboration with BMS; selinexor developed by Karyopharm Therapeutics; Ganetespib developed by Synta Pharmaceuticals; crenolanib, which is being developed by Arog Pharmaceuticals, under license from Pfizer; BVD-ERK developed by BioMed Valley Discoveries; tosedostat developed by CTI BioPharma; pidilizumab developed by Medivation, under license from CureTech; sorafenib (Nexavar) developed by Bayer; Bortezomib developed by Janssen and Takeda; Uprosertib developed by GSK; PLX-3397 developed by Plexxikon Inc.; Lenalidomide developed by Celgene; erlotinib developed by Roche Astellas and Chugai; Trametinib developed by GSK; Vorinostat developed by Merck and Co.; Selumetinib developed by Astra Zeneca; SGI-110 developed by Astex Pharmaceuticals;; OCV-501 developed by Otsuka Pharmaceuticals; Birinapant developed by Tetralogic Pharmaceuticals; Alvocidib developed by Tolero Pharmaceuticals Inc; Pracinostat developed by MEI Pharma; Rigosertib developed by Onconova Therapeutics , Baxter International and Symbio; Sapacitabine developed by Cyclacel Pharmaceuticals; and RP-323 under development by Rich Pharmaceuticals. Some of these treatments are currently developed for specific AML patient populations and lines of treatment (e.g., AC220 developed by Ambit Biosciences) and not for the entire AML population. Some of these treatments can be developed for administration to AML patients in combination with BL-8040.

***BL-7010***

If approved, BL-7010 will compete with other products for treatment of celiac disease that are currently undergoing development such as larazotide acetate (Alba Therapeutic Corp.), which inhibits the activity of Zonulin; latiglutenase (Alvine Pharmaceuticals Inc.), which is a combination of gluten targeting proteases and endopeptidases. Celiac patients are prescribed a gluten-free diet to relieve their disease symptoms. Nevertheless the symptoms persist in most cases despite the patient's following a gluten-free diet. BL-7010, as well as the treatments specified above, is envisioned to be prescribed to patients who are on a gluten-free diet but still suffer from disease symptoms.

***BL-5010***

If approved, BL-5010 will compete with a variety of approved destructive and non-destructive treatments for skin lesions. Surgery is currently the most common approved non-destructive treatment for skin lesions but is invasive and painful, and generally results in cosmetically undesirable outcomes. Destructive treatments are associated with pain. Destructive treatments include cryotherapy, laser therapy, electrodessication, curettage and several cream-based treatments. Picato (Leo Pharma) and Metvix® (Galderma Pharma) are cream-based treatments for skin lesions which have been approved in many countries.

***BL-7040***

If approved, BL-7040 will compete with currently marketed steroids, immunomodulators and immunomodulatory antibodies. Approved treatments for IBD currently include anti-TNFs, such as Remicade (infliximab, Janssen Biotech, Inc., a Johnson & Johnson company, Merck & Co. and Mitsubishi Tanabe Pharma), Humira (adalimumab, Abbott Laboratories and Eisai Co.), Cimzia (certolizumab, UCB, Inc.) and Simponi (golimumab, Janssen Biotech, Inc., Merck & Co. and Mitsubishi Tanabe Pharma), as well as antibodies inhibiting immune cell migration such as Tysabri (natalizumab, Biogen and Elan) and Vedolizumab (Takeda). In addition, there are generic brands of mesalazine, a 5-aminosalicylate, and the recently launched Budesonide MMX (Cosmo Pharmaceuticals, Ferring Pharmaceuticals and Santarus). The first biosimilar version of infliximab was approved for use in Europe in 2013. We are also aware of a number of potentially competitive compounds under development, including Xeljanz (tofacitinib, Pfizer Inc.), a Jak 1 inhibitor; Vedolizumab (Takeda, Millenium Pharmaceuticals), a MAdCAM inhibitor /integrin alpha-4/beta-7 antagonist; Ustekinomab (Johnson & Johnson), an anti-IL-12/IL23 mAb; JM-300 (Ajinomoto), an Integrin alpha-4/beta-7 antagonist; Etrolizumab a beta 7 targeting mAb developed by Roche; LP-02 developed by Lipid Therapeutics; and DIMS-0150 (Kappaproct) a TLR9-targeting oligo developed by InDex Pharmaceuticals.

***BL-8020***

HCV treatment consists of either a combination of interferon and ribavirin alone or together with a combination of direct anti-viral agents (DAAs) of several classes including NS3/4 protease inhibitors, NS5A inhibitors and NS5B inhibitors. Recently, treatment regimens that do not include interferon have been approved, and treatment regimens without ribavirin are at advanced stages of development. Approved anti-HCV treatments include Sovaldi (sofosbuvir) and Harvoni (a fixed combination of sofosbuvir and ledipasvir), both developed by Gilead Sciences; Viekira Pak (a fixed combination of paritaprevir/r + ombitasvir + dasabuvir ) developed by AbbVie; Olysio (simeprevir, Janssen Therapeutics and Medivir); Victrelis (boceprevir, Merck and Co); vaniprevir (developed by Merck and Co ); Incivek (telaprevir, Janssen Pharmaceuticals and Vertex Pharmaceuticals); asunaprevir and daclatasvir (developed by Bristol Myers Squibb); Compounds under development include: elbasvir (Merck and Co.) and ACH-3102 (developed by Achillion). BL-8020's mechanism of action suggests that it could potentially be suitable for treatment of other viral infections, each of which has numerous competing treatments approved or in advanced stages of development.

**Insurance**

We maintain insurance for our offices and laboratory in Israel. This insurance covers approximately $5.8 million of equipment, consumables and lease improvements against risk of fire, lightning, natural perils and burglary (the latter coverage limited to $250,000), and $1.5 million of consequential damages (covering fixed damages and extra expenses). For our clinical trial activities, we carry life science liability insurance covering general liability with a coverage amount of $10.0 million per occurrence, product liability with an annual coverage amount of $10.0 million in the aggregate, and clinical trial insurance with a coverage amount of $20.0 million in the aggregate. The maximum indemnity for a single occurrence, claim or circumstances under this insurance is $10.0 million. In addition to this policy, we carry excess liability insurance with a coverage amount of $10.0 million which increases the coverage limit provided by our life science insurance package. In addition, we maintain the following insurance: employer's liability with coverage of approximately $10.0 million for each occurrence and in the aggregate; third party liability with coverage of approximately $5.0 million for each occurrence and in the aggregate; all risk coverage of approximately $2.0 million for electronic and mechanical equipment; and directors' and officers' liability with coverage of $20.0 million for each occurrence and in the aggregate.

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

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

**Environmental Matters**

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

**Government Regulation and Funding**

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

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

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

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

Summaries of the United States, EU and Israeli regulatory processes follow below.

**United States**

In the United States, drugs are subject to rigorous regulation by the FDA. The U.S. Federal Food, Drug and Cosmetic Act, or FDCA, and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, record-keeping, packaging, labeling, adverse event reporting, advertising, promotion, marketing, distribution and import and export of pharmaceutical products. Failure to comply with applicable regulatory requirements may subject us to a variety of administrative or judicially imposed sanctions and/or prevent us from obtaining or maintaining required approvals or to market drugs. Failure to comply with the applicable U.S. requirements may subject us to stringent administrative or judicial sanctions, such as agency refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions or criminal prosecution.

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

- preclinical laboratory tests, animal studies and formulation studies;
- submission to the FDA of a request for an investigational new drug, or IND, to conduct human clinical testing;
- adequate and well controlled clinical trials to determine the safety and efficacy of the drug for each indication;
- submission to the FDA of an NDA;

- a potential public hearing of an outside advisory committee to discuss the application;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is manufactured; and
- FDA review and approval of the NDA.

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

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

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

***Clinical Trials***

Clinical trials involve the administration of the investigational drug to people under the supervision of qualified investigators in accordance with the principles of good clinical practice, or GCP. We conduct clinical trials under protocols detailing the trial objectives, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. We must submit each U.S. study protocol to the FDA as part of the IND. Foreign clinical trials may or may not be conducted under an IND. However, their safety assessments are included in the IND annual reports.

We conduct clinical trials typically in three sequential phases, but the phases may overlap or be combined. An institutional review board, or IRB, must review and approve each trial before it can begin. Phase 1 includes the initial administration of a tested drug to a small number of humans. These trials are closely monitored and may be conducted in patients, but are usually conducted in healthy volunteer subjects. These trials are designed to determine the metabolic and pharmacologic actions of the drug in humans and the side effects associated with increasing doses as well as, if possible, to gain early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to evaluate dosage tolerance and appropriate dosage, identify possible adverse effects and safety risks and preliminarily evaluate the efficacy of the drug for specific indications. Phase 3 trials are large trials used to further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. There can be no assurance that we or our licensees will successfully complete phase 1, phase 2 or phase 3 testing with respect to any therapeutic candidate within any specified period of time, if at all. Furthermore, clinical trials may be suspended at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. We and our licensees perform preclinical and clinical testing outside of the United States. The acceptability of the results of our preclinical and clinical testing by the FDA will be dependent upon adherence to applicable U.S. and foreign standards and requirements, including good laboratory practices, or GLP, GCP and the Declaration of Helsinki for protection of human subjects. Additionally, the FDA may require at least one pivotal clinical study to be conducted in the United States, in order to take into account medical practice and ethnic diversity in the United States.

***NDAs and BLAs***

After successful completion of the required clinical testing, an NDA, or in the case of certain biological products a Biological Product Application, or BLA, is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before product marketing may begin in the United States. The NDA/BLA must include the preclinical and clinical testing results and a compilation of detailed information relating to the product's pharmacology, toxicology, chemistry, manufacture and manufacturing controls. In certain cases, an application for marketing approval may include information regarding the safety and efficacy of a proposed drug that comes from trials not conducted by, or for, the applicant and for which trials the applicant has not obtained a specific right to reference. Such an application, known as a 505(b)(2) NDA, is permitted for new drug products that incorporate previously approved active ingredients, even if the proposed new drug incorporates an approved active ingredient in a novel formulation or for a new indication. Although 505(b)(2) is a type of NDA, it has been used in the US to obtain approval of follow-on biologics (also termed biosimilars) where limited clinical data is necessary to show that the follow-on is the same as the reference product. However, 505(b)(2) can be used to seek approval for a biologic only until March 23, 2020, and only for follow-on biologics of a class for which a product has already been approved under 505(b)(2). In this way, several natural source products and recombinant proteins have been approved as generic drugs under Section 505(b)(2) of the FDCA. As interpreted by the FDA, Section 505(b)(2) also permits the FDA to rely for such approvals on literature or on a finding by the FDA of safety and/or efficacy for a previously approved drug product. Under this interpretation, a 505(b)(2) NDA for changes to a previously approved drug product may rely on the FDA's finding of safety and efficacy of the previously approved product coupled with new clinical data and information needed by the FDA to support the change. NDAs submitted under 505(b)(2) are potentially subject to patent and non-patent exclusivity provisions which can block effective approval of the 505(b)(2) application until the applicable exclusivities have expired, which in the case of patents may be several years. The cost of preparing and submitting an NDA may be substantial. Under U.S. federal law, the submission of NDAs, including 505(b)(2) NDAs, is generally subject to substantial application user fees, and the manufacturer and/or sponsor under an NDA approved by the FDA is also subject to annual product and establishment user fees. These fees are typically increased annually. Separate fees are payable for an Abbreviated New Drug Application, or ANDA, and for Biosimilar Biological Product Development, or BPD.

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

Before approving an application, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve the application unless the FDA determines that the product is manufactured in substantial compliance with GMPs. If the FDA determines that the NDA or BLA is supported by adequate data and information, the FDA may issue an approval letter, or, in some cases, when the FDA desires some additional data or information an approvable letter. An approvable letter generally contains a statement of specific conditions that must be met to secure final approval of the application. Upon compliance with the conditions stated in the approvable letter, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of approval, the FDA may require additional trials or post-approval testing and surveillance to monitor the drug's safety or efficacy, the adoption of risk evaluation and mitigation strategies, and may impose other conditions, including labeling and marketing restrictions on the use of the drug, which can materially affect its potential market and profitability. Once granted, product approvals may be withdrawn if compliance with regulatory standards for manufacturing and quality control are not maintained or if additional safety problems are identified following initial marketing.

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

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

***Post-Marketing Requirements***

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

***Generic Competition***

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

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

The BPCIA provides the manufacturer of the innovator product with economic protection by granting a period of "exclusivity" during which follow-on products may not be approved. A BLA for approval of a follow-on biological product may not be submitted for 4 years after the reference product was initially approved. The FDA may not approve a BLA for a follow-on biological product until 12 years after the reference product was first licensed. No additional period of exclusivity will be granted to a previously licensed biologic product when subsequent applications are made for a new indication, route of administration, dosage form, or dosing strength. However, each of the periods of exclusivity may be extended by 6 months if studies of the innovator biological product in the pediatric population are requested by the U.S. Secretary of Health and Human Services and carried out.

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

ANDA applicants do not have to conduct extensive clinical trials to prove the safety or efficacy of the drug product. Rather, they are required to show that their drug is pharmaceutically equivalent to the innovator's drug and also conduct "bioequivalence" testing to show that the rate and extent by which the ANDA applicant's drug is absorbed does not differ significantly from the innovator product. Bioequivalence tests are typically in vivo studies in humans but they are smaller and less costly than the types of phase 3 trials required to obtain initial approval of a new drug. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, are listed as such by the FDA, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

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

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

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

***FDA Approval or Clearance of Medical Devices***

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

- Class I: general controls, such as labeling and adherence to Quality System Regulations, or QSRs;

- Class II: general controls, pre-market notification (510(k)), and specific controls such as performance standards, patient registries, and postmarket surveillance; and

- Class III: general controls and approval of a PMA.

A PMA application must provide a demonstration of safety and effectiveness, which generally requires extensive preclinical and clinical trial data. Information about the device and its components, device design, manufacturing and labeling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with QSR requirements, which govern testing, control, documentation and other aspects of quality assurance with respect to manufacturing. During the review period, an FDA advisory committee, typically a panel of clinicians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. The FDA is not bound by the advisory panel decision, but the FDA often follows the panel's recommendation. If the FDA finds the information satisfactory, it will approve the PMA. The PMA can include post-approval conditions including, among other things, restrictions on labeling, promotion, sale and distribution, or requirements to do additional clinical studies post-approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorize certain modifications to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA. During the review of a PMA, the FDA may request more information or additional studies and may decide that the indications for which we seek approval or clearance should be limited.

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

**European Economic Area**

A medicinal product may only be placed on the market in the European Economic Area, or EEA, composed of the 28 EU member states, plus Norway, Iceland and Lichtenstein, when a marketing authorization has been issued by the competent authority of a member state pursuant to Directive 2001/83/EC, as amended, or an authorization has been granted under the centralized procedure in accordance with Regulation (EC) No. 726/2004 or its predecessor, Regulation 2309/93. There are essentially three EU procedures created under prevailing European pharmaceutical legislation that, if successfully completed, allow an applicant to place a medicinal product on the market in the EEA.

***Centralized Procedure***

Regulation 726/2004/EC now governs the centralized procedure when a marketing authorization is granted by the European Commission, acting in its capacity as the European Licensing Authority on the advice of the European Medicines Agency, or EMA. That authorization is valid throughout the entire EEA and directly or (as to Norway, Iceland and Liechtenstein) indirectly allows the applicant to place the product on the market in all member states of the EEA. The EMA is the administrative body responsible for coordinating the existing scientific resources available in the member states for evaluation, supervision and pharmacovigilance of medicinal products. Certain medicinal products, as described in the Annex to Regulation 726/2004, must be authorized centrally. These are products that are developed by means of a biotechnological process in accordance with Paragraph 1 to the Annex to the Regulation or veterinary products designed to promote animal growth or increase yield in accordance with Paragraph 2. The mandatory centralized procedure is applicable to: (a) medicinal products for human use containing an active substance authorized in the EU after May 20, 2004 for which the therapeutic indication is the treatment of acquired immune deficiency syndrome, or AIDS, cancer, neurodegenerative disorder or diabetes;. (b) autoimmune diseases and other immune dysfunctions and viral diseases; all medicinal products that are designated as orphan medicinal products pursuant to Regulation 141/2000; and (c) advanced therapy medicinal products, such as gene therapy, tissue engineered and somatic cell therapy products. An applicant may also opt for assessment through the centralized procedure if it can show that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization centrally is in the interests of patients at the EU level. For each application submitted to the EMA for scientific assessment, the EMA is required to ensure that the opinion of the Committee for Medicinal Products for Human Use, or CHMP, is given within 210 days after receipt of a valid application or within 150 days by means of an accelerated procedure. If the opinion is positive, the EMA is required to send the opinion to the European Commission, which is responsible for preparing the decision granting a marketing authorization, within 67 days. If the initial opinion of the CHMP is negative, the applicant is afforded an opportunity to seek a re-examination of the opinion. The CHMP is required to re-examine its opinion within 60 days following receipt of the request by the applicant. A refusal of a centralized marketing authorization constitutes a prohibition on placing the given medicinal product on the market in the EU.

*Mutual Recognition and Decentralized Procedures.* With the exception of products that are authorized centrally, the competent authorities of the member states are responsible for granting marketing authorizations for medicinal products placed on their markets. If the applicant for a marketing authorization intends to market the same medicinal product in more than one member state, the applicant may seek an authorization progressively in the EU under the mutual recognition or decentralized procedure. Mutual recognition is used if the medicinal product has already been authorized in a member state. In this case, the holder of this marketing authorization requests the member state where the authorization has been granted to act as reference member state by preparing an updated assessment report that is then used to facilitate mutual recognition of the existing authorization in the other member states in which approval is sought (the so-called concerned member state(s)) in accordance with Article 28 of Directive 2001/83/EC. The reference member state must prepare an updated assessment report within 90 days of receipt of a valid application. This report together with the approved Summary of Product Characteristics, or SmPC (which sets out the conditions of use of the product), and a labeling and package leaflet are sent to the concerned member states for their consideration. The concerned member states are required to approve the assessment report, the SmPC and the labeling and package leaflet within 90 days of receipt of these documents. The total procedural time is 180 days.

The decentralized procedure is used in cases where the medicinal product has not received a marketing authorization in the EU at the time of application. The applicant requests a member state of its choice to act as reference member state to prepare an assessment report that is then used to facilitate agreement with the concerned member states and the grant of a national marketing authorization in all of these member states. In this procedure, the reference member state must prepare, for consideration by the concerned member states, the draft assessment report, a draft SmPC and a draft of the labeling and package leaflet within 120 days after receipt of a valid application. As in the case of mutual recognition, the concerned member states are required to approve these documents within 90 days of their receipt. In both procedures, national marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

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

Irrespective of whether the medicinal product is assessed centrally, de-centrally or through a process of mutual recognition, the medicinal product must be manufactured in accordance with the principles of good manufacturing practice as set out in Directive 2003/94/EC for medicines and investigational medicines for human use or Directive 91/412/EEC for medicines for veterinary use and Volume 4 of the "Rules Governing Medicinal Products in the European Community" and distributed in accordance with Directive 92/25/EEC and current guidance. Moreover, EU law requires the clinical results in support of clinical safety and efficacy to be based upon clinical trials conducted in the EU in compliance with the requirements of Directives 2001/20/EC and and 2005/28/EC, which implement good clinical practice in the conduct of clinical trials on medicinal products for human use. Clinical trials conducted outside the EU and used to support applications for marketing within the EU must have been conducted in a way consistent with the principles set out in Directive 2001/20/EC. The conduct of a clinical trial in the EU requires, pursuant to Directive 2001/20/EC, authorization by the relevant national competent authority where a trial takes place, and an ethics committee to have issued a favorable opinion in relation to the arrangements for the trial. It also requires that the sponsor of the trial, or a person authorized to act on his behalf in relation to the trial, be established in the EU.

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

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

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

***Cross-referral to Innovator's Data***

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

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

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

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

***Well-established Medicinal Use***

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

***Informed Consent***

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

***Law Relating to Pediatric Research***

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

In June 2013, the European Commission published a **report on the first five years of implementation of the Regulation.** The report concludes that pediatric development has become a more integral part of the overall development of medicinal products in the EU, with the Regulation working as a major catalyst to improve the situation for young patients

***Post-authorization Obligations***

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

***Approval of Medical Devices***

In the EEA there is a consolidated system for the authorization of medical devices as provided for in three core directive: the Medical Device Directive 93/42/EEC as amended by Directive 93/68/EEC on CE marking, Directive 90/385/EEC regarding active implantable medical devices and Directive 98/79/EC regarding in vitro diagnostic medical devices. The European Union requires that manufacturers of medical devices obtain the right to affix the CE mark to their products, which shows that the device has a Declaration of Conformity, before selling them in European Union member countries. The CE mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain the right to affix the CE mark to products, a manufacturer must obtain certification that its processes meet certain European quality standards, which vary according to the nature of the device. Compliance with the Medical Device Directive, as certified by a recognized European Notified Body, permits the manufacturer to affix the CE mark on its products and commercially distribute those products throughout the European Union without further conformance tests being required in other member states.

In September 2012, the European Commission adopted a Proposal for a Regulation of the European Parliament and of the Council on medical devices and a Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices which will, once adopted by the European Parliament and by the Council, replace the existing three medical devices directives.

**Israel**

***Israel Ministry of the Environment — Toxin Permit***

In accordance with the Israeli Dangerous Substances Law - 1993, the Ministry of the Environment is required to grant a permit in order to use toxic materials. Because we utilize toxic materials in the course of operation of our laboratories, we were required to apply for a permit to use these materials. Our current toxin permit will remain in effect until January 2018.

***Clinical Testing in Israel***

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

**Other Countries**

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

**Related Matters**

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

**Israeli Government Programs**

***Israel Office of the Chief Scientist***

*Research and Development Grants*. A number of our therapeutic products have been financed, in part, through funding from the OCS in accordance with the Israeli Law for the Encouragement of Industrial Research and Development, 1984 and related regulations, or the Research Law. Through December 31, 2014 we have received approximately NIS 76.1 million ($19.6 million) in aggregate funding from the OCS, of which approximately NIS 53.7 million ($13.8 million) was funding provided to our biotechnology incubator, which we undertook to repay from proceeds received from the sale of products developed under the incubator project. Under the terms of the biotechnology incubator, we have recorded a first-degree floating lien on all assets of the incubator against the repayment of funding received by the incubator for the projects developed under it. As previously described, we terminated the incubator at the end of 2013, and recorded the projects as having been terminated for repayment purposes. Through December 31, 2014, we have paid the OCS approximately NIS 24.3 million ($6.2 million) in royalties under our approved programs. As of December 31, 2014, we have a contingent obligation to the OCS (other than for BL-8040 – see below) in the total amount of NIS 13.2 million ($3.4 million) under all of our approved programs, of which NIS 12.5 million ($3.2 million) are attributed to projects recorded by the Company as terminated for repayment purposes (as a result of the actual termination of the license agreements with the relevant licensors) but which still require a formal termination process with the OCS. In connection with the in-licensing of BL-8040 from Biokine, and as a condition to OCS consent to the transaction, we agreed to abide by any obligations resulting from funds previously received by Biokine from the OCS. The contingent liability to the OCS assumed by us relating to this transaction amounts to NIS 10.6 million ($2.7 million) as of December 31, 2014. We have a full right of offset for amounts payable to the OCS from payments that we may owe to Biokine in the future. Therefore, the likelihood of any payment obligation to the OCS with regard to the Biokine transaction is remote. Under the Research Law and the terms of the grants, royalties on the revenues derived from sales of products developed with the support of the OCS are payable to the Israeli government, generally at the rate of 3% during the first three years of repayment, 4% during the subsequent three years and 5% from the seventh year onwards, although these terms would be different if we were to receive OCS approval to manufacture or to transfer the rights to manufacture our products developed with OCS grants outside of Israel. The obligation to make these payments terminates upon repayment of the amount of the received grants as adjusted for fluctuation in the U.S. dollar/shekel exchange rate, plus interest and any additional amounts as described below. However, we may be required to pay an increased total amount of royalties (possibly up to 300% of the grant amounts plus interest) if we receive approval to manufacture or to transfer the rights to manufacture our products developed with OCS grants outside of Israel, depending on the portion of total manufacturing that is performed outside of Israel, as further described below, and we may be required to pay additional amounts in respect of the technology developed under these projects that is otherwise transferred outside of Israel, as further described below. The amounts received bear interest equal to the 12-month London Interbank Offered Rate applicable to dollar deposits that is published on the first business day of each calendar year.

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

Under the Research Law, we are prohibited from transferring our OCS-financed technologies, technologies derived therefrom and related intellectual property rights outside of Israel except under limited circumstances and only with the approval of the OCS and upon making a payment to the OCS. We may not receive the required approvals for any proposed transfer and, if received, we may be required to pay the OCS an amount calculated in accordance with the applicable formula set out in the Research Law. The scope of the support received, the royalties that we may have already paid to the OCS, the amount of time that has elapsed between the date on which the technology was transferred and the date on which the OCS grants were received and the sale price and the form of transaction will be taken into account in order to calculate the amount of the payment to the OCS. The repayment amount is now subject to a maximum limit calculated in accordance with a formula set forth in regulations enacted during 2012. In addition, any decrease in the percentage of manufacture performed in Israel of any product or technology, as originally declared in the application to the OCS with respect to the product or technology, may require us to notify, or to obtain the approval of, the OCS, and may result in increased royalty payments to the OCS of up to 300% of the total grant amounts received in connection with the product or technology, plus interest, depending on the portion of total manufacturing that is performed outside of Israel.

Approval of the transfer of technology to residents of Israel is required, and may be granted in specific circumstances, only if the recipient agrees to abide by the provisions of applicable laws, including the restrictions on the transfer of know-how and the obligation to pay royalties. No assurances can be made that approval to any such transfer, if requested, will be granted.

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

*Biotechnology Incubator Program*. In 2001, the OCS launched a biotechnology incubator program for advancing Israel's biotechnology industry. In 2004, we submitted a proposal to operate a biotechnology incubator, and our proposal was accepted by the OCS. Accordingly, we entered into the incubator agreement with the OCS in January 2005. We operated the incubator until the incubator agreement expired in December 2013. In light of the expiry of the incubator agreement and in order to streamline our operations, we decided to transfer all the employees, activities and assets from the incubator to BioLineRx Ltd., and have wound down the incubator.

As of December 31, 2014, we received approximately $13.8 million from the OCS under the incubator agreement to fund 23 different development projects, 22 of which have terminated. Of our 10 current development projects, BL-1040 is the only project that has been funded under the incubator agreement.

***Israel Ministry of Health***

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

**C. Organizational Structure**

Our corporate structure consists of BioLineRx Ltd. and two wholly-owned entities: BioLine Innovations Jerusalem Ltd., or BIJ Ltd., and BioLineRx USA Inc. BIJ Ltd. was the general partner of BioLine Innovations Jerusalem Limited Partnership, or BIJ L.P., which was established as the entity to operate our incubator. BIJ Ltd. owned 1% of BIJ L.P.'s partnership interests, while BioLineRx was a limited partner of BIJ L.P. and owned the remaining 99% of BIJ L.P.'s partnership interests. Our incubator agreement with the OCS expired at the end of 2013. As a result, we decided to transfer all the employees, activities and assets from the incubator to BioLineRx Ltd., wound down the incubator, liquidated BIJ L.P. in December 2014 and are in the process of liquidating BIJ Ltd. BioLineRx USA Inc. has been inactive since the beginning of 2011, as a result of a decision by our Board of Directors to transfer all business development functions back to Israel, in order to reorganize our business development efforts and administer such efforts from our headquarters.

**D. Property, Plant and Equipment**

We are headquartered in Jerusalem, Israel. We are currently leasing one facility pursuant to a lease agreement with Kaps-Pharma Ltd. on a month-to-month basis with the expectation of moving to a new facility in the second quarter of 2015. The Jerusalem headquarters consists of approximately 1,700 square meters of space and lease payments are approximately $29,300 per month. This facility houses both our administrative and research operations and our central laboratory. The central laboratory consists of approximately 600 square meters and includes an analytical chemistry laboratory, a formulation laboratory and a tissue culture laboratory. Our central laboratory is compliant with both cGMP and GLP, which allows us to manufacture therapeutic supplies for our current clinical trials. We have outfitted a section of the central laboratory as a Class 1000 Clean Room for the synthesis of compounds that require a clean environment for development. All of our employees are based in this facility.

In August 2014, we signed a lease agreement with S.M.L. Solomon Industrial Buildings Ltd. and Infrastructure Management and Development Established by C.P.M. Ltd. for the lease of a facility in Modi'in, Israel (located between Tel Aviv and Jerusalem). This facility, to which we plan on moving all our operations and central laboratory in the second quarter of 2015, will consist of 1,663 square meters of space (approximately 17,900 square feet). Lease payments will be approximately $27,000 per month.

**ITEM 4A. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

*You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this annual report. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this annual report, particularly those in "Item 3. Key Information — Risk Factors."U.S. dollar amounts herein (other than amounts that were originally receivable or payable in dollars) have been translated for the convenience of the reader from the original NIS amounts at the representative rate of exchange as of December 31, 2014 ($1 = NIS 3.889). The dollar amounts presented should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated.*

We are a clinical stage biopharmaceutical development company dedicated to identifying, in-licensing and developing therapeutic candidates that have advantages over currently available therapies or address unmet medical needs. Our current development pipeline consists of six clinical therapeutic candidates: BL-1040, BL-8040, BL-7010, BL-5010, BL-7040 and BL-8020. In addition, we have four therapeutic candidates in pre-clinical development. We generate our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. Until December 31, 2013, we also operated, with substantial financial support of the OCS, a biotechnology incubator to evaluate therapeutic candidates. As of December 31, 2014, we received approximately NIS 53.7 million ($13.8) million in funding from the OCS to operate the incubator, and an additional NIS 22.4 million ($5.8 million) in funding outside of the incubator agreement. Such amounts include aggregate funding of approximately NIS 65.6 million ($16.9 million) for terminated programs. We are not required to repay funds received for terminated programs. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case by case basis, the commercialization of our therapeutic candidates independently.

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

- BL-1040 is a novel, resorbable polymer solution for use in the prevention of ventricular remodeling that may occur in patients who have suffered an acute myocardial infarction, or AMI. BL-1040 is being developed as a medical device. In March 2010, we announced encouraging results from a phase 1/2 clinical trial. We have entered into an exclusive, worldwide, royalty-bearing out-licensing arrangement with Bellerophon with respect to the development, manufacture and commercialization of BL-1040. In December 2011, Bellerophon commenced PRESERVATION I, a CE Mark registration clinical trial of BL-1040 (initially called IK-5001, and now called "Bioabsorbable Cardiac Matrix" device, or BCM device). Enrollment for this trial was completed in December 2014, with 303 AMI patients having been recruited and treated. There are almost 90 sites activated worldwide for this trial, 16 of which are in the United States. The study, which includes a six-month follow-up period, is anticipated to be completed in mid-2015.

- BL-8040 is a novel, short peptide that functions as a high-affinity antagonist for CXCR4, which we intend to develop for acute myeloid leukemia, or AML, stem cell mobilization and other hematological indications.

Ø In June 2013, we commenced a phase 2 trial for the treatment of AML, which is currently being conducted at four world-leading cancer research centers in the U.S. and at five premier sites in Israel. The trial is currently in the midst of the dose-escalation stage and when this stage is completed, will continue to the expansion stage at the optimal dose chosen during the dose escalation stage. In November 2014, we announced that in light of continued encouraging pharmacodynamic and excellent safety data from the ongoing Phase 2 clinical trial in AML, we filed with the FDA an amendment to the study protocol to test additional cohorts at higher doses in the current dose-escalation stage of the trial. The amendment also includes an increase in the total expected study enrollment, from up to 50 under the original protocol, to up to 70 patients.

Ø In September 2014, we commenced a Phase 1 trial for the use of BL-8040 as a treatment for stem cell mobilization at Hadassah Medical Center in Jerusalem. All healthy volunteers have completed the treatment phase and results are expected during the first quarter of 2015.

Ø In addition, we are planning to commence the following trials for BL-8040 in the first half of 2015: (a) a Phase 2b trial in Germany, in collaboration with the German Study Alliance Leukemia Group, as a consolidation treatment for AML patients who have responded to standard induction treatment; (b) a Phase 1/2 trial, in collaboration with the MD Anderson Cancer Center, for the treatment of AML patients with the FLT3-ITD mutation; and (c) a Phase 1/2 trial, also in collaboration with the MD Anderson Cancer Center, for BL-8040 as a treatment for hypoplastic myelodysplastic syndrome and aplastic anemia.

Ø In September 2013, the U.S. Food & Drug Administration, or FDA, granted an Orphan Drug Designation to BL-8040 as a therapeutic for the treatment of AML; and in January 2014, the FDA granted an Orphan Drug Designation to BL-8040 as a treatment for stem cell mobilization.

- BL-7010 is a novel, non-absorbable, orally available, high-molecular-weight co-polymer intended for the treatment of celiac disease. In December 2013, we commenced a Phase 1/2 trial for BL-7010 at Tampere Hospital in Finland, a leading site for celiac research. In November 2014, we reported the final results of the study. BL-7010 was found to be safe and well tolerated in both single- and repeated-dose administrations. Based on these results, we selected the dosing regimen of one gram, three times per day, of BL-7010 as the optimal repeated dose for the upcoming efficacy study which we plan to commence in the second half of 2015.

- BL-5010 is a customized, proprietary pen-like applicator containing a novel, acidic, aqueous solution for the non-surgical removal of skin lesions. In December 2010, we announced positive results from a phase 1/2 clinical trial of BL-5010. We have received European confirmation from the British Standards Institution Notified Body in the UK of the regulatory pathway classification of both BL-5010 and BL-5010P as a Class 2a medical device. In December 2014, we entered into an exclusive out-licensing arrangement with Omega Pharma for the rights to BL-5010 for over-the-counter, or OTC, indications in the territory of Europe, Australia and additional selected countries.

- BL-7040 is an orally available synthetic oligonucleotide which we are developing for the treatment of inflammatory bowel disease, or IBD. In April 2013, we announced positive results from a phase 2a proof-of-concept study to evaluate the effectiveness of BL-7040 for the treatment of IBD at five sites in Israel. In November 2013, we announced additional results from this study showing significant improvement of disease measurements in biopsies taken from IBD patients treated with BL-7040. During the third quarter of 2014, we conducted a pharmacokinetic study which indicated that BL-7040 reaches the target organ (the colon) and appears to have a local, as opposed to systemic, effect. We are currently discussing this therapeutic candidate with a number of potential co-development partners, as well as planning the next stages of development.

- BL-8020 is an orally available treatment for the hepatitis C virus, or HCV, with a unique mechanism of action involving the inhibition of HCV-induced autophagy in host cells. In April 2013, we commenced a phase 1/2 clinical trial to evaluate the safety, tolerability and effectiveness of BL-8020 at two sites in France. In January 2014, we entered into a collaboration agreement whereby, among other things, the licensors agreed to take over the development of the drug and we agreed to supply, at the licensors' request, the drug needed for a clinical trial to be administered by the licensors.

In 2009, we entered into an exclusive, worldwide, royalty-bearing licensing arrangement with Bellerophon. Under the agreement, we granted Bellerophon an exclusive, worldwide license to develop, manufacture and commercialize BL-1040 for use in the prevention, mitigation and treatment of injuries to the myocardial tissue of the heart. Under the arrangement, Bellerophon is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or products related thereto. We received an upfront payment of $7.0 million upon the execution of the license agreement. Upon successful completion of the phase 1/2 clinical trial, Bellerophon paid us a milestone payment of $10.0 million in March 2010, and we are entitled to receive additional milestone and royalty payments upon the occurrence of certain events.

In June 2013, we signed an out-licensing agreement with CTTQ, the leading Chinese pharmaceutical company in the liver disease therapeutic area, for the development and commercialization of BL-8030, an orally available treatment for HCV. Under the terms of the agreement, we granted CTTQ exclusive rights to develop, manufacture and commercialize BL-8030 in China and Hong Kong. CTTQ paid us a small upfront license fee, and is obligated to pay future development, regulatory and commercialization milestones, for a total potential deal value of approximately $30 million. In addition, we have the right to receive high single-digit royalties on future sales of the drug. We have retained the right to develop and commercialize BL-8030 in other parts of the world.

In January 2014, we signed a collaboration agreement with JHL Biotech, or JHL, a biopharmaceutical company that develops, manufactures, and commercializes biologic medicines, pursuant to which we will collaborate with JHL in the development and commercialization of BL-9020, a novel monoclonal antibody in the preclinical development stage for the treatment of Type 1 diabetes. JHL Biotech will be responsible for all process development and manufacturing of BL-9020 during its pre-clinical and clinical development stages, and we will be responsible for all pre-clinical development of BL-9020. JHL will have global manufacturing rights to BL-9020, along with development and commercialization rights in China and Southeast Asia, and we will have development and commercialization rights in the rest of the world. In all development and manufacturing of BL-9020, JHL will adhere to FDA guidelines and regulations. Each party will have rights to all development and regulatory data generated under the agreement in order to commercialize BL-9020 in its respective territory. Each party will also be entitled to single-digit royalties on the sale of BL-9020 in the other party's respective territory.

In December 2014, we entered into a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates. Under the agreement, we intend, in collaboration with Novartis, to co-develop a number of pre-clinical and early clinical therapeutic projects through clinical proof-of-concept for potential future licensing by Novartis.

In December 2014, we entered into an exclusive out-licensing arrangement with Omega Pharma for the rights to BL-5010 for over-the-counter or OTC indications in the territory of Europe, Australia and additional selected countries. We will retain the rights to BL-5010 in the United States and the rest of the world. Under our out-licensing arrangement with Omega Pharma, Omega Pharma is obligated to use commercially reasonable best efforts to obtain regulatory approval in the licensed territory for at least two OTC indications and to commercialize BL-5010 for those two OTC indications. In addition, Omega Pharma will sponsor and manufacture BL-5010 in the relevant regions. Omega Pharma will pay us an agreed amount for each unit sold, and we will be entitled to certain commercial milestone payments. In addition, we will have full access to all clinical and research and development data generated during the performance of the development plan and may use these data in order to develop or license the product in other territories and fields of use where we retain the rights.

**History of Losses**

Since inception in 2003, we have generated significant losses in connection with our research and development, including the clinical development of BL-1020. As of December 31, 2014, we had an accumulated deficit of NIS 545.4 million. Although we have previously recognized revenues in connection with our out-licensing arrangement with Bellerophon for BL-1040 and our former out-licensing arrangement with Cypress Bioscience for BL-1020, we may continue to generate losses in connection with the research and development activities relating to our pipeline of therapeutic candidates. Such research and development activities are budgeted to expand over time and will require further resources if we are to be successful. As a result, we may continue to incur operating losses, which may be substantial over the next several years, and we may need to obtain additional funds to further pursue our research and development programs.

We have funded our operations primarily through the sale of equity securities (both in public and private offerings), funding received from the OCS, payments received under the licensing arrangements with Bellerophon and Cypress Bioscience, and interest earned on investments. We expect to continue to fund our operations over the next several years through our existing cash resources, potential future milestone payments that we expect to receive from Bellerophon, potential future upfront or milestone payments that we may receive from out-licensing transactions for our other therapeutic candidates, interest earned on our investments and additional capital to be raised through public or private equity offerings or debt financings. As of December 31, 2014, we held approximately $34.7 million of cash, cash equivalents and short-term bank deposits, based on the exchange rate reported by the Bank of Israel as of December 31, 2014. In March 2015, we completed an underwritten public offering for gross proceeds of approximately $28.8 million. See "– Liquidity and Capital Resources."

**Revenues**

Our revenues to date have been generated primarily from milestone payments under our licensing arrangement with Bellerophon and the amounts we received from Cypress Bioscience. We entered into a license and collaboration agreement with Bellerophon in 2009, in respect of which Bellerophon paid us an up-front payment of $7.0 million. In addition, upon successful completion of the phase 1/2 clinical trial, Bellerophon paid us a milestone payment of $10.0 million, which was subject to a 15% withholding tax in the United States. We received a full refund of the tax withheld from the U.S. Internal Revenue Service in the third quarter of 2011. In June 2010, we entered into a license agreement with Cypress Bioscience. Under the terms of the license agreement, we received an upfront fee of $30.0 million. The license agreement with Cypress Bioscience was terminated, effective as of May 31, 2011.

Under the terms of our agreement with Bellerophon, in addition to the payments mentioned above, the maximum future development-related payments to which we are entitled is $115.5 million. We are also entitled to maximum commercialization milestone payments of $150.0 million, subject to the terms and conditions of the license agreement. Certain payments we have received from Bellerophon have been subject to a 15% withholding tax in the United States, and certain payments we may receive in the future, if at all, may also be subject to a 15% withholding tax in the United States. Receipt of any milestone payment under the Bellerophon agreement depends on many factors, some of which are beyond our control. We cannot assure you that we will receive any of these future payments. We believe that we may be entitled to a refund of withholding taxes paid in connection with future payments from the U.S. government but there can be no assurance that we will be able to obtain such a refund. In addition, we may be able to use U.S. taxes withheld from future payments to us as credits against Israeli corporate income tax when we have income, if at all, but there can be no assurance that we will be able to realize the credits. Our payments to our in-licensors are to be made from the net consideration received from our out-licensees.

We expect our revenues for the next several years to be derived primarily from payments under our current out-licensing and other collaboration arrangements, including future royalties on product sales. Furthermore, we may receive payments under future out-licensing and collaboration agreements.

**Research and Development**

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

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

| Project | Status | Expected or Recent Near Term Milestone |
|---|---|---|
| BL-1040 | Patient enrollment completed for CE registration pivotal trial (conducted by Bellerophon) | PRESERVATION 1 study results expected in mid-2015 |
| BL-8040 | 1.Phase 2 study for AML<br>2.Phase 1 study in stem cell mobilization<br>3.Phase 2b consolidation treatment for AML<br>4.Phase 1/2 study for AML patients with FLT3-ITD mutation<br>5.Phase 1/2 study for hMDS and AA | 1.Completion of dose-escalation stage of study in H1 2015; full study results in H2 2015<br>2.Results of phase 1 study for stem cell mobilization by the end of Q1 2015<br>3.Commencement of study expected H1 2015<br>4.Commencement of study expected H1 2015<br>5.Commencement of study expected H1 2015 |
| BL-7010 | Completed Phase 1/2 study | Randomized, controlled efficacy study expected to commence in H2 2015 |
| BL-5010 | Out-licensed to Omega Pharma | Commercialization in Europe during 2016 |
| BL-7040 | Phase 2 trial completed | Potential co-development collaboration or licensing transaction |
| BL-8020 | Phase 1/2 study (collaboration with Licensors) | Determination by Licensors of the next steps in the clinical development plan of the compound, including an assessment regarding potential additional viral indications for development. |

In addition to the projects set forth above, we have four projects that are in the preclinical stages of development. Such projects have significantly lower costs due to their stage of development. See “Item 4. Information on the Company — Business Overview — Therapeutic Candidates in Preclinical Development.”

Prior to 2013, we recorded costs for each development project on a “direct cost” basis only. Direct costs, which include contract research organization expenses, consulting expenses, patent expenses, materials and other, similar expenses, were recorded to the project for which such expenses are incurred. However, salary and overhead costs, including, but not limited to, salary expenses (including salaries for research and development personnel), facilities, depreciation and stock-based compensation, were shared among all of our projects and were not recorded on a project-by-project basis. We did not allocate direct salaries to projects due to the fact that our project managers were generally involved in several projects at different stages of development, and the related salary expense was not significant to the overall cost of the applicable projects. In addition, indirect labor costs relating to our departments that support the research and development process, such as chemistry, manufacturing and controls (CMC), pre-clinical analysis, laboratory testing and initial drug sample production, as well as rent and other administrative overhead costs, were shared by many different projects and were never considered by management to be of significance in its decision-making process with respect to any specific project. Accordingly, such costs were not specifically allocated to individual projects. Beginning in 2013, as the result of a decision to reduce the total number of development projects in our pipeline, along with the fact that the number of more advanced clinical projects in our pipeline has increased on a proportionate basis, we decided to record costs for each development project on a “full cost” basis. Accordingly, beginning in 2013, costs for each development project included salary and overhead costs, as well as direct costs.

Set forth below is a summary of the costs allocated to our main projects on an individual basis, as well as the costs allocated to our less significant projects on an aggregate basis, for the years ended December 31, 2012, 2013 and 2014, and on an aggregate basis since project inception. Certain of such costs are covered by OCS funding, although OCS funds received have not been deducted from the project costs in the table.

| | Year Ended December 31, | | | Total Costs Since Project Inception |
|---|---|---|---|---|
| | 2012 | 2013 | 2014 | |
| | (U.S. $ in thousands) | | | |
| BL-1040 | – | – | – | 10,227 |
| BL-8040 | 723 | 3,910 | 4,698 | 9,331 |
| BL-7010 | 560 | 1,905 | 3,756 | 6,495 |
| BL-5010 | 132 | 251 | 1,282 | 3,669 |
| BL-7040 | 500 | 650 | 287 | 1,902 |
| BL-8020 | 794 | 918 | 160 | 1,872 |
| Other projects | 10,017 | 3,529 | 1,090 | 87,415 |
| Total project costs[(1)] | 12,726 | 11,163 | 11,273 | 120,911 |

(1) Does not include indirect project costs and overhead for years prior to 2013, including payroll and related expenses (including stock-based compensation), facilities, depreciation and impairment of intellectual property, which are included in total research and development expenses in our financial statements for such years

The costs and expenses of our projects have been partially financed by funds we have received from the OCS. Such funds are deducted from the related research and development expenses as the costs are incurred. For additional information regarding the OCS funding process, see “Government Regulation and Funding — Israeli Government Programs.” There can be no assurance that we will continue to receive funds from the OCS in amounts sufficient to fund our operations, if at all. In addition, under our licensing agreement with Bellerophon, Bellerophon is responsible for the costs associated with conducting all future development activities for BL-1040. See “Item 4. Information on the Company — Business Overview —Out-Licensing Agreement with Bellerophon.”

From our inception through December 31, 2014, we have incurred research and development expense of approximately NIS 600.9 million ($154.5 million). We expect that a large percentage of our research and development expense in the future will be incurred in support of our current and future preclinical and clinical development projects. Due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage of our preclinical product development projects, we are unable to estimate with any certainty the costs we will incur in the continued development of the therapeutic candidates in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test our product candidates in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for each product candidate. If we are not able to enter into an out-licensing arrangement with respect to any therapeutic candidate prior to the commencement of later stage clinical trials, we may fund the trials for the therapeutic candidate ourselves.

While we are currently focused on advancing each of our product development projects, our future research and development expenses will depend on the clinical success of each therapeutic candidate, as well as ongoing assessments of each therapeutic candidate’s commercial potential. In addition, we cannot forecast with any degree of certainty which therapeutic candidates may be subject to future out-licensing arrangements, when such out-licensing arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. See “Item 3. Key Information — Risk Factors — If we or our licensees are unable to obtain U.S. and/or foreign regulatory approval for our therapeutic candidates, we will be unable to commercialize our therapeutic candidates.”

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

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

- the number of sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the number of patients that participate in the clinical trials;
- the duration of patient follow-up;
- whether the patients require hospitalization or can be treated on an out-patient basis;
- the development stage of the therapeutic candidate; and
- the efficacy and safety profile of the therapeutic candidate.

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

**Sales and Marketing Expenses**

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

**General and Administrative Expenses**

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

**Non-Operating Expense and Income**

Non-operating expense and income includes fair-value adjustments of derivative liabilities on account of the warrants issued in the private and direct placements which we conducted in 2012 and 2013. These fair-value adjustments are highly influenced by our share price at each period end (revaluation date). Non-operating expense and income also includes the pro-rata share of issuance expenses from the private and direct placements related to the warrants. In addition, non-operating expense and income includes the initial commitment and finder’s fees, as well as other one-time expenses, associated with the initial set-up of the share purchase agreements with LPC and an at-the-market equity offering sales agreement with Stifel, Nicolaus & Company, Incorporated. The at-the-market equity offering sales agreement was terminated in March 2014.

**Financial Expense and Income**

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

**Critical Accounting Policies and Estimates**

We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the year ended December 31, 2014. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

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

**Functional Currency**

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

Effective January 1, 2015, our reporting and functional currency will be the dollar, which we expect will reduce, to some extent, our exposure to the currency fluctuation risks.

**Revenue Recognition**

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

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

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

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

**Accrued Expenses**

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

**Investments in Financial Assets**

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

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

**Government Participation in Research and Development Expenses**

We have received research and development funding from the State of Israel through the OCS, both in the form of loans extended to our biotechnology incubator, as well as in the form of grants. As described in Item 4. Business Overview — Government Regulation and Funding — Israeli Government Programs — Israel Office of the Chief Scientist, the activities of our biotechnology incubator have been terminated; however, we may still be eligible for funding from the OCS in the form of grants. In accordance with the OCS programs, we are entitled to specific funding with respect to a development project only after we incur development costs related to the project. Such funding qualifies as “forgivable loans” in accordance with IAS 20, “Accounting for Government Grants and Disclosure of Government Assistance,” since it is repayable only if we generate revenues related to the underlying project.

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

Liabilities to the OCS in respect of out-licensing transactions are generally discussed and negotiated with the OCS, due to the fact that such licensing transactions do not fit into the standard development funding model contemplated by the Israeli Research and Development Law. In June 2010, we received a notification regarding the payment due in connection with the BL-1040 project, which we have paid in full. Accordingly, we have no further liabilities to the OCS with respect to BL-1040.

**Stock-based Compensation**

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

**Warrants**

In connection with the private placement of approximately 5.25 million of our ADSs in February 2012, we issued warrants to purchase approximately 2.6 million of our ADSs at an exercise price of $3.57, subject to typical adjustments. The warrants are exercisable for a period of five years from the date of issuance. Since the exercise price was not deemed to be fixed, the warrants are not qualified for classification as an equity instrument and have therefore been classified as a non-current financial liability.

In connection with the direct placement to Orbimed of approximately 2.67 million of our ADSs in February 2013, we issued warrants to purchase 1.6 million of our ADSs at an exercise price of $3.94, subject to typical adjustments. The warrants are exercisable for a period of five years from the date of issuance. Since the exercise price was not deemed to be fixed, the warrants are not qualified for classification as an equity instrument and have therefore been classified as a non-current financial liability

**Recent Accounting Changes and Pronouncements**

We adopted the following standard for the first time for the fiscal year beginning January 1, 2014:

Amendment to IAS 32, “Financial Instruments: Presentation”, on asset and liability offsetting, which clarifies some of the requirements for offsetting financial assets and financial liabilities on the balance sheet.

A number of new standards and amendments to standards and interpretations are effective for annual periods beginning after January 1, 2014, and have not been applied in preparing these consolidated financial statements. None of these is expected to have a significant effect on our consolidated financial statements, except the following set out below, for which the impact has not been fully assessed.

IFRS 15, “Revenue from Contracts with Customers,” which is the converged standard on revenue recognition. It replaces IAS 11, “Construction Contracts”, IAS 18,”Revenue” and related interpretations. Revenue is recognized when a customer obtains control of a good or service. A customer obtains control when it has the ability to direct the use of and obtain the benefits from the good or service. The core principle of IFRS 15 is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. An entity recognizes revenue in accordance with that core principle by applying the following steps: Step 1: identify the contract(s) with a customer; Step 2: identify the performance obligations in the contract; Step 3: determine the transaction price; Step 4: allocate the transaction price to the performance obligations in the contract; and Step 5: recognize revenue when (or as) the entity satisfies a performance obligation. IFRS 15 also includes a cohesive set of disclosure requirements that will result in an entity providing users of financial statements with comprehensive information about the nature, amount, timing and uncertainty of revenue and cash flows arising from the entity’s contracts with customers.

IFRS 9, “Financial Instruments,” which replaces most of the guidance in IAS 39. IFRS 9 retains but simplifies the mixed measurement model and establishes three primary measurement categories for financial assets: amortized cost, fair value through other comprehensive income (OCI) and fair value through P&L. The basis of classification depends on the entity’s business model and the contractual cash flow characteristics of the financial asset. Investments in equity instruments are required to be measured at fair value through profit or loss with the irrevocable option at inception to present changes in fair value in OCI. There is now a new expected credit loss model that replaces the incurred loss impairment model used in IAS 39. For financial liabilities there were no changes to classification and measurement except for the recognition of changes in own credit risk in other comprehensive income, for liabilities designated at fair value, through profit or loss. IFRS 9 relaxes the requirements for hedge effectiveness by replacing the bright line hedge effectiveness tests. It requires an economic relationship between the hedged item and hedging instrument and for the “hedged ratio” to be the same as the one management actually use for risk management purposes. Contemporaneous documentation is still required but is different to that currently prepared under IAS 39.

**Results of Operations -- Overview**

***Revenues***

We did not record any revenues for the years ended December 31, 2012, 2013 and 2014.

***Cost of revenues***

We did not record any cost of revenues for the years ended December 31,2012, 2013 and 2014.

***Research and development expenses***

At December 31, 2011, our drug development pipeline consisted of 15 therapeutic candidates. During 2012, we added four new compounds to our pipeline and discontinued the development of five compounds from the pipeline, so that our drug development pipeline as of December 31, 2012 consisted of 14 therapeutic candidates. During 2013, we added two new compounds to our pipeline and discontinued the development of six additional compounds from the pipeline, so that our drug development pipeline as of December 31, 2013 consisted of 10 therapeutic candidates. During 2014, we added one new compound to our pipeline and discontinued the development on additional compound from the pipeline, so that our drug development pipeline as of the date of this report consists of 10 therapeutic candidates.

**Comparison of the Year Ended December 31, 2014 to the Year Ended December 31, 2013**

***Research and development expenses***

Research and development expenses for the year ended December 31, 2014 were NIS 42.5 million ($10.9 million), a decrease of NIS 1.6 million ($0.4 million), or 3.7%, compared to NIS 44.1 million ($11.3 million) for the year ended December 31, 2013. The decrease resulted primarily from termination of the BL-1020 CLARITY clinical trial in March 2013 and certain one-time costs associated with several clinical-stage projects in 2013, partially offset by increased spending on BL-8040, BL-7010 and BL-5010 in 2014.

***Sales and marketing expenses***

Sales and marketing expenses for the year ended December 31, 2014 were NIS 5.7 million ($1.5 million), an increase of NIS 1.6 million ($0.4 million), or 38.6%, compared to NIS 4.1 million ($1.1 million) for the year ended December 31, 2013. The increase resulted primarily from professional fees related to increased business development activities, including professional services related to the collaboration agreement with Novartis and the out-licensing agreement with Omega regarding BL-5010.

***General and administrative expenses***

General and administrative expenses for the year ended December 31, 2014 were NIS 13.6 million ($3.5 million), an increase of NIS 0.4 million ($0.1 million) or 2.8%, compared to NIS 13.2 million ($3.4 million) for the year ended December 31, 2012. The small increase resulted primarily from an increase in salary-related payments.

***Non-operating income (expense), net***

We recognized net non-operating income of NIS 11.0 million ($2.8 million) for the year ended December, 2014, an increase of NIS 6.8 million ($1.7 million), compared to net non-operating income of NIS 4.2 million ($1.1 million) for the year ended December 31, 2013. Non-operating income for both periods primarily relates to fair-value adjustments of liabilities on account of warrants issued in the private and direct placements which we conducted in February 2012 and 2013. These fair-value adjustments were highly influenced by our share price at each period end (revaluation date).

***Financial income (expense), net***

We recognized net financial income of NIS 11.2 million ($2.9 million) for the year ended December 31, 2014, a change of NIS 15.5 million ($4.0 million), compared to net financial expenses of NIS 4.3 million ($1.1 million) for the year ended December 31, 2013. Net financial income and expenses result primarily from changes in the average exchange rate of the dollar in relation to the NIS during the respective periods, which have a direct effect on our net assets denominated in dollars.

**Comparison of the Year Ended December 31, 2013 to the Year Ended December 31, 2012**

***Research and development expenses***

Research and development expenses for the year ended December 31, 2013 were NIS 44.1 million, a decrease of NIS 20.2 million, or 31%, compared to NIS 64.3 million for the year ended December 31, 2012. Without regard to a NIS 6.0 million one-time reversal of amounts previously accrued to the OCS in respect of BL-1020, research and development expenses decreased by NIS 14.2 million. The decrease resulted primarily from lower expenses in 2013 associated with BL-1020, due to termination of the CLARITY clinical trial in March 2013, which was partially offset by a ramp-up in spending on other clinical-stage projects introduced during 2011 and 2012.

***Sales and marketing expenses***

Sales and marketing expenses for the year ended December 31, 2013 were NIS 4.1 million, an increase of NIS 0.9 million , or 28%, compared to NIS 3.2 million for the year ended December 31, 2012. The increase resulted primarily from increased business development activities, as well as professional services incurred in connection with the collaboration agreement signed with JHL Biotech.

***General and administrative expenses***

General and administrative expenses for the year ended December 31, 2013 were NIS 13.2 million , a decrease of NIS 0.8 million or 6%, compared to NIS 14.0 million for the year ended December 31, 2012. The small decrease resulted primarily from one-time expenses for professional services incurred in 2012.

***Non-operating income (expense), net***

We recognized net non-operating income of NIS 4.2 million for the year ended December, 2013, an increase of NIS 0.2 million, compared to net non-operating income of NIS 4.0 million for the year ended December 31, 2012. Non-operating income for both periods primarily relates to fair-value adjustments of liabilities on account of warrants. These fair-value adjustments were highly influenced by our share price at each period end (revaluation date).

***Financial income (expense), net***

We recognized net financial expenses of NIS 4.3 million for the year ended December 31, 2013, a change of NIS 5.5 million, compared to net financial income of NIS 1.3 million for the year ended December 31, 2012. Net financial income and expenses result primarily from changes in the average exchange rate of the dollar in relation to the NIS during the respective periods, which have a direct effect on our net assets denominated in dollars.

**Quarterly Results of Operations**

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

| | Three Months Ended | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | March 31 | June 30 | Sept. 30 | Dec. 31 | March 31 | June 30 | Sept. 30 | Dec. 31 |
| | 2013 | | | | 2014 | | | |
| | (in thousands of NIS) | | | | | | | |
| **Consolidated Statements of Operations** | | | | | | | | |
| Revenues | – | – | – | – | – | – | – | – |
| Cost of revenues | – | – | – | – | – | – | – | – |
| Research and development expenses, net | (19,443) | (12,087) | (8,190) | (4,337) | (9,510) | (9,677) | (10,440) | (12,816) |
| Sales and marketing expenses | (771) | (1,063) | (731) | (1,536) | (1,283) | (987) | (1,070) | (2,345) |
| General and administrative expenses | (3,522) | (3,604) | (2,663) | (3,436) | (3,463) | (2,888) | (2,779) | (4,461) |
| Operating loss | (23,736) | (16,754) | (11,584) | (9,309) | (14,256) | (13,522) | (14,289) | (19,622) |
| Non-operating income (expenses), net | 12,262 | 1,579 | (4,627) | (5,023) | 5,883 | 962 | 4,835 | (732) |
| Financial income, net | 663 | 1,320 | 501 | 116 | 1,258 | 121 | 8,069 | 4,762 |
| Financial expenses, net | (2,029) | (1,713) | (1,956) | (1,148) | (284) | (1,653) | (1,122) | – |
| Net loss | (12,840) | (15,568) | (17,666) | (15,364) | (7,399) | (14,122) | (2,507) | (15,592) |

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

**Liquidity and Capital Resources**

Since inception, we have funded our operations primarily through public and private offerings of our equity securities, grants and loans from the OCS, and payments received under our strategic licensing arrangements. At December 31, 2014, we held approximately NIS 134.9 million ($34.7 million) in cash, cash equivalents and short-term bank deposits. In March 2015, we closed an underwritten public offering of our ADSs for gross proceeds of $28.8 million. We have invested substantially all of our available cash funds in short-term bank deposits.

Pursuant to the share purchase agreement with LPC signed in May 2014, we may sell, from time to time, and at our discretion, up to $20 million of our ADSs to LPC during the 36-month term of the purchase agreement. From the effective date of the purchase agreement through the date of this annual report, we have not yet sold any ADSs to LPC under the facility.

Net cash used in operating activities was NIS 56.4 million for the year ended December 31, 2014, NIS 70.5 million for the year ended December 31, 2013, and NIS 75.1 million for the year ended December 31, 2012. The NIS 14.1 million ($3.6 million) decrease in net cash used in operating activities during 2014 resulted primarily from a large decrease in net trade payables and accruals during the 2013 period.

Net cash used in investing activities for the year ended December 31, 2014 was NIS 70.7 million compared to net cash used for investing activities of NIS 19.8 million for the year ended December 31, 2013, and net cash provided by investing activities of NIS 51.3 million for the year ended December 31, 2012. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits and other investments during the respective periods.

Net cash provided by financing activities for the year ended December 31, 2014 was NIS 117.8, compared to net cash provided by financing activities of NIS 55.2 million for the year ended December 31, 2013, and net cash provided by financing activities of NIS 58.9 million for the year ended December 31, 2012. The cash flows from financing activities in 2014 primarily reflect the underwritten public offering of our ADSs in March 2014 and the investment by Novartis in December 2014. The cash flows from financing activities in 2013 reflect the direct placement to OrbiMed completed in February 2013, as well as funding under the previous share purchase agreement with LPC. The cash flows from financing activities in 2012 reflect the private placement completed in February 2012.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Although we believe our existing cash and other resources will be sufficient to fund our projected cash requirements into 2018, we will require significant additional financing in the future to fund our operations. Additional financing may not be available on acceptable terms, if at all. Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues we receive under our collaboration or licensing arrangements;
- the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval of our therapeutic candidates;
- the ability of our collaborators to achieve development milestones, marketing approval and other events or developments under our collaboration agreements;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of establishing sales and marketing capabilities or contracting with third parties to provide these capabilities for us;
- the costs of acquiring or undertaking development and commercialization efforts for any future product candidates;
- the magnitude of our general and administrative expenses;
- any cost that we may incur under current and future licensing arrangements relating to our therapeutic candidates; and
- payments to the OCS.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through payments received under our collaborations, debt or equity financings, or by out-licensing other product candidates. We cannot be certain that additional funding will be available to us on acceptable terms, or at all.

If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts.

**Off-Balance Sheet Arrangements**

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

**Contractual Obligations**

The following table summarizes our significant contractual obligations at December 31, 2014:

| | Total | Less than 1 year | 1-3 years | 3-5 years | More than 5 years |
|---|---|---|---|---|---|
| | (in thousands of NIS) | | | | |
| Car leasing obligations | 1,762 | 841 | 921 | – | – |
| Premises leasing obligations | 4,698 | 902 | 1,752 | 1,752 | 292 |
| Purchase commitments | 7,618 | 7,521 | 97 | – | – |
| Total | 14,078 | 9,264 | 2,770 | 1,752 | 292 |

The premises leasing obligations in the foregoing table include our commitments under the lease agreement for a facility in Modi'in. See "Item 4. Information on the Company — Property, Plant and Equipment." The term of the lease will begin on June 15, 2015 and end June 30, 2020. During the lease term, we are obligated to pay initial monthly rental payments of approximately $18,085 and initial monthly parking charges of approximately $1,750. We are furthermore obligated to pay building maintenance charges during the lease term not exceeding NIS 26,310 per month (currently, approximately $6,578).

The foregoing table does not include our in-licensing agreements. Under our in-licensing agreements, we are obligated to make certain payments to our licensors upon the achievement of agreed upon milestones. We are unable at this time to estimate the actual amount or timing of the costs we will incur in the future under these agreements; however, we do not expect any material milestones to be achieved within the next 12 months. If all of the milestones are achieved over the life of each in-licensing agreement, we will be required to pay approximately $5.5 million, in the aggregate, to the applicable licensors. Some of the in-licensing agreements are accompanied by consulting, support and cooperation agreements, pursuant to which we are required to pay the licensors a fixed monthly amount, over a period stipulated in the applicable agreement, for their assistance in the continued research and development under the applicable license. All of our in-licensing agreements are terminable at-will by us upon prior written notice of 30 to 90 days. We are unable at this time to estimate the actual amount or timing of the costs we will incur in the future under these agreements. See "Item 4. Information on the Company — Business Overview — In-Licensing Agreements."

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

### A. Directors and Senior Management

The following table sets forth information for our executive officers and directors as of March 1, 2015. Unless otherwise stated, the address for our directors and officers is c/o BioLineRx Ltd., P.O. Box 45158, 19 Hartum Street, Jerusalem 9777518, Israel.

| Name | Age | Position(s) |
|---|---|---|
| Kinneret Savitsky, Ph.D. | 48 | Chief Executive Officer |
| Philip Serlin, CPA, MBA | 54 | Chief Financial and Operating Officer |
| Leah Klapper, Ph.D. | 50 | Chief Scientific Officer |
| Arnon Aharon, M.D. | 46 | Vice President of Medical Affairs |
| David Malek, MBA | 37 | Vice President of Business Development |
| Aharon Schwartz, Ph.D. | 72 | Chairman of the Board |
| Michael J. Anghel, Ph.D. | 75 | Director |
| Nurit Benjamini, MBA | 48 | External Director |
| B.J. Bormann, Ph.D. | 56 | Director |
| Raphael Hofstein, Ph.D. | 64 | Director |
| Avraham Molcho, M.D. | 57 | External Director |
| Sandra Panem, Ph.D. | 68 | Director |

*Kinneret Savitsky, Ph.D.*, has served as our Chief Executive Officer since January 2010. Prior to becoming our Chief Executive Officer, from 2004 through 2005, she served as our Vice President Drug Development and from 2005 through 2010 she served as the General Manager of BIJ, our wholly-owned subsidiary. Prior to joining BIJ, Dr. Savitsky served as the Vice President of Biology of Compugen Ltd. (Nasdaq: CGEN), from 2000 to 2004, and held other senior positions at Compugen from 1997 through 2000. During 2010 and 2011, Dr. Savitsky served as a director on our Board of Directors; she currently serves as an external director at Evogene Ltd. (Nasdaq:EVGN, TASE:EVGN). Dr. Savitsky received her Ph.D. in human genetics from Tel Aviv University, a Master's degree in human genetics from Tel Aviv University and a B.Sc. in biology from The Hebrew University of Jerusalem.

*Philip Serlin, CPA, MBA*, has served as our Chief Financial and Operating Officer since May 2009. From January 2008 to August 2008, Mr. Serlin served as the Chief Financial Officer and Chief Operating Officer of Kayote Networks Inc. From January 2006 to December 2007, he served as the Chief Financial Officer of Tescom Software Systems Testing Ltd. (TASE:TSCM), an IT services company publicly traded in both Tel Aviv and London. His background also includes senior positions at Chiaro Networks Ltd. and at Deloitte, where he was head of the SEC and U.S. Accounting Department at the National Office in Tel Aviv, as well as seven years at the SEC at its Washington, D.C., headquarters. Mr. Serlin currently serves as an external director at Vascular Biogenics Ltd. (Nasdaq:VBLT) and as a director at Kitov Pharmaceuticals Holdings Ltd. (TASE:KTOV). Mr. Serlin is a CPA and holds a B.Sc. in accounting from Yeshiva University and a Master's degree in economics and public policy from The George Washington University.

*Leah Klapper, Ph.D.*, has served as our Chief Scientific Officer since January 1, 2014. From 2010 to 2013, Dr. Klapper served as the General Manager of BIJ. Prior to that, from 2005 through 2009, she served as Vice President of Preclinical Development of BIJ. From 2001 through 2005, Dr. Klapper served as Vice President of Research and Development at CureTech Ltd., a biotechnology company developing novel immune-modulating molecules, where she founded the research laboratory and led the company from the bench to clinical studies. Dr. Klapper gained extensive post-doctoral training at the Fred Hutchinson Cancer Research Center in Seattle, Washington. Dr. Klapper received her Ph.D. from the Weizmann Institute, her M.Sc. from the Department of Pharmacology at Tel Aviv University and a B.Sc. in life sciences from Tel Aviv University.

*Arnon Aharon, M.D.*, has served as our Vice President of Medical Affairs since January 2014. Prior to joining the Company, Dr. Aharon served as Clinical Director, Medical Director or VP of Development at several biotechnology companies, the most recent being Thrombotech Ltd. (from 2009 to 2012) and LycoRed Ltd. (from 2009 to 2013). In addition, Dr. Aharon was a partner in R&D Integrative Solutions, a firm that provides consulting services to the biotechnology industry and academic centers. Dr. Aharon holds a B.Sc. in medical sciences and an M.D. from Tel Aviv University.

*David Malek, MBA*, has served as our Vice President of Business Development since October 2011. Prior to joining the Company, from 2006 to 2011 Mr. Malek served at Sanofi-Aventis in a number of management positions, including Marketing, Finance and Business Development. Most recently, he served as Director of Oncology - New Products and Business Development. Mr. Malek received an MBA from the Tuck Business School at Dartmouth University and a B.A. in statistics and political science from the University of Haifa.

*Aharon Schwartz, Ph.D.*, has served as the Chairman of our Board of Directors since 2004. He served in a number of positions in Teva from 1975 through 2011, the most recent being Vice President, Head of Teva Innovative Ventures from 2008. Dr. Schwartz is currently chairman of the boards of numerous life science companies, including DPharm Ltd., BioCancell Ltd., CureTech Ltd. and Biomas Ltd. Dr. Schwartz also serves on the board of directors of Protalix Ltd. and as a consultant to Clal Biotechnology Industries Ltd. Dr. Schwartz received his Ph.D. in organic chemistry from the Weizmann Institute, his M.Sc. in organic chemistry from the Technion and a B.Sc. in chemistry and physics from the Hebrew University of Jerusalem. Dr. Schwartz recently received a second Ph.D. from the Hebrew University of Jerusalem in the history and philosophy of science.

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

*Nurit Benjamini, MBA*, has served as an external director on our Board of Directors and as the chairperson of our Audit Committee of our Board of Directors since 2010. In addition, Ms. Benjamini has served on our Investment Monitoring Committee since 2010 and on our Compensation Committee since 2012. Since December 2013, Ms. Benjamini has served as the Chief Financial Officer of TabTale Ltd. a company that develops, designs and manufactures interactive digital content to be displayed on electronic devices and websites. From 2011 to 2013, Ms. Benjamini served as the Chief Financial Officer of Wixpress Ltd.; from 2007 through 2011, she served as the Chief Financial Officer of CopperGate Communications Ltd.; and from 2000 through 2007, she served as the Chief Financial Officer of Compugen Ltd. (Nasdaq: CGEN). Prior to that, from 1993 through 1998, Ms. Benjamini served as the Chief Financial Officer of Aladdin Knowledge Systems Ltd., and from 1998 through 2000, as the Chief Financial Officer of Phone-Or Ltd. and Ms. Benjamini serves on the board of directors, and as chairperson of the audit committee, of Allot Communications Ltd. (Nasdaq:ALLT, TASE:ALLT). Ms. Benjamini holds a B.A. in economics and business and an M.B.A. in finance, both from Bar Ilan University, Israel.

*BJ Bormann, Ph.D.*, has served on our Board of Directors since August 2013. Dr. Bormann currently serves as the CEO of Harbour Antibodies BV, a Netherlands based company that licenses transgenic mice that generate human antibodies. Dr. Bormann also serves as the Chief Business Advisor for NanoMedical Systems, Inc. of Austin, Texas that licenses a unique implantable drug delivery device. Prior to these current engagements, Dr. Bormann was Senior Vice President responsible for world-wide alliances, licensing and business development at Boehringer Ingelheim Pharmaceuticals, Inc. from 2007 to 2013. From 1996 to 2007, she served in a number of positions at Pfizer, Inc., the last one being Vice President of Pfizer Global Research and Development and world-wide Head of Strategic Alliances. Dr. Bormann serves on the board of directors of various companies, including Supportive Therapeutics, LLC, Harbour Antibodies and the Institute for Pediatric Innovation. Dr. Bormann received her Ph.D. in biomedical science from the University of Connecticut Health Center and her B.Sc. from Fairfield University in biology. Dr. Bormann completed postdoctoral training at Yale Medical School in the department of pathology.

*Raphael Hofstein, Ph.D.*, has served on our Board of Directors since 2003, our Audit Committee since 2007 and our Compensation Committee since 2012. Dr. Hofstein has served as the President and Chief Executive Officer of MaRS Innovation (a commercialization company of the University of Toronto and 10 affiliated hospitals) since June 2009. From 2000 through June 2009, Dr. Hofstein was the President and Chief Executive Officer of Hadasit Medical Research Services and Development Ltd., or Hadasit, the technology transfer company of Hadassah University Hospitals. He has served as chairman of the board of directors of Hadasit since 2006. Prior to joining Hadasit, Dr. Hofstein was the President of Mindsense Biosystems Ltd. and the Business Unit Director of Ecogen Inc. and has held a variety of other positions, including manager of R&D and chief of immunochemistry at the International Genetic Science Partnership. Dr. Hofstein serves on the board of directors of numerous companies, including Hadasit Bio-Holdings Ltd. (TASE:HDST). Dr. Hofstein received his Ph.D. and M.Sc. from the Weizmann Institute of Science, and his B.Sc. in chemistry and physics from the Hebrew University in Jerusalem. Dr. Hofstein completed postdoctoral training at Harvard Medical School in both the departments of biological chemistry and neurobiology.

*Avraham Molcho, M.D., MBA*, has served as an external director on our Board of Directors and on our Audit Committee since 2010. In addition, Dr. Molcho has served on our Compensation Committee since 2012. Dr. Molcho is the Founder and Chairman of Biologic Design, a technology platform that encourages human antibody discoveries, and is a venture partner at Forbion Capital Partners, a Dutch life sciences venture capital firm. In 2012, he became the co-founder, CEO and director of Ayana Pharma Ltd. (formerly DoxoCure), a privately-held company engaged in the manufacturing of liposome-based therapeutics. He currently serves on the board of directors of Circulite Inc. and NovoGI. From 2006 through 2008, Dr. Molcho served as the Chief Executive Officer and Chairman of Neovasc Medical, a privately-held Israeli medical device company. From 2001 through 2006, Dr. Molcho was a managing director and the head of life sciences of Giza Venture Capital and, in that capacity, was involved in the founding of our company. He was also the Deputy Director General of Abarbanel Mental Health Center, the largest acute psychiatric hospital in Israel, from 1999 to 2001. Dr. Molcho holds an M.D. from Tel-Aviv University School of Medicine and an MBA from Tel-Aviv University Recanati Business School.

*Sandra Panem, Ph.D.*, has been a member of our Board since February 2014. She is currently a managing partner at Cross Atlantic Partners, which she joined in 2000. From 1994 to 1999, Dr. Panem was President of Vector Fund Management, the then asset management affiliate of Vector Securities International. Prior thereto, Dr. Panem served as Vice President and Portfolio Manager for the Oppenheimer Global BioTech Fund, a mutual fund that invested in public and private biotechnology companies. Previously, she was Vice President at Salomon Brothers Venture Capital, a fund focused on early and later-stage life sciences and technology investments. Dr. Panem was also a Science and Public Policy Fellow in economic studies at the Brookings Institution, and an Assistant Professor of Pathology at the University of Chicago. Dr. Panem currently serves on the boards of directors of Acorda Therapeutics, Inc. (NASDAQ:ACOR), Labcyte, Inc., GenomeQuest, Inc. and MDx Medical, Inc. Previously, Dr. Panem served on numerous boards of public and private companies, including Martek Biosciences (Nasdaq:MATK), IBAH Pharmaceuticals (Nasdaq:IBAH), Confluent Surgical and Molecular Informatics. She received a B.S. in biochemistry and a Ph.D. in microbiology from the University of Chicago.

**B. Compensation**

**Employment Agreements**

We have entered into written employment agreements with each of our executive officers, the terms of which are consistent with the provisions of the Executive Compensation Policy of the Company which was approved by our shareholders in December 2013 (the "Compensation Policy"). All of these agreements contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable law.

In addition, we have entered into agreements with each executive officer and director pursuant to which we have agreed to indemnify each of them to the fullest extent permitted by law to the extent that these liabilities are not covered by directors' and officers' insurance. The terms of these agreements and of our directors' and officers' insurance are consistent with the provisions of the Compensation Policy.

**Compensation of Directors and Senior Management**

The following table presents in the aggregate all compensation we paid to all of our directors and senior management as a group for the year ended December 31, 2014. The table does not include any amounts we paid to reimburse any of such persons for costs incurred in providing us with services during this period.

| | Salaries, fees, commissions and bonuses (NIS) | Pension, retirement, options and other similar benefits (NIS) |
|---|---|---|
| All directors and senior management as a group, consisting of 12 persons | 5,504,000 | 2,729,000 |

In accordance with the Companies Law, the following table presents information regarding compensation actually received by our five most highly paid executive officers during the year ended December 31, 2014.

| Name and Position | Salary | Social benefits[1] | Bonuses | Value of Options Granted[2] | All Other Compensation[3] | Total |
|---|---|---|---|---|---|---|
| | *(in thousands of U.S. dollars)* | | | | | |
| Kinneret Savitsky, Chief Executive Officer | 231 | 56 | 135 | 102 | 20 | 544 |
| Philip Serlin, Chief Financial and Operating Officer | 170 | 53 | 99 | 84 | 23 | 429 |
| David Malek, Vice President of Business Development | 143 | 33 | 98 | 59 | 18 | 351 |
| Leah Klapper, Chief Scientific Officer | 156 | 33 | 59 | 73 | 20 | 341 |
| Arnon Aharon, Vice President of Medical Affairs | 139 | 31 | 46 | 22 | 15 | 253 |

(1) "Social Benefits" include payments to the National Insurance Institute, advanced education funds, managers' insurance and pension funds; vacation pay; and recuperation pay as mandated by Israeli law.

(2) Consists of amounts recognized as share-based compensation expense on the Company's statement of comprehensive loss for the year ended December 31, 2014.

(3) "All Other Compensation" includesautomobile-related expenses pursuant to the Company's automobile leasing program, telephone, basic health insurance and holiday presents.

For additional information concerning our equity compensation plans, see "— Beneficial Ownership of Executive Officers and Directors — Stock Option Plans."

**C. Board Practices**

**Board of Directors**

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

Under the Companies Law, we are not required to have a majority of independent directors. We are required to appoint at least two external directors. See "— External Directors."

According to our Articles of Association, our Board of Directors must consist of at least five and not more than 10 directors, including external directors. Currently, our Board of Directors consists of seven directors, including two external directors as required by the Companies Law. Pursuant to our Articles of Association, other than the external directors, for whom special election requirements apply under the Companies Law as detailed below, our directors are elected at a general or special meeting of our shareholders and serve on the Board of Directors until they are removed by the majority of our shareholders at a general or special meeting of our shareholders or upon the occurrence of certain events, in accordance with the Companies Law and our Articles of Association. In addition, our Articles of Association allow our Board of Directors to appoint directors to fill vacancies on the Board of Directors to serve until the next general meeting or special meeting, or earlier if required by our Articles of Association or applicable law. We have held elections for each of our non-external directors at each annual meeting of our shareholders since our initial public offering in Israel. External directors are elected for an initial term of three years and may be elected, under certain conditions, to two additional terms, although the term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including the NASDAQ Capital Market, may be further extended under certain conditions. External directors may be removed from office only pursuant to the terms of the Companies Law. Our last annual meeting of shareholders was held in September 2014. For additional information concerning external directors, see "— External Directors."

The Companies Law provides that an Israeli company may, under certain circumstances, exculpate an office holder from liability with respect to a breach of his duty of care toward the company if appropriate provisions allowing such exculpation are included in its articles of association. See "— Exculpation, insurance and indemnification of office holders." Our Articles of Association contain such provisions, and we have entered into agreements with each of our office holders undertaking to indemnify them to the fullest extent permitted by law, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance.

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

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

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

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

**External Directors**

Under Israeli law, the boards of directors of companies whose shares are publicly traded are required to include at least two members who qualify as external directors. Each of our current external directors, Dr. Avraham Molcho and Ms. Nurit Benjamini, was elected as an external director by our shareholders in July 2010. Their initial terms expired in July 2013, at which time they were each re-elected by the shareholders of the Company for a second three-year term as external directors.

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

- the majority of the shares that are voted at the meeting, including at least a majority of the shares held by non-controlling shareholders who do not have a personal interest in the election of the external director (other than a personal interest not deriving from a relationship with a controlling shareholder) who voted at the meeting, excluding abstentions, vote in favor of the election of the external director; or

- the total number of shares held by non-controlling, disinterested shareholders (as described in the preceding bullet point) that are voted against the election of the external director does not exceed 2% of the aggregate voting rights in the company.

After an initial term of three years, external directors may be re-elected to serve in that capacity for up to two additional terms of three years provided that either (a) the board of directors has recommended such re-election and such re-election is approved by a majority vote at a shareholders' meeting, subject to the conditions described above for election of external directors, (b) (1) the re-election has been recommended by one or more shareholders holding at least 1% of the company's voting rights and is approved by a majority of non-controlling, disinterested shareholders who hold among them at least 2% of the company's voting rights; and (2) pursuant to Amendment 22 of the Companies Law, effective as of January 2014, the external director who has been nominated in such fashion by the shareholders is not a linked or competing shareholder, and does not have or has not had, on or within the two years preceding the date of such person's appointment to serve as another term as external director, any affiliation with a linked or competing shareholder, or (c) pursuant to the recently enacted Amendment 26 to the Companies Law, effective as of November 2014, the external director has proposed himself for reappointment and the reappointment was approved by the majority described in (b)(1) above. The term "linked or competing shareholder" means the shareholder(s) who nominated the external director for reappointment or a material shareholder of the company holding more than 5% of the shares in the company, provided that at the time of the reappointment, such shareholder(s) of the company, the controlling shareholder of such shareholder(s) of the company, or a company under such shareholder(s) of the company's control, has a business relationship with the company or are competitors of the company; the Israeli Minister of Justice, in consultation with the Israeli Securities Authority, may determine that certain matters will not constitute a business relationship or competition with the company. The term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including the Nasdaq Capital Market, may be extended beyond the initial three terms permitted under the Companies Law indefinitely in increments of additional three-year terms, provided in each case that the following conditions are met: (a) the audit committee and the board of directors confirm that, in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the re-election for such additional period(s) is beneficial to the company; (b) the re-election is approved by the shareholders by a special majority required for the re-election of external directors; and (c) the term of office of the external director, and the considerations of the audit committee and the Board of Directors in deciding to recommend re-election of the external director for such additional term of office, are presented to the shareholders prior to the vote on re-election. External directors may be removed from office by the same percentage of shareholders required for their election or by a court, in each case, only under limited circumstances, including ceasing to meet the statutory qualification for appointment or violating the duty of loyalty to the company. If an external directorship becomes vacant and there are less than two external directors on the board of directors at the time, then the board of directors is required under the Companies Law to call a shareholders' meeting immediately to appoint a replacement external director. Each committee of the board of directors that exercises the powers of the board of directors must include at least one external director. Under the Companies Law external directors of a company are prohibited from receiving, directly or indirectly, any compensation from the company other than for their services as external directors pursuant to the provisions and limitations set forth in regulations promulgated under the Companies Law.

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

The term "affiliation" includes:

- an employment relationship;
- a business or professional relationship even if not maintained on a regular basis (excluding insignificant relationships);
- control; and
- service as an office holder, excluding service as a director in a private company prior to the first offering of its shares to the public if such director was appointed as a director of the private company in order to serve as an external director following the public offering.

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

In addition, no person may serve as an external director if that person's professional activities create, or may create, a conflict of interest with that person's responsibilities as a director or otherwise interfere with that person's ability to serve as an external director or if the person is an employee of the Israel Securities Authority or of an Israeli stock exchange. Furthermore, a person may not continue to serve as an external director if he or she received direct or indirect compensation from us for his or her role as a director. This prohibition does not apply to compensation paid or given for service as an external director in accordance with regulations promulgated under the Companies Law or amounts paid pursuant to indemnification and/or exculpation contracts or commitments and insurance coverage.

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

If at the time an external director is appointed all members of the board of directors are of the same gender, the external director must be of the other gender. A director of one company may not be appointed as an external director of another company if a director of the other company is acting as an external director of the first company at such time.

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

**Audit Committee**

Under the Companies Law, the board of directors of a public company must appoint an audit committee. The audit committee must be comprised of at least three directors, including all of the external directors, and one of the external directors must serve as chairperson of the committee. The audit committee of a company may not include:

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

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

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

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

- he or she meets the qualifications for being appointed as an external director, except for (i) the requirement that the director be an Israeli resident (which does not apply to companies such as ours whose securities have been offered outside of Israel or are listed outside of Israel) and (ii) the requirement for accounting and financial expertise or professional qualifications; and

- he or she has not served as a director of the company for a period exceeding nine consecutive years. For this purpose, a break of less than two years in the service shall not be deemed to interrupt the continuation of the service.

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

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

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

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

- oversight of the company's independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of the our independent registered public accounting firm to our Board of Directors in accordance with Israeli law;

- recommending the engagement or termination of the office of the our internal auditor; and

- reviewing and pre-approving the terms of audit and non-audit services provided by our independent auditors.

Our Audit Committee provides assistance to our Board of Directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our Audit Committee also oversees the audit efforts of our independent accountants and takes those actions as it deems necessary to satisfy itself that the accountants are independent of management. Pursuant to the Companies Law, the audit committee of a company shall be responsible for: (i) determining whether there are delinquencies in the business management practices of a company, including in consultation with an internal auditor or independent auditor, and making recommendations to the company's board of directors to improve such practices; (ii) determining whether to approve certain related party transactions (including compensation of office holders or transactions in which an office holder has a personal interest and whether such transaction is material or otherwise an extraordinary transaction); (iii) where the company's board of directors approves the working plan of the internal auditor, examining such working plan before its submission to the board and proposing amendments thereto; (iv) examining internal controls and the internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of his responsibilities (taking into consideration the special needs and size of a company); (v) examining the scope of the auditor's work and compensation and submitting its recommendation with respect thereto to the corporate body considering the appointment thereof (either the board or the general meeting of shareholders); and (vi) establishing procedures for the handling of employees' complaints as to the management of the business and the protection to be provided to such employees. Pursuant to Amendment 22, effective as of January 10, 2014, the responsibilities of the audit committee under the Companies Law also include the following matters: (i) the establishment of procedures to be followed in respect of related party transactions with a controlling shareholder (where such are not extraordinary transactions), which may include, where applicable, the establishment of a competitive process for such transaction, under the supervision of the audit committee, or individual, or other committee or body selected by the audit committee, in accordance with criteria determined by the audit committee; and (ii) to determine procedures for approving certain related party transactions with a controlling shareholder, which having been determined by the audit committee not to be extraordinary transactions, were also determined by the audit committee not to be negligible transactions. Under the Companies Law, the approval of the audit committee is required for specified actions and transactions with office holders and controlling shareholders. See "— Approval of Related Party Transactions under Israeli Law."

**Compensation Committee**

In December 2012, Amendment 20 to the Companies Law, or Amendment 20, went into effect. Amendment 20 requires, among other things, that the board of directors of Israeli publicly-traded companies appoint a compensation committee comprised of at least three members, including all of the external directors of a company, and one of the external directors must serve as chairman of the committee. Such compensation committee may not include:

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

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

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

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

The responsibilities of the compensation committee include the following:

- to make recommendations to the board of directors as to a compensation policy for officers, as well as to recommend once every three years to extend the compensation policy, subject to receipt of the required corporate approvals;

- to make recommendations to the board of directors as to any updates to the compensation policy which may be required;
- to review the implementation of the compensation policy by the company;
- to approve transactions relating to terms of office and employment of certain company office holders, which require the approval of the compensation committee pursuant to the Companies Law;
- to exempt, under certain circumstances, a transaction relating to terms of office and employment from the requirement of approval of the shareholders meeting; and

In November 2012, in order to comply with the requirements of Amendment 20, our Board of Directors established a Compensation Committee, comprised of Nurit Benjamini and Dr. Avraham Molcho, our two external directors, and Dr. Raphael Hofstein. Nurit Benjamini serves as the Chairperson of our Compensation Committee.

Under Amendment 20, a board of directors of an Israeli publicly-traded company, following the recommendation of the compensation committee, is required to establish a compensation policy, to be approved by the shareholders of the company, and pursuant to which the terms of office and compensation of the company's officer holders will be decided.

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

The board of directors of a publicly-traded company is obligated to adopt a compensation policy after considering the recommendations of the compensation committee. The final adoption of the compensation policy is subject to the approval of the shareholders of the company, which such approval is subject to certain special majority requirements, as set forth in Amendment 20, pursuant to which one of the following must be met:

(i) the majority of the votes includes at least a majority of all the votes of shareholders who are not controlling shareholders of the company or who do not have a personal interest in the compensation policy and participating in the vote; abstentions shall not be included in the total of the votes of the aforesaid shareholders; or

(ii) the total of opposing votes from among the shareholders described in subsection (i) above does not exceed 2% of all the voting rights in the company**.**

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

In December 2013, a general meeting of our shareholders approved the Compensation Policy which had been recommended by our Compensation Committee and approved by our Board of Directors. The Compensation Policy governs the terms of compensation for our directors and office holders, in accordance with the requirements of the Companies Law. Below is a summary discussion of the provisions of the Compensation Policy:

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

Compensation is considered performance-based to the extent that a direct link is maintained between compensation and performance and that rewards are consistent with long-term stakeholder value creation.

At the company level, we analyze the overall compensation trends of the market in order to make informed decisions about our compensation approach. With specific reference to our office holders, we have used a benchmarking analysis based on an internally developed list of publicly traded companies that represent, as closely as possible, our peer group, and as further set out in the Compensation Policy.

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

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

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

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

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

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

All compensation arrangements of office holders are to be approved in the manner prescribed by applicable law. Our Compensation Committee will review the Compensation Policy on an annual basis, and monitor its implementation, and recommend to our Board of Directors and shareholders to amend the Policy as it deems necessary from time to time. The term of the Compensation Policy shall be three years as of the date of its adoption on December 19, 2013. Following such three year term, the Compensation Policy, including any revisions recommended by our Compensation Committee and approved by our Board of Directors, as applicable, will be brought once again to the shareholders for approval.

In September 2014, the general meeting of our shareholders approved an amendment to the Compensation Policy to expressly authorize the purchase of insurance policies (including run-off policies) to cover the liability of directors and office holders. See " – Exculpation, insurance and indemnification of office holders"

**Nominating Committee**

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

**Financial Statement Review Committee**

Our Board of Directors appointed a Financial Statement Review Committee, which consists of members with accounting and financial expertise or the ability to read and understand financial statements. According to a resolution of our Board of Directors, the Audit Committee has been assigned the responsibilities and duties of a financial statement review committee, as permitted under relevant regulations promulgated under the Companies Law. From time to time as necessary and required to approve our financial statements, the Audit Committee holds separate meetings, prior to the scheduled meetings of the entire Board of Directors regarding financial statement approval. The function of a financial statement review committee is to discuss and provide recommendations to its board of directors (including the report of any deficiency found) with respect to the following issues: (1) estimations and assessments made in connection with the preparation of financial statements; (2) internal controls related to the financial statements; (3) completeness and propriety of the disclosure in the financial statements; (4) the accounting policies adopted and the accounting treatments implemented in material matters of the company; (5) value evaluations, including the assumptions and assessments on which evaluations are based and the supporting data in the financial statements. Our independent auditors and our internal auditor are invited to attend all meetings of the Audit Committee when it is acting in the role of the Financial Statement Review Committee or at which matters concerning the financial statements are discussed. Our internal auditor is invited to attend all meetings of our Audit Committee.

**Investment Monitoring Committee**

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

**Internal Auditor**

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

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

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

**Approval of Related Party Transactions under Israeli Law**

***Fiduciary duties of office holders***

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

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

The duty of loyalty requires an office holder to act in good faith and for the benefit of the company, and includes the duty to:

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

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

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

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

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

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

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

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

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

Under Amendment 20, a transaction with an office holder in a public company regarding his or her terms of office and employment should be determined in accordance with the company's compensation policy. Nonetheless, provisions were established that allow a company, under special circumstances, to approve terms of office and employment that are not in line with the approved compensation policy. Accordingly, pursuant to Amendment 20, the approval requirements for the compensation and/or terms of office of a specific office holder may require the approval of each of the compensation committee, board of directors and the shareholders, in that order. As such, under Amendment 20, the following approvals are required for the following transactions:

A transaction with an office holder in a public company that is neither a director nor the Chief Executive Officer regarding his or her terms of office and employment requires approval by the (i) compensation committee; and (ii) the board of directors. Approval of terms of office and employment for such officers which do not comply with the compensation policy may nonetheless be approved subject to two cumulative conditions: (i) the compensation committee and thereafter the board of directors, approved the terms after having taken into account the various considerations and mandatory requirements set forth in Amendment 20 with respect to office holder compensation, and (ii) the shareholders of the company have approved the terms by means of the following special majority requirements (the "Special Majority Requirements"), as set forth in Amendment 20, pursuant to which the shareholder approval must either include at least one-half of the shares held by non-controlling and disinterested shareholders who actively participate in the voting process (without taking abstaining votes into account), or, alternatively, the total shareholdings of the non-controlling and disinterested shareholders who vote against the transaction must not represent more than two percent of the voting rights in the company.

A transaction with the chief executive officer in a public company regarding his or her terms of office and employment requires approval by the (i) compensation committee; (ii) the board of directors and (iii) the shareholders of the company by the Special Majority Requirements. Approval of terms of office and employment for the chief executive officer which do not comply with the compensation policy may nonetheless be approved subject to two cumulative conditions: (i) the compensation committee and thereafter the board of directors, approved the terms after having taken into account the various considerations and mandatory requirements set forth in Amendment 20 with respect to office holder compensation, and (ii) the shareholders of the company have approved the terms by means of the Special Majority Requirements, as detailed above.

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

A transaction with a director in a public company regarding his or her terms of office and employment requires approval by the (i) compensation committee; (ii) the board of directors and (iii) the shareholders of the company. Approval of terms of office and employment for directors of a company which do not comply with the compensation policy may nonetheless be approved subject to two cumulative conditions: (i) the compensation committee and thereafter the board of directors, approved the terms after having taken into account the various considerations and mandatory requirements set forth in Amendment 20 with respect to office holder compensation, and (ii) the shareholders of the company have approved the terms by means of the Special Majority Requirements, as detailed above.

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

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

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

Under Amendment 20, extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, including a private placement in which a controlling shareholder has a personal interest, as well as transactions for the provision of services whether directly or indirectly by a controlling shareholder or his or her relative, or a company such controlling shareholder controls, require the approval of the audit committee, the board of directors and the shareholders, in that order. Extraordinary Transactions concerning the terms of engagement of a controlling shareholder or a controlling shareholder's relative, whether as an office holder or an employee, require the approval of the compensation committee, the board of directors and the shareholders, in that order. In addition, the approval of such extraordinary transactions by the shareholders require at least a majority of the shares voted by the shareholders of the company participating and voting in a shareholders' meeting, provided that one of the following requirements is fulfilled:

- at least a majority of the shares held by shareholders who have no personal interest in the transaction and are voting at the meeting must be voted in favor of approving the transaction, excluding abstentions; or

- the shares voted by shareholders who have no personal interest in the transaction who vote against the transaction represent no more than 2% of the voting rights in the company.

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

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

**Duties of shareholders**

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

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

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

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

In addition, any controlling shareholder, any shareholder that knows that its vote can determine the outcome of a shareholder vote and any shareholder that, under a company's articles of association, has the power to appoint or prevent the appointment of an office holder, or has another power with respect to a company, is under a duty to act with fairness towards the company. The Companies Law does not describe the substance of this duty except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness, taking the shareholder's position in the company into account.

**Exculpation, insurance and indemnification of office holders**

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

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

- financial liability imposed on him or her in favor of another person pursuant to a judgment, settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned events and amount or criteria;

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (1) no indictment was filed against such office holder as a result of such investigation or proceeding; and (2) no financial liability, such as a criminal penalty, was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf or by a third party or in connection with criminal proceedings in which the office holder was acquitted or as a result of a conviction for an offense that does not require proof of criminal intent.

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

- a breach of duty of loyalty to the company, to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;

- a breach of duty of care to the company or to a third party, including a breach arising out of the negligent conduct of the office holder; and

- a financial liability imposed on the office holder in favor of a third party.

An Israeli company may not indemnify or insure an office holder against any of the following:

- a breach of duty of loyalty, except to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;

- a breach of duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;

- an act or omission committed with intent to derive illegal personal benefit; or

- a fine or forfeit levied against the office holder.

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

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

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

Our office holders are currently covered by a directors and officers' liability insurance policy. The terms of such directors and officers insurance are consistent with the provisions of the Compensation Policy which was approved by our shareholders in December 2013, and with the provisions of an amendment to the Compensation Policy which approved by our shareholders in September 2014. The purpose of the amendment was to clarify that we are authorized to purchase insurance policies (including run-off policies) to cover the liability of directors and office holders that are in office at such time and that shall be in office from time to time, including directors and office holders that may have a controlling interest in the Company. Such insurance policies are authorized within the following limits: (1) the premium for each policy period shall not exceed $250,000, (2) the maximum aggregate limit of liability pursuant to the policies shall not exceed $20 million for each insurance period, and (3) the maximum deductible shall not exceed $250,000. In addition, the Compensation Committee is authorized to increase the coverage purchased and/or the premium paid for such policies by up to 20% per year, as compared to the previous year, or cumulatively for a number of years, without an additional shareholders' approval to the extent permitted under the Companies Law. As of the date of this Annual Report on Form 20-F, no claims for directors' and officers' liability insurance have been filed under this policy and we are not aware of any pending or threatened litigation or proceeding involving any of our directors or officers in which indemnification is sought. Pursuant to the approval of our shareholders which was obtained in September 2014, we carry directors' and officers' insurance covering each of our directors and executive officers for acts and omissions. See also "Certain Transactions and Related Party Transactions — Indemnification Agreements."

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

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

**D. Employees**

As of December 31, 2014, we had 46 employees, all of whom are employed in Israel. Of our employees, 18 hold M.D. or Ph.D. degrees.

| | December 31, | | |
|---|---|---|---|
| | **2012** | **2013** | **2014** |
| Management and administration | 13 | 13 | 12 |
| Research and development | 37 | 27 | 31 |
| Sales and marketing | 2 | 3 | 3 |

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

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

**E. Beneficial Ownership of Executive Officers and Directors**

The following table sets forth information regarding the beneficial ownership of our outstanding ordinary shares as of March 20, 2015 of each of our directors and executive officers individually and as a group.

| | Number of Shares Beneficially Held | Percent of Class |
|---|---|---|
| **Directors** | | |
| Aharon Schwartz[(1)] | 104,168 | * |
| Michael J. Anghel[(2)] | 104,168 | * |
| Nurit Benjamini[(3)] | 137,500 | * |
| B.J. Bormann[(4)] | 79,168 | * |
| Raphael Hofstein[(5)] | 304,168 | * |
| Avraham Molcho[(6)] | 137,500 | * |
| Sandra Panem[(7)] | 62,500 | |
| **Executive officers** | | |
| Kinneret Savitsky[(8)] | 1,897,202 | * |
| Philip Serlin[(9)] | 804,200 | * |
| Leah Klapper[(10)] | 692,759 | * |
| David Malek[(11)] | 337,500 | * |
| Arnon Aharon[(12)] | - | – |
| **All directors and executive officers as a group (12 persons)[(13)]** | 4,660,833 | * |

* Less than 1.0%.

(1) Includes 104,168 ordinary shares issuable upon exercise of outstanding options within 60 days of March 20, 2015. Does not include 145,832ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 20, 2015.

(2) Includes 104,168 ordinary shares issuable upon exercise of outstanding options within 60 days of March 20, 2015. Does not include 145,832 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 20, 2015.

(3) Includes 137,500 ordinary shares issuable upon exercise of outstanding options within 60 days of March 20, 2015. Does not include 62,500 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 20, 2015.

(4) Includes 79,168 ordinary shares issuable upon exercise of outstanding options within 60 days of March 20, 2015. Does not include 170,832 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 20, 2015.

(5) Includes 304,168 ordinary shares issuable upon exercise of outstanding options within 60 days of March 20, 2015. Does not include 145,832 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 20, 2015.

(6) Includes 137,500 ordinary shares issuable upon exercise of outstanding options within 60 days of March 20, 2015. Does not include 62,500 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 20, 2015.

(7) Includes 62,500 ordinary shares issuable upon exercise of outstanding options within 60 days of March 20, 2015. Does not include 162,500 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 20, 2015.

(8) Includes 981,170 ordinary shares issuable upon exercise of outstanding options within 60 days of March 20, 2015. Does not include 1,575,000 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 20, 2015.

(9) Includes 804,200 ordinary shares issuable upon exercise of outstanding options within 60 days of March 20, 2015. Does not include 1,755,000 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 20, 2015.

(10) Includes 692,759 ordinary shares issuable upon exercise of outstanding options within 60 days of March 20, 2015. Does not include 1,705,000 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 20, 2015.

(11) Includes 337,500 ordinary shares issuable upon exercise of outstanding options within 60 days of March 20, 2015. Does not include 1,677,500 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 20, 2015.

(12) Does not include 1,336,000 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 20, 2015.

(13) Includes 3,553,527 ordinary shares issuable upon exercise of outstanding options within 60 days of March 20, 2015. Does not include 8,944,328 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 20, 2015.

**Stock Option Plans**

***2003 Share Option Plan***

In 2003, we adopted the BioLineRx Ltd. 2003 Share Incentive Plan, or the Plan. The Plan provides for the granting of options and ordinary shares to our directors, employees, consultants and service providers, and to the directors, employees, consultants and service providers of our subsidiaries and affiliates. The Plan provides for options to be issued at the determination of our Board of Directors in accordance with applicable law. As of December 31, 2014, there were 32,450,716 ordinary shares issuable upon the exercise of outstanding options under the Plan.

In November 2011, our Board of Directors approved the re-pricing of approximately 3,700,000 outstanding “underwater” employee stock options (out of a total of approximately 6,200,000 stock options outstanding). The weighted average remaining vesting period of the options subject to re-pricing was 1.1 years, with a weighted average exercise price of NIS 4.07 per share. The terms of the re-pricing were as follows: (i) the exercise price of the options was reduced to NIS 1.80 per share and (ii) one additional year of vesting was added to the remaining vesting period of the options. The re-pricing was not applicable to options which were already vested, and it did not apply to options held by Directors or consultants. With respect to each eligible optionee, the re-pricing terms applied only if the eligible optionee consented to the new terms. Without such consent, the terms remained unchanged (in respect of that optionee).

In November 2012, our Board of Directors approved a two-year extension to the exercise period for 3,867,910 previously issued and outstanding employee stock options. This extension brought the total exercise period of such options in line with the seven-year exercise period generally used for most employee stock options that were previously granted.

In August 2013, our Board of Directors approved amendments to the Plan to take into account changes in laws and regulations that had occurred since its adoption and to extend the term of the plan until November 2023.

From time to time, our Board of Directors has approved an increase in the number of shares reserved for the purpose of option grants pursuant to the Plan. As of December 31, 2014, the number of shares so reserved was approximately 5.8 million.

***Administration of Our Share Incentive Plan***

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

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

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

## ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

### A. Major Shareholders

The following table sets forth certain information regarding the beneficial ownership of our outstanding ordinary shares as of March 20, 2015 by each person who we know beneficially owns 5.0% or more of the outstanding ordinary shares. Each of our shareholders has identical voting rights with respect to its shares. All of the information with respect to beneficial ownership of the ordinary shares is given to the best of our knowledge. The beneficial ownership of ordinary shares is based on the 534,900,507 ordinary shares outstanding as of March 20, 2015 and is determined in accordance with the rules of the SEC and generally includes any ordinary shares over which a person exercises sole or shared voting or investment power. For purposes of the table below, we deem shares subject to options or warrants that are currently exercisable or exercisable within 60 days of March 20, 2015, to be outstanding and to be beneficially owned by the person holding the options or warrants for the purposes of computing the percentage ownership of that person but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. To our knowledge, none of our shareholders of record are U.S. holders. Our principal shareholders do not have different or special voting rights.

| | Number of Shares Beneficially Held | Percent of Class |
|---|---|---|
| Novartis Pharma AG[(1)] | 50,000,000 | 9.3 |
| Rima Senvest Management, L.L.C. [(2)] | 36,763,380 | 6.8 |
| Pan Atlantic Bank and Trust Limited[(3)] | 34,803,965 | 6.4 |
| Broadfin Healthcare Master Fund, Ltd.[(4)] | 31,000,000 | 5.8 |
| OrbiMed Israel Partners Limited Partnership[(5)] | 27,350,000 | 5.0 |

(1) Based upon information provided by the shareholder in its Schedule 13G filed with the SEC on December 22, 2014. Novartis AG is the parent of Novartis Pharma AG and as such is indicated as sharing voting and dispositive power with respect to the ordinary shares underlying the securities held by Novartis Pharma AG and is deemed to have beneficial ownership of such securities. The address of the principal business office of each of Novartis Pharma AG and Novartis AG is Lichtstrasse 35, 4056 Basel, Switzerland.

(2) Includes 3,496,500 ordinary shares issuable upon exercise of outstanding warrants within 60 days of March 20, 2015. Based upon information provided by the shareholder in its Schedule 13G filed with the SEC on January 7, 2015 and on additional information available to us. In such filing, Richard Mashaal is indicated as having shared voting and dispositive power with respect to the ordinary shares held by Rima Senvest Management LLC and as having beneficial ownership of such securities. Mr. Mashaal disclaims beneficial ownership in the shares reported in the Schedule 13G except to the extent of his pecuniary interest therein. The address of the principal business office of Rima Senvest Management LLC is 540 Madison Avenue, 32nd Floor, New York, New York 10022.

(3) Includes 7,000,000 ordinary shares issuable upon exercise of outstanding warrants within 60 days of March 20, 2015. Based upon information provided by the shareholder in its Schedule 13D/A filed with the SEC on March 10, 2014. Pan Atlantic Bank and Trust Limited is a wholly owned subsidiary of FCMI Financial Corporation (FCMI). All of the outstanding shares of FCMI are owned by Albert D. Friedberg, members of his family and trusts for the benefit of members of his family. Mr. Friedberg retains possession of the voting and dispositive power over the FCMI shares held by members of the Friedberg family and trusts for the benefit of members of his family and, as a result, controls and may be deemed the beneficial owner of 100% of the outstanding shares of and sole controlling person of FCMI. By virtue of his control of FCMI, Mr. Friedberg may be deemed to possess voting and dispositive power over the shares owned directly by its wholly-owned subsidiary, Pan Atlantic Bank and Trust Limited. The address of the principal business office of Pan Atlantic Bank and Trust Limited is “Whitepark House,” 1st Floor, Whitepark Road, St. Michael BB11135, Barbados, West Indies.

(4) Based upon information provided by the shareholder in its Schedule 13G filed with the SEC on March 16, 2015. In such filing, Broadfin Capital, LLC (Broadfin Capital) and Kevin Kotler are indicated as having shared voting and dispositive power with respect to the ordinary shares underlying the securities held by Broadfin Healthcare Master Fund, Ltd. (Broadfin Fund) and as having beneficial ownership of such securities. Broadfin Capital and Mr. Kotler disclaim beneficial ownership in the shares reported in the Schedule 13G except to the extent of their pecuniary interest therein. The address of the principal business office of Broadfin Fund is 20 Genesis Close, Ansbacher House, Second Floor, P.O. Box 1344, Grand Cayman KY1-1108, Cayman Islands.

(5) Includes 16,000,000 ordinary shares issuable upon exercise of outstanding options within 60 days of March 20, 2015. Based upon information provided by the shareholder in its Schedule 13G/A filed with the SEC on February 17, 2015. OrbiMed Israel GP Ltd. (“OrbiMed Israel”) is the general partner of OrbiMed Israel BioFund GP Limited Partnership (“OrbiMed BioFund”), which is the general partner of the shareholder, OrbiMed Israel Partners Limited Partnership, an Israel limited partnership (“OrbiMed Partners”). OrbiMed Israel, as the general partner of OrbiMed BioFund, and OrbiMed BioFund, as the general partner of OrbiMed Partners, may be deemed to share voting and investment power with respect to the ordinary shares underlying the securities held by OrbiMed Partners. The principal business office of each of the OrbiMed entities is 89 Medinat HaYehudim St., Building E, 11th Floor, Herzliya 46766, Israel.

**B. Related Party Transactions**

**Early Development Program Agreement**

We entered into an agreement with Pan Atlantic pursuant to which Pan Atlantic committed to provide up to $5.0 million of funding for us to in-license and develop early development stage therapeutic candidates. Pursuant to this early development program, we were entitled to request from Pan Atlantic twice a year up to $625,000 for an aggregate of up to approximately $1.25 million per year, unless otherwise agreed by Pan Atlantic, for our early development research projects, provided that we match the program funds at a rate of $0.20 per every dollar invested by Pan Atlantic. Pan Atlantic fulfilled its entire $5,000,000 funding obligation under this program during 2012. As part of the agreement, Pan Atlantic had the right to invest up to $5.0 million in our first public offering outside of Israel, which right it exercised by participating in the public offering we carried out in March 2014. The full $6,000,000 of funds earmarked for the EDP program were completely utilized as of December 31, 2013. Pan Atlantic does not have any rights to any products developed through the EDP program.

**Agreements with Directors and Officers**

***Employment Agreements***

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

***Indemnification Agreements***

Our Articles of Association and Executive Compensation Policy approved by our shareholders permit us to exculpate, indemnify and insure our directors and officeholders to the fullest extent permitted by the Companies Law. We have entered into agreements with each of our office holders undertaking to indemnify them to the fullest extent permitted by law, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance. We have obtained directors’ and officers’ insurance for each of our officers and directors. See “Item 6. Directors, Senior Management and Employees — Board Practices — Exculpation, insurance and indemnification of office holders.”

**C. Interests of Experts and Counsel**

Not applicable.

## ITEM 8. FINANCIAL INFORMATION

### A. Consolidated Statements and other Financial Information

See Item 18.

### Legal Proceedings

We are not involved in any material legal proceedings.

### Dividend Distributions

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

### B. Significant Changes

None.

**ITEM 9. THE OFFER AND LISTING**

**A. Offer and Listing Details**

**Price Range of our ADSs**

Our ADSs have been trading on the Nasdaq Capital Market under the symbol "BLRX" since July 2011.

The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our ADSs on the Nasdaq Capital Market in U.S. dollars.

| | U.S.$ Price Per ADS | |
|---|---|---|
| | **High** | **Low** |
| **Annual:** | | |
| 2014 | 3.07 | 1.23 |
| 2013 | 4.75 | 1.58 |
| 2012 | 5.55 | 2.23 |
| 2011 (from July 25, 2011) | 5.59 | 2.75 |
| | | |
| **Quarterly:** | | |
| Fourth Quarter 2014 | 1.83 | 1.23 |
| Third Quarter 2014 | 2.19 | 1.46 |
| Second Quarter 2014 | 2.27 | 1.94 |
| First Quarter 2014 | 3.07 | 2.21 |
| Fourth Quarter 2013 | 2.96 | 2.20 |
| Third Quarter 2013 | 2.29 | 1.62 |
| Second Quarter 2013 | 1.91 | 1.58 |
| First Quarter 2013 | 4.75 | 1.68 |
| | | |
| **Most Recent Six Months:** | | |
| March 2015 (through March 20, 2015) | 2.84 | 1.95 |
| February 2015 | 2.59 | 1.81 |
| January 2015 | 2.10 | 1.71 |
| December 2014 | 1.83 | 1.23 |
| November 2014 | 1.45 | 1.25 |
| October 2014 | 1.54 | 1.33 |
| September 2014 | 1.69 | 1.46 |

On March 20, 2015, the last reported sales price of our ADSs on the Nasdaq Capital Market was $2.06 per ADS. As of March 20, 2015 there was one shareholder of record of our ADSs. The number of record holders is not representative of the number of beneficial holders of our ADSs.

**Price Range of our Ordinary Shares**

Our ordinary shares have been trading on the TASE under the symbol "BLRX" since February 2007.

The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our ordinary shares on the TASE in NIS and U.S. dollars. U.S. dollar per ordinary share amounts are calculated using the U.S. dollar representative rate of exchange on the date to which the high or low market price is applicable, as reported by the Bank of Israel.

| | NIS | | U.S.$ | |
|---|---|---|---|---|
| | Price Per Ordinary Share | | Price Per Ordinary Share | |
| | High | Low | High | Low |
| **Annual:** | | | | |
| 2014 | 1.05 | 0.48 | 0.30 | 0.12 |
| 2013 | 1.79 | 0.59 | 0.49 | 0.16 |
| 2012 | 2.12 | 0.89 | 0.56 | 0.23 |
| 2011 | 3.24 | 1.13 | 0.91 | 0.30 |
| 2010 | 4.75 | 2.86 | 1.26 | 0.80 |
| | | | | |
| **Quarterly:** | | | | |
| Fourth Quarter 2014 | 0.71 | 0.48 | 0.18 | 0.12 |
| Third Quarter 2014 | 0.73 | 0.57 | 0.21 | 0.15 |
| Second Quarter 2014 | 0.80 | 0.68 | 0.23 | 0.20 |
| First Quarter 2014 | 1.05 | 0.77 | 0.30 | 0.22 |
| Fourth Quarter 2013 | 1.08 | 0.80 | 0.30 | 0.23 |
| Third Quarter 2013 | 0.85 | 0.60 | 0.24 | 0.17 |
| Second Quarter 2013 | 0.73 | 0.59 | 0.20 | 0.16 |
| First Quarter 2013 | 1.79 | 0.63 | 0.49 | 0.17 |
| | | | | |
| **Most Recent Six Months:** | | | | |
| March 2015 (through March 19, 2015) | 1.02 | 0.77 | 0.26 | 0.19 |
| February 2015 | 0.92 | 0.71 | 0.24 | 0.18 |
| January 2015 | 0.84 | 0.67 | 0.21 | 0.17 |
| December 2014 | 0.71 | 0.48 | 0.18 | 0.12 |
| November 2014 | 0.54 | 0.48 | 0.14 | 0.12 |
| October 2014 | 0.58 | 0.50 | 0.16 | 0.13 |
| September 2014 | 0.62 | 0.57 | 0.17 | 0.15 |

On March 19, 2015, the last reported sales price of our ordinary shares on the TASE was NIS 0.83 per share, or $0.21 per share (based on the exchange rate reported by the Bank of Israel for such date). On March 19, 2015, the exchange rate of the NIS to the dollar was $1.00 = NIS 4.006, as reported by the Bank of Israel. As of March 19, 2015, there were three shareholders of record of our ordinary shares. The number of record holders is not representative of the number of beneficial holders of our ordinary shares.

**B. Plan of Distribution**

Not applicable.

**C. Reasons for the Offer and Use of Proceeds**

Not applicable.

**ITEM 10. ADDITIONAL INFORMATION**

**A. Share Capital**

Not applicable

**B. Memorandum and Articles of Association**

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

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

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

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

**Dividends**

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

Pursuant to the Companies Law, we may only distribute dividends from our profits accrued over the previous two years, as defined in the Companies Law, according to our then last reviewed or audited financial reports, provided that the date of the financial reports is not more than six months prior to the date of distribution, or we may distribute dividends with court approval. In each case, we are only permitted to pay a dividend if there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

**Election of Directors**

Our ordinary shares do not have cumulative voting rights in the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors, other than with respect to the special approval requirements for the election of external directors described under "Item 6. Directors, Senior Management and Employees — Board Practices — External Directors."

Pursuant to our Articles of Association, other than the external directors, for whom special election requirements apply under the Companies Law, our directors are elected at a general or special meeting of our shareholders and serve on the Board of Directors until they are removed by the majority of our shareholders at a general or special meeting of our shareholders or upon the occurrence of certain events, in accordance with the Companies Law and our Articles of Association. In addition, our Articles of Association allow our Board of Directors to appoint directors to fill vacancies on the Board of Directors to serve until the next general meeting or special meeting, or earlier if required by our Articles of Association or applicable law. We have held elections for each of our non-external directors at each annual meeting of our shareholders since our initial public offering in Israel. External directors are elected for an initial term of three years and may be removed from office pursuant to the terms of the Companies Law. See "Item 6. Directors, Senior Management and Employees — Board Practices — External Directors."

**Shareholder Meetings**

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

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

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

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

Pursuant to our Articles of Association, holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting.

**Quorum**

The quorum required for our general meetings of shareholders consists of at least two shareholders present in person, by proxy or written ballot who hold or represent between them at least 25% of the total outstanding voting rights.

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

**Resolutions**

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

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

- an appointment or removal of directors;

- an approval of transactions with office holders or interested or related parties;

- an approval of a merger or any other matter in respect of which there is a provision in the articles of association providing that decisions of the general meeting may also be passed by written ballot;

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

- other matters which may be prescribed by Israel's Minister of Justice.

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

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

Unless otherwise stated under the Companies Law, or provided in a company's articles of association a resolution at a shareholders meeting requires approval by a simple majority of the voting rights represented at the meeting, in person, by proxy or written ballot, and voting on the resolution. Under the Companies Law, unless otherwise provided in a company's articles of association or under applicable law, all resolutions of the shareholders of a company require a simple majority.

Under Amendment 20, the board of directors of an Israeli publicly traded company is required to establish a compensation policy, to be approved by the shareholders of the company, pursuant to which the terms of office and compensation of the company's officer holders will be decided. The final adoption of such compensation policy is subject to the approval of the shareholders, which approval is subject to certain special majority requirements, as set forth in the Companies Law, pursuant to which one of the following must be met:

(i) the majority of the votes includes at least a majority of all the votes of shareholders who are not controlling shareholders of the company or who do not have a personal interest in the compensation policy and participating in the vote; abstentions shall not be included in the total of the votes of the aforesaid shareholders; or

(ii) the total of opposing votes from among the shareholders described in subsection (i) above does not exceed 2% of all the voting rights in the company**.**

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

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

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

**Access to Corporate Records**

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

**Acquisitions under Israeli Law**

***Full Tender Offer***

A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the same class for the purchase of all of the issued and outstanding shares of the same class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved the tender offer except that if the total votes to reject the tender offer represent less than 2% of the company's issued and outstanding share capital, in the aggregate, approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer). However, a shareholder that had its shares so transferred may petition the court within six months from the date of acceptance of the full tender offer, whether or not such shareholder agreed to the tender, to determine whether the tender offer was for less than fair value and whether the fair value should be paid as determined by the court unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights. If the shareholders who did not accept the tender offer hold 5% or more of the issued and outstanding share capital of the company or of the applicable class, the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

***Special Tender Offer***

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

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

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

***Merger***

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

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

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

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

***Antitakeover Measures***

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

**C. Material Contracts**

For a discussion of our out-licensing and in-licensing agreements, see Item 4. The following are summary descriptions of certain other material contracts to which we are a party. The descriptions provided below do not purport to be complete and are qualified in their entirety by the complete agreements, which are attached as exhibits to this Annual Report on Form 20-F.

***Share Purchase Agreement with LPC***

On May 28, 2014, we entered into a purchase agreement with LPC, pursuant to which LPC agreed to purchase from us up to $20 million of our ADSs (subject to certain limitations) from time to time over a 36-month period. Also on May 28, 2014, we entered into a registration rights agreement with LPC, pursuant to which we filed a registration statement on May 30, 2014 with the SEC for 10,400,000 of our ADSs, covering the ADSs that have been issued or may be issued to LPC under the purchase agreement. The registration statement was declared effective on June 12, 2014.

In consideration for entering into the purchase agreement, we issued to 150,000 ADSs to LPC upon execution of the purchase agreement as an initial commitment fee, and we will issue additional ADSs to LPC as an additional commitment fee in connection with each purchase by LPC under the purchase agreement equal to 2.5% of the amount of ADSs issued on each applicable purchase date. We will issue these additional commitment ADSs only when, and if, we elect to sell ADSs to LPC under the purchase agreement.

We can sell up to $200,000 worth of ADSs to LPC (which amount may be increased based on the trading price of our ADSs on the applicable purchase date), so long as at least one business day has passed between (i) the date on which LPC received all of the purchased ADSs in connection with the most recent prior purchase and (ii) the date we direct LPC to make a purchase. We control the timing and amount of any sales of our ADSs to LPC. Each time we direct LPC to purchase ADSs, subject to the terms of the purchase agreement, LPC will be obligated to purchase such amounts directed by us. LPC does not have the right to require us to sell any ADSs to them under the purchase agreement and we have no obligation to sell any shares under the purchase agreement.

The purchase price of the ADSs sold to LPC under the purchase agreement will be based on the market price of our ADSs immediately preceding the time of sale as computed under the purchase agreement, without any fixed discount and as more fully described in the purchase agreement. In addition, on any business day on which we have properly directed LPC to make a regular purchase, we can also accelerate the amount of our ADSs to be purchased under certain circumstances. Accelerated purchases may be made in amounts of up to the lesser of (i) 25% of the aggregate ADSs traded on Nasdaq during normal trading hours on the accelerated purchase date and (ii) three times the number of ADSs purchased pursuant to the corresponding regular purchase.

LPC may not assign or transfer its rights and obligations under the purchase agreement. We may at any time in our sole discretion terminate the purchase agreement without fee, penalty or cost. The purchase agreement will automatically terminate on July 1, 2017.

As of the date of this report, we have not yet sold any ADSs to LPC in accordance with the purchase agreement.

***Investment and Collaboration Agreement with Novartis***

In December 2014, we entered into a multi-year strategic collaboration agreement with Novartis Pharma AG, or Novartis designed to facilitate development and commercialization of Israeli-sourced pharmaceutical candidates. Novartis will evaluate projects identified and presented by us for co-development and future licensing under the collaboration. The parties intend to co-develop a number of pre-clinical and clinical therapeutic projects up to clinical proof of concept. As part of the agreement, Novartis made an initial equity investment in BioLineRx of $10 million, for 12.8% of our then current shares outstanding. Novartis has agreed to certain restrictions on the percentage of our outstanding capital it may own, on the exercise of its rights as a shareholder and on its sales of the shares it owns.

The parties have agreed on the establishment of a joint steering committee, or JSC, to oversee, implement and coordinate the collaboration contemplated by the agreement and on a process for screening and selecting projects. For each clinical project which the JSC selects for in-licensing by us within the framework of the collaboration (a “Selected Project”), Novartis will pay us a fixed, non-refundable option fee of $5 million (the “Option Fee”), as well as fund 50% of the anticipated remaining development costs associated with establishing clinical proof-of-concept, in the form of an additional equity investment in BioLineRx. The parties have agreed on procedures for funding and continuing the development of a Selected Project if cost overruns arise. We will retain full control over the development process of Selected Projects; provided, however, Novartis and we will continue to consult on the progress of the implementation of the development plan for the Selected Project.

For each Selected Project, Novartis will have, during a defined period (the "ROFN Period"), a first right to commence exclusive negotiations to obtain a sublicense with respect to the particular Selected Project. If no definitive sublicense agreement has been entered into prior to the end of the ROFN Period (or any longer period that may be agreed in writing between the parties), we will be entitled to pursue licensing or similar opportunities with third parties ("Third Party Opportunities") with respect to such Selected Project.

The arrangements between Novartis and us set out in the agreement are to be mutually exclusive and neither may take any action to circumvent the other with respect to the matters set out in the Agreement.

Before entering into a sublicense agreement with Novartis with respect to a specific project, all data, results, developments, inventions and know-how and all intellectual property rights therein and thereto, generated or discovered in the course of performing research and development activities in the context of any project ("Project IP") shall be our exclusive property, regardless of whether Novartis has funded any activities that resulted in Project IP.

The term of the Agreement, unless earlier terminated as permitted by the agreement, will continue in effect until the first to occur of (i) payment by Novartis of the Option Fee in respect of a certain number of "Projects," as defined in the Agreement or (ii) the later of (A) three years from the effective date of the agreement or (B) the presentation by us to Novartis at the JSC of a certain number of projects of the types agreed on by the parties.

**D. Exchange Controls**

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

**E. Taxation**

*The following description is not intended to constitute a complete analysis of all tax consequences relating to the ownership or disposition of our ordinary shares or ADSs, both referred to in this Item 10E as the Shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign, including Israeli, or other taxing jurisdiction.*

**Israeli Tax Considerations**

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

***General Corporate Tax Structure in Israel***

Israeli companies are generally subject to corporate tax at the rate of 26.5% of their taxable income beginning in 2014 and thereafter. Capital gains derived by an Israeli company are now generally subject to tax at the same rate as the corporate tax rate.

In May 2012, the Israeli Tax Authority, or ITA, approved our eligibility for tax benefits as a "Benefited Enterprise" under the Law for the Encouragement of Capital Investments, 5719-1959, as amended, or Investments Law, with respect to a portion of the consideration deriving from certain of our development programs, or Eligible Projects. Subject to compliance with the applicable requirements, the portion of our undistributed income derived from our Benefited Enterprise programs will be entitled to a tax exemption for a period of ten years commencing in the first year in which we generate taxable income after setting off our losses for Israeli tax purposes from prior years in the amount of approximately $120 million. The ten-year period may not extend beyond 14 years from the beginning of the Benefited Enterprise's election year. We received Benefited Enterprise status with respect to the Eligible Projects beginning in the 2009 tax year, so depending on when the Benefited Enterprise programs begin to generate taxable income, the benefit period could continue through 2022. However, any distribution of income derived from our Benefited Enterprise programs will result in such income being subject to a rate of corporate tax no greater than 25%.

Beginning with tax year 2014, we have the option to transition to a "Preferred Enterprise" regime under the Investments Law, according to which all of our income which is eligible for benefits under the regime would be subject to flat corporate tax rates of 9% in 2014 and thereafter, whether or not distributed. If we were to move our operations to a different part of the country, these rates may be increased. A transition to a Preferred Enterprise regime may not be reversed.

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

Should we not meet the requirements for maintaining these benefits, they may be reduced or cancelled and, among other things, our income deriving from the Eligible Projects (assuming we are profitable after offsetting losses) would be subject to Israeli corporate tax at the standard rate, which is set at 26.5% for 2014 and onwards. If these tax benefits are reduced or eliminated, the amount of taxes that we pay would likely increase, as all of our operations would consequently be subject to corporate tax at the standard rate, which could adversely affect our results of operations.

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

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

However, in the case of both Israeli individual shareholders and Israeli resident corporations, under the Investments Law, dividends distributed from taxable income accrued during the period of benefit of a Benefited Enterprise and which are attributable to a Benefited Enterprise are subject to tax at the rate of 15%, if the dividend is distributed during the tax benefit period under the Investment Law or within 12 years after that period. A weighted average rate may be set if the dividend is distributed from mixed types of income (regular and Benefited Enterprise income). This 15% tax rate similarly applies to dividends sourced from profits attributable to a Preferred Enterprise which are paid to Israeli resident individual shareholders, while such dividends paid to Israeli resident corporations are generally tax-exempt.

*Taxation of Non-Israeli Shareholders on Receipt of Dividends.* Non-residents of Israel are generally subject to Israeli income tax on the receipt of dividends paid on our Shares at the rate of 25% (or 30% if such person is a "substantial shareholder" at the time receiving the dividend or on any date in the 12 months preceding such date), which tax will be withheld at the source, unless a lower rate is provided in a tax treaty between Israel and the shareholder's country of residence. If the income out of which the dividend is being paid is sourced from profits attributable to a Benefited Enterprise under the Investments Law, the rate is generally not more than 15%.

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

A "substantial shareholder" is generally a person who alone, or together with his relative or another person who collaborates with him on a regular basis, holds, directly or indirectly, at least 10% of any of the "means of control" of the corporation. "Means of control" generally include the right to vote, receive profits, nominate a director or an officer, receive assets upon liquidation, or instruct someone who holds any of the aforesaid rights regarding the manner in which he or she is to exercise such right(s), and all regardless of the source of such right.

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

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

*Capital Gains Taxes Applicable to Israeli Resident Shareholders.* An individual is subject to a tax at a rate of 25% on actual capital gains derived from the sale of shares, as long as the individual is not a substantial shareholder in the company issuing the shares.

An individual who is a substantial shareholder is subject to tax at a rate of 30% in respect of actual capital gains derived from the sale of shares issued by the company in which he or she is a substantial shareholder. The determination of whether the individual is a substantial shareholder will be made on the date that the securities are sold. In addition, the individual will be deemed to be a substantial shareholder if at any time during the 12 months preceding the date he or she had been a substantial shareholder.

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

In addition, under the U.S.-Israel Tax Treaty, the sale, exchange or disposition of our Shares by a shareholder who is a U.S. resident (for purposes of the U.S.-Israel Tax Treaty) holding the Shares as a capital asset is exempt from Israeli capital gains tax unless (1) the shareholder holds, directly or indirectly, shares representing 10% or more of our voting capital during any part of the 12-month period preceding such sale, exchange or disposition; (2) the capital gains arising from such sale are attributable to a permanent establishment of the shareholder located in Israel; (3) a shareholder who is an individual is present in Israel for a period or periods aggregating 183 days or more during a taxable year. In either case, the sale, exchange or disposition of Shares would be subject to Israeli tax, to the extent applicable; however, under the U.S.-Israel Tax Treaty, the U.S. resident would be permitted to claim a credit for the tax against the U.S. federal income tax imposed with respect to the sale, exchange or disposition, subject to the limitations in U.S. laws applicable to foreign tax credits. The U.S.-Israel Tax Treaty does not relate to U.S. state or local taxes.

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

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

The following is a general summary of the material U.S. federal income tax considerations relating to the purchase, ownership and disposition of our Shares by U.S. Investors (as defined below) that hold such Shares as capital assets. This summary is based on the Internal Revenue Code of 1986, as amended, or the Code, the regulations of the U.S. Department of the Treasury issued pursuant to the Code, or the Treasury Regulations, and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect, or to different interpretation. This summary is for general information only and does not address all of the tax considerations that may be relevant to specific U.S. Investors in light of their particular circumstances or to U.S. Investors subject to special treatment under U.S. federal income tax law (such as banks, insurance companies, tax-exempt entities, retirement plans, regulated investment companies, partnerships, dealers in securities, brokers, real estate investment trusts, certain former citizens or residents of the United States, persons who acquire Shares as part of a straddle, hedge, conversion transaction or other integrated investment, persons that have a "functional currency" other than the U.S. dollar, persons that own (or are deemed to own, indirectly or by attribution) 10% or more of our shares or persons that generally mark their securities to market for U.S. federal income tax purposes). This summary does not address any U.S. state or local or non-U.S. tax considerations or any U.S. federal estate, gift or alternative minimum tax considerations.

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

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

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

***Taxation of U.S. Investors***

The discussions under "— Distributions" and under "— Sale, Exchange or Other Disposition of Ordinary Shares" below assumes that we will not be treated as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. However, we have not determined whether we will be a PFIC in 2015, and it is possible that we will be a PFIC in 2015 or in any subsequent year. For a discussion of the rules that would apply if we are treated as a PFIC, see the discussion under "— Passive Foreign Investment Company."

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

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

Since the rules governing foreign tax credits are complex, U.S. Investors should consult their own tax advisor regarding the availability of foreign tax credits in their particular circumstances. In addition, the U.S. Treasury Department has expressed concerns that parties to whom ADSs are pre-released may be taking actions that are inconsistent with the claiming of foreign tax credits by U.S. holders of ADSs. Accordingly, the creditability of Israeli taxes could be affected by future actions that may be taken by the U.S. Treasury Department or parties to whom ADSs are pre-released.

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

Distributions treated as dividends that are received by an individual U.S. Investor from "qualified foreign corporations" generally qualify for a reduced maximum tax rate so long as certain holding period and other requirements are met. Dividends paid by us in a taxable year in which we are not a PFIC are expected to be eligible for the reduced maximum tax rate. However, any dividend paid by us in a taxable year in which we are a PFIC will be subject to tax at regular ordinary income rates. As mentioned above, we have not determined whether we are currently a PFIC or not.

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

*Medicare Tax.* In addition, with respect to taxable years beginning after December 31, 2012, certain U.S. persons, including individuals, estates and trusts, will be subject to an additional 3.8% Medicare tax on unearned income. For individuals, the additional Medicare tax applies to the lesser of (i) "net investment income" or (ii) the excess of "modified adjusted gross income" over $200,000 ($250,000 if married and filing jointly or $125,000 if married and filing separately). "Net investment income" generally equals the taxpayer's gross investment income reduced by the deductions that are allocable to such income. Investment income generally includes passive income such as interest, dividends, annuities, royalties, rents, and capital gains. U.S. Investors are urged to consult their own tax advisors regarding the implications of the additional Medicare tax resulting from their ownership and disposition of Shares.

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

***Passive Foreign Investment Company***

In general, a corporation organized outside the United States will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (i) at least 75% of its gross income is "passive income" or (ii) on average at least 50% of its assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in the public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

Under the tests described above, whether or not we are a PFIC will be determined annually based upon the composition of our income and the composition and valuation of our assets, all of which are subject to change.

We believe that we were a PFIC for U.S. federal income tax purposes for years prior to 2009 and in 2011, 2012 and 2014. We were not a PFIC in 2009, 2010 and 2013, and we have not yet determined whether we will be a PFIC in 2015. Because the PFIC determination is highly fact intensive and made at the end of each taxable year, there can be no assurance that we will not be a PFIC in 2015 or in any subsequent year. Upon request, we will annually inform U.S. Investors if we and any of our subsidiaries were a PFIC with respect to the preceding year.

U.S. Investors should be aware of certain tax consequences of investing directly or indirectly in us if we are a PFIC. A U.S. Investor is subject to different rules depending on whether the U.S. Investor makes an election to treat us as a "qualified electing fund," known as a QEF election, for the first taxable year that the U.S. Investor holds Shares, which is referred to in this disclosure as a "timely QEF election," makes a "mark-to-market" election with respect to the Shares (if such election is available) or makes neither election.

*QEF Election.* A U.S. Investor who makes a timely QEF election, referred to in this disclosure as an "Electing U.S. Investor," with respect to us must report for U.S. federal income tax purposes his pro rata share of our ordinary earnings and net capital gain, if any, for our taxable year that ends with or within the taxable year of the Electing U.S. Investor. The "net capital gain" of a PFIC is the excess, if any, of the PFIC's net long-term capital gains over its net short-term capital losses. The amount so included in income generally will be treated as ordinary income to the extent of such Electing U.S. Investor's allocable share of the PFIC's ordinary earnings and as long-term capital gain to the extent of such Electing U.S. Investor's allocable share of the PFIC's net capital gains. Such Electing U.S. Investor generally will be required to translate such income into U.S. dollars based on the average exchange rate for the PFIC's taxable year with respect to the PFIC's functional currency. Such income generally will be treated as income from sources outside the United States for U.S. foreign tax credit purposes. Amounts previously included in income by such Electing U.S. Investor under the QEF rules generally will not be subject to tax when they are distributed to such Electing U.S. Investor. The Electing U.S. Investor's tax basis in Shares generally will increase by any amounts so included under the QEF rules and decrease by any amounts not included in income when distributed.

An Electing U.S. Investor will be subject to U.S. federal income tax on such amounts for each taxable year in which we are a PFIC, regardless of whether such amounts are actually distributed to such Electing U.S. Investor. However, an Electing U.S. Investor may, subject to certain limitations, elect to defer payment of current U.S. federal income tax on such amounts, subject to an interest charge. If an Electing U.S. Investor is an individual, any such interest will be treated as non-deductible "personal interest."

Any net operating losses or net capital losses of a PFIC will not pass through to the Electing U.S. Investor and will not offset any ordinary earnings or net capital gain of a PFIC recognized by Electing U.S. Investors in subsequent years (although such losses would ultimately reduce the gain, or increase the loss, recognized by the Electing U.S. Investor on its disposition of the Shares).

So long as an Electing U.S. Investor's QEF election with respect to us is in effect with respect to the entire holding period for Shares, any gain or loss recognized by such Electing U.S. Investor on the sale, exchange or other disposition of such Shares generally will be long-term capital gain or loss if such Electing U.S. Investor has held such Shares for more than one year at the time of such sale, exchange or other disposition. Preferential tax rates for long-term capital gain will apply to individual U.S. Investors. The deductibility of capital losses is subject to limitations.

A U.S. Investor makes a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. Upon request, we will annually furnish U.S. Investors with information needed in order to complete IRS Form 8621 (which form would be required to be filed with the IRS on an annual basis by the U.S. Investor) and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC. A QEF election will not apply to any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Each U.S. Investor is encouraged to consult its own tax advisor with respect to tax consequences of a QEF election with respect to us.

*Mark-to-Market Election.* Alternatively, if our Shares are treated as "marketable stock," a U.S. Investor would be allowed to make a "mark-to-market" election with respect to our Shares, provided the U.S. Investor completes and files IRS Form 8621 in accordance with the relevant instructions and related Treasury Regulations. If that election is made, the U.S. Investor generally would include as ordinary income in each taxable year the excess, if any, of the fair market value of the Shares at the end of the taxable year over such holder's adjusted tax basis in the Shares. The U.S. Investor would also be permitted an ordinary loss in respect of the excess, if any, of the U.S. Investor's adjusted tax basis in the Shares over their fair market value at the end of the taxable year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. A U.S. Investor's tax basis in the Shares would be adjusted to reflect any such income or loss amount. Gain realized on the sale, exchange or other disposition of the Shares would be treated as ordinary income, and any loss realized on the sale, exchange or other disposition of the Shares would be treated as ordinary loss to the extent that such loss does not exceed the net mark-to-market gains previously included in income by the U.S. Investor, and any loss in excess of such amount will be treated as capital loss. Amounts treated as ordinary income will not be eligible for the favorable tax rates applicable to qualified dividend income or long-term capital gains.

Generally, stock will be considered marketable stock if it is "regularly traded" on a "qualified exchange" within the meaning of applicable Treasury regulations. A class of stock is regularly traded on an exchange during any calendar year during which such class of stock is traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter. Our ADSs will be marketable stock as long as they remain listed on the Nasdaq Capital Market and are regularly traded. A mark-to-market election will not apply to our ADSs held by a U.S. Investor for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election will not apply to any PFIC subsidiary that we own. Each U.S. Investor is encouraged to consult its own tax advisor with respect to the availability and tax consequences of a mark-to-market election with respect to our ADSs.

*Default PFIC Rules*. A U.S. Investor who does not make a timely QEF election or a mark-to-market election, referred to in this disclosure as a "Non-Electing U.S. Investor," will be subject to special rules with respect to (a) any "excess distribution" (generally, the portion of any distributions received by the Non-Electing U.S. Investor on the Shares in a taxable year in excess of 125% of the average annual distributions received by the Non-Electing U.S. Investor in the three preceding taxable years, or, if shorter, the Non-Electing U.S. Investor's holding period for his Shares), and (b) any gain realized on the sale or other disposition of such Shares. Under these rules:

- the excess distribution or gain would be allocated ratably over the Non-Electing U.S. Investor's holding period for the Shares;
- the amount allocated to the current taxable year and any year prior to us becoming a PFIC would be taxed as ordinary income; and
- the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year.

If a Non-Electing U.S. Investor who is an individual dies while owning our Shares, the Non-Electing U.S. Investor's successor would be ineligible to receive a step-up in tax basis of the Shares. Non-Electing U.S. Investors are encouraged to consult their tax advisors regarding the application of the PFIC rules to their specific situation.

A Non-Electing U.S. Investor who wishes to make a QEF election for a subsequent year may be able to make a special "purging election" pursuant to Section 1291(d) of the Code. Pursuant to this election, a Non-Electing U.S. Investor would be treated as selling his or her stock for fair market value on the first day of the taxable year for which the QEF election is made. Any gain on such deemed sale would be subject to tax under the rules for Non-Electing U.S. Investors as discussed above. Non-Electing U.S. Investors are encouraged to consult their tax advisors regarding the availability of a "purging election" as well as other available elections.

To the extent a distribution on our Shares does not constitute an excess distribution to a Non-Electing U.S. Investor, such Non-Electing U.S. Investor generally will be required to include the amount of such distribution in gross income as a dividend to the extent of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) that are not allocated to excess distributions. The tax consequences of such distributions are discussed above under "— Taxation of U.S. Investors — Distributions." Each U.S. Investor is encouraged to consult its own tax advisor with respect to the appropriate U.S. federal income tax treatment of any distribution on our Shares.

If we are treated as a PFIC for any taxable year during the holding period of a Non-Electing U.S. Investor, we will continue to be treated as a PFIC for all succeeding years during which the Non-Electing U.S. Investor is treated as a direct or indirect Non-Electing U.S. Investor even if we are not a PFIC for such years. A U.S. Investor is encouraged to consult its tax advisor with respect to any available elections that may be applicable in such a situation, including the "deemed sale" election of Code Section 1298(b)(1). In addition, U.S. Investors should consult their tax advisors regarding the IRS information reporting and filing obligations that may arise as a result of the ownership of shares in a PFIC.

We may invest in the equity of foreign corporations that are PFICs or may own subsidiaries that own PFICs. U.S. Investors will be subject to the PFIC rules with respect to their indirect ownership interests in such PFICs, such that a disposition of the shares of the PFIC or receipt by us of a distribution from the PFIC generally will be treated as a deemed disposition of such shares or the deemed receipt of such distribution by the U.S. Investor, subject to taxation under the PFIC rules. There can be no assurance that a U.S. Investor will be able to make a QEF election or a mark-to-market election with respect to PFICs in which we invest. Each U.S. Investor is encouraged to consult its own tax advisor with respect to tax consequences of an investment by us in a corporation that is a PFIC.

**The U.S. federal income tax rules relating to PFICs are complex. U.S. Investors are urged to consult their own tax advisors with respect to the purchase, ownership and disposition of Shares, any elections available with respect to such Shares and the IRS information reporting obligations with respect to the purchase, ownership and disposition of Shares.**

***Certain Reporting Requirements***

Certain U.S. Investors are required to file IRS Form 926, Return by U.S. Transferor of Property to a Foreign Corporation, and certain U.S. Investors may be required to file IRS Form 5471, Information Return of U.S. Persons With Respect to Certain Foreign Corporations, reporting transfers of cash or other property to us and information relating to the U.S. Investor and us. Substantial penalties may be imposed upon a U.S. Investor that fails to comply. Each U.S. Investor should consult its own tax advisor regarding these requirements.

In addition, recently enacted legislation imposes new reporting requirements for the holder of certain foreign financial assets, including equity of foreign entities, if the aggregate value of all of these assets exceeds $50,000. The Shares are expected to be subject to these new reporting requirements unless the Shares are held in an account at a domestic financial institution. The requirement to file a report is effective for taxable years beginning after March 18, 2010. Penalties apply to any failure to file a required report. U.S. Investors should consult their own tax advisors regarding the application of this legislation.

***Backup Withholding Tax and Information Reporting Requirements***

Generally, information reporting requirements will apply to distributions on our Shares or proceeds on the disposition of our Shares paid within the United States (and, in certain cases, outside the United States) to U.S. Investors other than certain exempt recipients, such as corporations. Furthermore, backup withholding (currently at 28%) may apply to such amounts if the U.S. Investor fails to (i) provide a correct taxpayer identification number, (ii) report interest and dividends required to be shown on its U.S. federal income tax return, or (iii) make other appropriate certifications in the required manner. U.S. Investors who are required to establish their exempt status generally must provide such certification on IRS Form W-9.

Backup withholding is not an additional tax. Amounts withheld as backup withholding from a payment may be credited against a U.S. Investor's U.S. federal income tax liability and such U.S. Investor may obtain a refund of any excess amounts withheld by filing the appropriate claim for refund with the IRS and furnishing any required information in a timely manner.

**U.S. Investors should consult their own tax advisors concerning the tax consequences relating to the purchase, ownership and disposition of the Shares.**

**F. Dividends and Paying Agents**

Not applicable

**G. Statement by Experts**

Not applicable.

**H. Documents on Display**

We are currently subject to the information and periodic reporting requirements of the Exchange Act, and file periodic reports and other information with the SEC through its electronic data gathering, analysis and retrieval (EDGAR) system. Our securities filings, including this Annual Report and the exhibits thereto, are available for inspection and copying at the public reference facilities of the SEC located at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains a website at *http://www.sec.gov* from which certain filings may be accessed.

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

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

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

**I. Subsidiary Information**

Not applicable.

**ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURE ON MARKET RISK**

Market risk is the risk of loss related to changes in market prices, including interest rates and foreign exchange rates, of financial instruments that may adversely impact our consolidated financial position, results of operations or cash flows. We do not use derivative financial instruments for trading purposes. Accordingly, we have concluded that there is no material market risk exposure of the type contemplated by Item 11, and that no quantitative tabular disclosures are required. We are exposed to certain other types of market risks, as described below.

**Risk of Interest Rate Fluctuation**

Our investments consist primarily of cash, cash equivalents and short-term bank deposits. We may also invest in investment-grade marketable securities with maturities of up to three years, including commercial paper, money market funds, and government/non-government debt securities. The primary objective of our investment activities is to preserve principal while maximizing the income that we receive from our investments without significantly increasing risk and loss. Our investments are exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments. We manage this exposure by performing ongoing evaluations of our investments. Due to the short-term maturities of our investments to date, their carrying value has always approximated their fair value. It will be our policy to hold investments to maturity in order to limit our exposure to interest rate fluctuations.

**Foreign Currency Exchange Risk**

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

From time to time, we engage in hedging transactions. Although the Israeli rate of inflation has not had a material adverse effect on our financial condition during 2012, 2013 or 2014, we may, in the future, decide to enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

**ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

**A. Debt Securities**

Not applicable.

**B. Warrants and Rights**

Not applicable.

**C. Other Securities**

Not applicable.

**D. American Depositary Shares**

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

**Description of the ADSs**

Each of our ADSs represents 10 of our ordinary shares. Our ADSs trade on the Nasdaq Capital Market.

The form of the deposit agreement for the ADS and the form of American Depositary Receipt (ADR) that represents an ADS have been incorporated by reference as exhibits to this Annual Report on Form 20-F. Copies of the deposit agreement are available for inspection at the principal office of The Bank of New York Mellon, located at 101 Barclay Street, New York, New York 10286, and at the principal office of our custodians, Bank Leumi Le-Israel, 34 Yehuda Halevi St., Tel-Aviv 65546, Israel and Bank Hapoalim B.M., 104 Hayarkon Street, Tel Aviv 63432, Israel.

**Dividends, Other Distributions and Rights**

Amounts distributed to ADS holders will be reduced by any taxes or other governmental charges required to be withheld by the custodian or the Depositary. If the Depositary determines that any distribution in cash or property is subject to any tax or governmental charges that the Depositary or the custodian is obligated to withhold, the Depositary may use the cash or sell or otherwise dispose of all or a portion of that property to pay the taxes or governmental charges. The Depositary will then distribute the balance of the cash and/or property to the ADS holders entitled to the distribution, in proportion to their holdings.

*Cash dividends and cash distributions.* The Depositary will convert into dollars all cash dividends and other cash distributions that it or the custodian receives in a foreign currency. The Depositary will distribute to the ADS holders the amount it receives, after deducting any currency conversion expenses. If the Depositary determines that any foreign currency it receives cannot be converted and transferred on a reasonable basis, it may distribute the foreign currency (or an appropriate document evidencing the right to receive the currency), or hold that foreign currency uninvested, without liability for interest, for the accounts of the ADS holders entitled to receive it.

*Distributions of ordinary shares.* If we distribute ordinary shares as a dividend or free distribution, the Depositary may, with our approval, and will, at our request, distribute to ADS holders new ADSs representing the ordinary shares. The Depositary will distribute only whole ADSs. It will sell the ordinary shares that would have required it to use fractional ADSs and then distribute the proceeds in the same way it distributes cash. If the Depositary deposits the ordinary shares but does not distribute additional ADSs, the existing ADSs will also represent the new ordinary shares.

If holders of ordinary shares have the option of receiving a dividend in cash or in shares, we may also grant that option to ADS holders.

*Other distributions.* If the Depositary or the custodian receives a distribution of anything other than cash or shares, the Depositary will distribute the property or securities to the ADS holder, in proportion to such holder’s holdings upon payment of its fees. If the Depositary determines that it cannot distribute the property or securities in this manner or that it is not feasible to do so, then, after consultation with us, it may distribute the property or securities by any means it thinks are equitable and practical, or it may sell the property or securities and distribute the net proceeds of the sale to the ADS holders. The Depositary may sell a portion of any distributed property that is sufficient to pay its fees.

*Rights to subscribe for additional ordinary shares and other rights.* If we offer our holders of ordinary shares any rights to subscribe for additional ordinary shares or any other rights, the Depositary will, if requested by us:

- make the rights available to all or certain holders of ADSs, by means of warrants or otherwise, if lawful and practically feasible; or
- if it is not lawful or practically feasible to make the rights available, attempt to sell those rights or warrants or other instruments.

In that case, the Depositary will allocate the net proceeds of the sales to the account of the ADS holders entitled to the rights. The allocation will be made on an averaged or other practicable basis without regard to any distinctions among holders.

If registration under the Securities Act of 1933, as amended, is required in order to offer or sell to the ADS holders the securities represented by any rights, the Depositary will not make the rights available to ADS holders unless a registration statement is in effect or such securities are exempt from registration. We do not, however, have any obligation to file a registration statement or to have a registration statement declared effective. If the Depositary cannot make any rights available to ADS holders and cannot dispose of the rights and make the net proceeds available to ADS holders, then it will allow the rights to lapse, and the ADS holders will not receive any value for them.

*Voting of the underlying shares.* Under the deposit agreement, an ADS holder is entitled, subject to any applicable provisions of Israeli law, our Articles of Association and bylaws and the deposited securities, to exercise voting rights pertaining to the shares represented by its ADSs. If we so request, the Depositary will send to ADS holders such information as is contained in the notice of meeting that the Depositary receives from us, as well as a statement that holders of as the close of business on the specified record date will be entitled to instruct the Depositary as to the exercise of voting rights and a statement as to the manner in which the such instructions may be given. Under the terms of the Deposit Agreement, the Depositary shall endeavor (insofar as is practicable and in accordance with the applicable law and the articles of association of the Company) to vote or cause to be voted the number of shares represented by ADSs in accordance with the instructions provided by the holders of ADSs to the Depositary. If no instructions are received by the Depositary from any holder of ADSs with respect to any of the shares represented by the ADSs evidenced by such holder's receipts on or before the date established by the Depositary for such purpose, then the Depositary will deem the holder of the shares to have instructed the Depositary to give a discretionary proxy to a person designated by us with respect to the shares represented by such ADSs, and the Depositary will give such instruction. In such case, the restrictions of the Israeli Companies Law with respect to "personal interest," as described elsewhere in this annual report, would apply as well.

*Changes affecting deposited securities.* If there is any change in nominal value or any split-up, consolidation, cancellation or other reclassification of deposited securities, or any recapitalization, reorganization, business combination or consolidation or sale of assets involving us, then any securities that the Depositary receives in respect of deposited securities will become new deposited securities. Each ADS will automatically represent its share of the new deposited securities, unless the Depositary delivers new ADSs as described in the following sentence. The Depositary may distribute new ADSs or ask ADS holders to surrender their outstanding ADRs in exchange for new ADRs describing the new deposited securities.

*Amendment of the deposit agreement.* The Depositary and we may agree to amend the form of the ADSs and the deposit agreement at any time, without the consent of the ADS holders. If the amendment adds or increases any fees or charges (other than taxes or other governmental charges) or prejudices an important right of ADS holders, it will not take effect as to outstanding ADSs until 30 days after the Depositary has sent the ADS holders a notice of the amendment. At the expiration of that 30-day period, each ADS holder will be considered by continuing to hold its ADSs to agree to the amendment and to be bound by the deposit agreement as so amended. The Depositary and we may not amend the deposit agreement or the form of ADRs to impair the ADS holder's right to surrender its ADSs and receive the ordinary shares and any other property represented by the ADRs, except to comply with mandatory provisions of applicable law.

*Termination of the deposit agreement.* The Depositary will terminate the deposit agreement if we ask it to do so and will notify the ADS holders at least 30 days before the date of termination. The Depositary may also terminate the deposit agreement if it resigns and a successor depositary has not been appointed by us and accepted its appointment within 60 days after the Depositary has given us notice of its resignation. After termination of the deposit agreement, the Depositary will no longer register transfers of ADSs, distribute dividends to the ADS holders, accept deposits of ordinary shares, give any notices, or perform any other acts under the deposit agreement whatsoever, except that the Depositary will continue to:

- collect dividends and other distributions pertaining to deposited securities;
- sell rights as described under the heading "Dividends, Other Distributions and Rights — Rights to subscribe for additional shares and other rights" above; and
- deliver deposited securities, together with any dividends or other distributions received with respect thereto and the net proceeds of the sale of any rights or other property, in exchange for surrendered ADRs.

Four months after termination, the Depositary may sell the deposited securities and hold the proceeds of the sale, together with any other cash then held by it, for the pro rata benefit of ADS holders that have not surrendered their ADSs. The Depositary will not have liability for interest on the sale proceeds or any cash it holds.

**Charges of Depositary**

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

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

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

**Liability of Holders for Taxes, Duties or Other Charges**

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

**ITEM 13. DEFAULTS, DIVIDENDS, ARREARAGES AND DELINQUENCIES**

Not applicable.

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

Not applicable.

**ITEM 15. CONTROLS AND PROCEDURES**

(a) **Disclosure Controls and Procedures**

We have performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that the material financial and non-financial information required to be disclosed to the SEC is recorded, processed, summarized and reported timely. Based on our evaluation, our management, including the CEO and CFO, has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report are effective. Notwithstanding the foregoing, there can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within the Company to disclose material information otherwise required to be set forth in our reports.

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

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

Our management, including the CEO and CFO, conducted an evaluation, pursuant to Rule 13a-15(c) promulgated under the Exchange Act, of the effectiveness, as of the end of the period covered by this Annual Report, of its internal control over financial reporting based on the framework in *Internal Control —Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013). Based on the results of this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2014.

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

Not applicable.

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

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 16. [RESERVED]**

**ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERTS**

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

**ITEM 16B. CODE OF ETHICS**

In July 2011, our Board of Directors adopted a Code of Business Conduct and Ethics (the "Code") that applies to all our employees, including without limitation our chief executive officer, chief financial officer and controller. Our Code may be viewed on our website at *www.biolinerx.com*. A copy of our Code may be obtained, without charge, upon a written request addressed to our investor relations department, P.O. Box 45158, 19 Hartum Street, Jerusalem 9777518, Israel (Telephone no. +972-2-548-9100) (e-mail: info@BioLineRx.com).

## ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

### Fees Paid to Independent Registered Public Accounting Firm

The following table sets forth, for each of the years indicated, the fees billed by our independent registered public accounting firms (members of PricewaterhouseCoopers International Ltd.).

| | Year Ended December 31, | |
|---|---|---|
| | **2013** | **2014** |
| **Services Rendered** | (in NIS 000's) | |
| Audit Fees(1) | 352 | 398 |
| Audit-Related Fees (2) | 48 | 49 |
| Tax Fees(3) | 259 | 116 |
| All Other Fees | – | – |
| Total | 659 | 563 |

(1) Audit fees consist of services that would normally be provided in connection with statutory and regulatory filings or engagements, including services that generally only the independent accountant can reasonably provide.
(2) Audit related services relate to reports to the OCS and work regarding a public listing or offering.
(3) Tax fees relate to tax compliance, planning and advice.

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

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

Not applicable.

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

Not applicable.

## ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

## ITEM 16G. CORPORATE GOVERNANCE

### Nasdaq Listing Rules and Home Country Practices

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

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

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

- *Quorum*. While the Marketplace Rules of the Nasdaq Stock Market require that the quorum for purposes of any meeting of the holders of a listed company's common voting stock, as specified in the company's bylaws, be no less than 33 1/3% of the company's outstanding common voting stock, under Israeli law, a company is entitled to determine in its articles of association the number of shareholders and percentage of holdings required for a quorum at a shareholders meeting. Our Articles of Association provide that a quorum of two or more shareholders holding at least 25% of the voting rights in person or by proxy is required for commencement of business at a general meeting. However, the quorum set forth in our Articles of Association with respect to an adjourned meeting consists of any number of shareholders present in person or by proxy.

- *Independent Directors*. Our Board of Directors includes two external directors in accordance with the provisions contained in Sections 239-249 of the Companies Law and Rule 10A-3 of the general rules and regulations promulgated under the Securities Act of 1933, rather than a majority of external directors. Israeli law does not require, nor do our independent directors conduct, regularly scheduled meetings at which only they are present. We are required, however, to ensure that all members of our Audit Committee are "independent" under the applicable Nasdaq and SEC criteria for independence (as a foreign private issuer we are not exempt from the SEC independence requirement), and we must also ensure that a majority of the members of our Audit Committee are unaffiliated directors as defined in the Companies Law. Furthermore, Israeli law does not require, nor do our independent directors conduct, regularly scheduled meetings at which only they are present, which the Marketplace Rules of the Nasdaq Stock Market otherwise require.

- *Audit Committee*. Our Audit Committee complies with all of the requirements under Israeli law, and is composed of two external directors, which are all of our external directors, and only one other director, who cannot be the chairman of our Board of Directors. Consistent with Israeli law, the independent auditors are elected at a meeting of shareholders instead of being appointed by the Audit Committee.

- *Nomination of our Directors*. With the exception of our external directors and directors elected by our Board of Directors due to vacancy, our directors are elected by a general or special meeting of our shareholders, to hold office until they are removed from office by the majority of our shareholders at a general or special meeting of our shareholders. See "— Board of Directors." The nominations for directors, which are presented to our shareholders, are generally made by our directors, but nominations may be made by one or more of our shareholders as provided in our Articles of Association, under the Companies Law or in an agreement between us and our shareholders. Currently, there is no agreement between us and any shareholder regarding the nomination of directors. In accordance with our Articles of Association, under the Companies Law, any one or more shareholders holding, in the aggregate, either (1) 5% of our outstanding shares and 1% of our outstanding voting power or (2) 5% of our outstanding voting power, may nominate one or more persons for election as directors at a general or special meeting by delivering a written notice of such shareholder's intent to make such nomination or nominations to our registered office. Each such notice must set forth all of the details and information as required to be provided in our Articles of Association.

- *Compensation Committee and Compensation of Officers*. Israeli law, and our amended and restated articles of association, do not require that a compensation committee composed solely of independent members of our Board of Directors determine (or recommend to the board of directors for determination) an executive officer's compensation, as required underNasdaq's listing standards related to compensation committee independence and responsibilities; nor do they require that the Company adopt and file a compensation committee charter. Instead, our compensation committee has been established and conducts itself in accordance with provisions governing the composition of and the responsibilities of a compensation committee as set forth in the Companies Law, and is composed of two external directors, which are all of our external directors, and one additional director, who is not the chairman of our Board of Directors or otherwise employed by the Company. Additionally, we comply with the requirements set forth under the Companies Law, pursuant to which transactions with office holders regarding their terms of office and employment, and transaction with a controlling shareholder in a company regarding his or her employment and/or his or her terms of office with the company, may require the approval of the compensation committee, the board of directors and under certain circumstances the shareholders, either in accordance with our previously approved compensation policy or, in special circumstances in deviation therefrom, taking into account certain considerations set forth in the Companies Law. See "Item 6. Directors, Senior Management and Employees — Board Practices — Compensation Committee" for information regarding the Compensation Committee, and "Item 6. Directors, Senior Management and Employees — Approval of Related Party Transactions under Israeli Law" for information regarding the special approvals required with respect to approval of terms of office and employment of office holders, pursuant to the Companies Law, as set forth under Amendment 20. The requirements for shareholder approval of any office holder compensation, and the relevant majority or special majority for such approval, are all as set forth in the Companies Law. Thus, we will seek shareholder approval for all corporate actions with respect to office holder compensation requiring such approval under the requirements of the Companies Law, including seeking prior approval of the shareholders for the compensation policy and for certain office holder compensation, rather than seeking approval for such corporate actions in accordance with Nasdaq Listing Rules.

- *Approval of Related Party Transactions*. All related party transactions are approved in accordance with the requirements and procedures for approval of interested party acts and transactions, set forth in sections 268 to 275 of the Companies Law, and the regulations promulgated thereunder, which require the approval of the audit committee, the compensation committee, the board of directors and shareholders, as may be applicable, for specified transactions, rather than approval by the audit committee or other independent body of our Board of Directors as required under the Marketplace Rules of the Nasdaq Stock Market.

- *Shareholder Approval*. We seek shareholder approval for all corporate actions requiring such approval in accordance with the requirements of the Companies Law, which are different or in addition to the requirements for seeking shareholder approval under Nasdaq Listing Rule 5635, rather than seeking approval for corporation actions in accordance with such listing rules.

- *Equity Compensation Plans.* We do not necessarily seek shareholder approval shareholder approval for the establishment of, and amendments to, stock option or equity compensation plans (as set forth in NASDAQ Listing Rule 5635(c)), as such matters are not subject to shareholder approval under Israeli law. Our equity compensation plan is available to our employees, none of whom are currently U.S. employees, and provide features necessary to comply with applicable non-U.S. tax laws.

**ITEM 16H. MINE SAFETY DISCLOSURE**

Not applicable.

**ITEM 17. FINANCIAL STATEMENTS**

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

**ITEM 18. FINANCIAL STATEMENTS**

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

## ITEM 19. EXHIBITS

| Exhibit Number | Exhibit Description |
|---|---|
| 2.1[5] | Articles of Association of the Registrant, as amended May 15, 2012. |
| 2.2[2] | Form of Deposit Agreement dated as of July 21, 2011 among BioLineRx, Ltd., The Bank of New York Mellon, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder. |
| 2.3[2] | Form of American Depositary Receipt; the Form is Exhibit A of the Form of Depositary Agreement. |
| 4.3[1] | Employment Agreement with Kinneret Savitsky, Ph.D., dated October 13, 2004. |
| 4.5[1] | Employment Agreement with Philip Serlin, dated May 24, 2009. |
| 4.6†[1] | License Agreement entered into as of January 10, 2005, by and between BioLine Innovations Jerusalem L.P. and B.G. Negev Technologies and Applications Ltd. |
| 4.7[1] | Assignment Agreement dated as of January 1, 2009 entered into by and between BioLine Innovations Jerusalem L.P. and BioLineRx Ltd. |
| 4.16†[1] | License Agreement between Innovative Pharmaceutical Concepts, Inc. and BioLineRx Ltd. dated November 25, 2007. |
| 4.17† | Amended and Restated License and Commercialization Agreement by and among Ikaria Development Subsidiary One LLC and BioLineRx Ltd. and BioLine Innovations Jerusalem L.P. dated August 26, 2009, as amended and supplemented. |
| 4.18[10] | BioLineRx Ltd. Amended and Restated 2003 Share Incentive Plan. |
| 4.19[1] | Lease Agreement between Kaps-Pharma Ltd. and BioLine Innovations Jerusalem L.P., dated July 10, 2005, and Extension to Lease Agreement, dated December 4, 2008. |
| 4.20[1] | Amendment to Employment Agreement with Kinneret Savitsky, Ph.D., dated January 2, 2004. |
| 4.21[1] | Employment Agreement with Leah Klapper, Ph.D., dated January 27, 2005. |
| 4.28[1] | Sponsored Research Agreement entered into as of June 23, 2011 by and between Yissum Research Development Company of the Hebrew University of Jerusalem Ltd. and BioLineRx Ltd. |
| 4.29[1] | License Agreement entered into as of June 23, 2011 by and between Yissum Research Development Company of the Hebrew University of Jerusalem Ltd. and BioLineRx Ltd. |
| 4.30[4] | Employment Agreement with David Malek, dated August 8, 2011 |
| 4.31[3] | Form of Warrant to purchase American Depositary Shares |
| 4.32[7] | Form of Warrant to purchase American Depositary Shares |
| 4.33†[8] | License Agreement entered into as of September 2, 2012 by and between BioLineRx Ltd. and Biokine Therapeutics Ltd. |
| 4.34[10] | Consulting Agreement with Arnon Aharon, M.D., dated January 1, 2014 |

| Exhibit Number | Exhibit Description |
|---|---|
| 4.35[10]† | License Agreement entered into as of February 15, 2011 by Valorisation-Recherche, Limited Partnership, and BioLineRx Ltd. |
| 4.36[9] | Executive Compensation Plan |
| 4.37 | Lease Agreement entered into as of August 7, 2014 between S.M.L. Solomon Industrial Buildings Ltd. and Infrastructure Management and Development Established by C.P.M. Ltd. as Lessor and the Registrant as Lessee, as amended December 9, 2014 (English summary of the Hebrew original) |
| 4.38† | Investment and Collaboration Agreement entered into as of December 16, 2014 between Novartis Pharma AG and the Registrant |
| 4.39† | License Agreement entered into as of December 22, 2014 by the Registrant |
| 8.1[1] | List of subsidiaries of the Registrant. |
| 12.1 | Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 12.2 | Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 13.1 | Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 13.2 | Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 15.1[3] | Form of Purchase Agreement between BioLineRx Ltd. and the Purchasers named therein, dated February 15, 2012 |
| 15.4[7] | Subscription Agreement between BioLineRx Ltd. and OrbiMed Israel Partners Limited Partnership, dated February 6, 2013 |
| 15.5 | Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Registrant. |
| 15.6[6] | Purchase Agreement between BioLineRx Ltd. and Lincoln Park, LLC, dated May 28, 2014 |
| 15.7[6] | Registration Rights Agreement between BioLineRx Ltd. and Lincoln Park, LLC, dated May 28, 2014 |

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† 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 S-8 (No. 333-183976) filed on September 19, 2012.

(6) Incorporated by reference to the Registrant's Form 6-K filed on May 30, 2014.

(7) Incorporated by reference to the Registrant's Form 6-K filed on February 6, 2013.

(8) Incorporated by reference to the Registrant's Form 6-K filed on October 16, 2012.

(9) Incorporated by reference to the Registrant's Form 6-K filed on November 13, 2013.

(10) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 17, 2014.

**SIGNATURES**

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

BIOLINERX LTD.

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

Date: March 23, 2015

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

**Audited Consolidated Financial Statements at December 31, 2014 and 2013 and for each of the three years in the period ended December 31, 2014**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the shareholders of
**BioLineRx Ltd.**

We have audited the accompanying consolidated statements of financial position of BioLineRx Ltd. ("BioLineRx") and its consolidated entities as of December 31, 2014 and 2013 and the related consolidated statements of comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of BioLineRx's Board of Directors and management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by BioLineRx's Board of Directors and management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of BioLineRx and its consolidated entities as of December 31, 2014 and 2013 and their results of operations, changes in equity and cash flows for each of the three years in the period ended December 31, 2014, in conformity with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB").

Tel Aviv, Israel
March 23, 2015

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

*Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel,*
*P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il*

**BioLineRx Ltd.**

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

| | Note | December 31, | | Convenience translation into USD (Note 1b) December 31, |
|---|---|---|---|---|
| | | 2013 | 2014 | 2014 |
| | | NIS in thousands | | In thousands |
| **Assets** | | | | |
| **CURRENT ASSETS** | | | | |
| Cash and cash equivalents | 5 | 30,888 | 22,519 | 5,790 |
| Short-term bank deposits | 6 | 32,345 | 112,354 | 28,890 |
| Prepaid expenses | | 896 | 859 | 221 |
| Other receivables | 14a | 1,249 | 1,000 | 257 |
| Total current assets | | 65,378 | 136,732 | 35,158 |
| | | | | |
| **NON-CURRENT ASSETS** | | | | |
| Restricted deposits | 12b | 573 | 644 | 166 |
| Long-term prepaid expenses | 14b | 169 | 190 | 49 |
| Property and equipment, net | 7 | 2,471 | 2,804 | 721 |
| Intangible assets, net | 8 | 878 | 457 | 117 |
| Total non-current assets | | 4,091 | 4,095 | 1,053 |
| **Total assets** | | 69,469 | 140,827 | 36,211 |
| | | | | |
| **Liabilities and equity** | | | | |
| **CURRENT LIABILITIES** | | | | |
| Accounts payable and accruals: | | | | |
| Trade | 14c | 7,945 | 6,431 | 1,654 |
| Other | 14c | 2,499 | 4,869 | 1,252 |
| Total current liabilities | | 10,444 | 11,300 | 2,906 |
| | | | | |
| **NON-CURRENT LIABILITIES** | | | | |
| Retirement benefit obligations | | 152 | - | - |
| Warrants | 9c | 18,187 | 5,833 | 1,500 |
| Total non-current liabilities | | 18,339 | 5,833 | 1,500 |
| **COMMITMENTS AND CONTINGENT LIABILITIES** | 12 | | | |
| Total liabilities | | 28,783 | 17,133 | 4,406 |
| | | | | |
| **EQUITY** | 9 | | | |
| Ordinary shares | | 2,414 | 3,911 | 1,006 |
| Share premium | | 509,857 | 628,710 | 161,664 |
| Capital reserve | | 34,192 | 36,470 | 9,378 |
| Accumulated deficit | | (505,777) | (545,397) | (140,242) |
| Total equity | | 40,686 | 123,694 | 31,806 |
| **Total liabilities and equity** | | 69,469 | 140,827 | 36,211 |

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

**BioLineRx Ltd.**

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

| | Note | Year ended December 31, | | | Convenience translation into USD (Note 1b) |
|---|---|---|---|---|---|
| | | 2012 | 2013 | 2014 | 2014 |
| | | NIS in thousands | | | In thousands |
| **RESEARCH AND DEVELOPMENT EXPENSES, NET** | 14d | (64,304) | (44,057) | (42,443) | (10,914) |
| **SALES AND MARKETING EXPENSES** | 14e | (3,227) | (4,101) | (5,685) | (1,462) |
| **GENERAL AND ADMINISTRATIVE EXPENSES** | 14f | (14,026) | (13,225) | (13,591) | (3,495) |
| **OPERATING LOSS** | | (81,557) | (61,383) | (61,719) | (15,871) |
| **NON-OPERATING INCOME, NET** | 14g | 3,958 | 4,191 | 10,948 | 2,815 |
| **FINANCIAL INCOME** | 14h | 8,819 | 2,600 | 12,754 | 3,280 |
| **FINANCIAL EXPENSES** | 14i | (7,490) | (6,846) | (1,603) | (412) |
| **NET LOSS AND COMPREHENSIVE LOSS** | | (76,270) | (61,438) | (39,620) | (10,188) |
| | | NIS | | | USD |
| **LOSS PER ORDINARY SHARE – BASIC AND DILUTED** | 11 | (0.45) | (0.27) | (0.12) | (0.03) |
| **WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE** | 11 | 169,404,730 | 224,885,157 | 324,338,834 | 324,338,834 |

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

**BioLineRx Ltd.**

STATEMENTS OF CHANGES IN EQUITY

| | Ordinary shares | Share premium | Capital reserve | Accumulated deficit | Total |
|---|---|---|---|---|---|
| | | | NIS in thousands | | |
| **BALANCE AT JANUARY 1, 2012** | 1,236 | 421,274 | 31,317 | (368,069) | 85,758 |
| **CHANGES IN 2012:** | | | | | |
| Issuance of share capital, net | 601 | 42,700 | - | - | 43,301 |
| Employee stock options exercised | * | 272 | (270) | - | 2 |
| Employee stock options forfeited and expired | - | 383 | (383) | - | - |
| Share-based compensation | - | - | 3,138 | - | 3,138 |
| Comprehensive loss for the year | - | - | - | (76,270) | (76,270) |
| **BALANCE AT DECEMBER 31, 2012** | 1,837 | 464,629 | 33,802 | (444,339) | 55,929 |
| **CHANGES IN 2013:** | | | | | |
| Issuance of share capital, net | 573 | 42,313 | - | - | 42,886 |
| Employee stock options exercised | 2 | 1,465 | (1,457) | - | 10 |
| Warrants exercised | 2 | 257 | - | - | 259 |
| Employee stock options forfeited and expired | - | 1,193 | (1,193) | - | - |
| Share-based compensation | - | - | 3,040 | - | 3,040 |
| Comprehensive loss for the year | - | - | - | (61,438) | (61,438) |
| **BALANCE AT DECEMBER 31, 2013** | 2,414 | 509,857 | 34,192 | (505,777) | 40,686 |
| **CHANGES IN 2014:** | | | | | |
| Issuance of share capital, net | 1,497 | 117,359 | - | - | 118,856 |
| Employee stock options exercised | * | 77 | (77) | - | - |
| Employee stock options forfeited and expired | - | 1,417 | (1,417) | - | - |
| Share-based compensation | - | - | 3,772 | - | 3,772 |
| Comprehensive loss for the year | - | - | - | (39,620) | (39,620) |
| **BALANCE AT DECEMBER 31, 2014** | 3,911 | 628,710 | 36,470 | (545,397) | 123,694 |

* Represents an amount less than NIS 1,000.

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

**BioLineRx Ltd.**

STATEMENTS OF CHANGES IN EQUITY

| | Ordinary shares | Share premium | Capital reserve | Accumulated deficit | Total |
|---|---|---|---|---|---|
| | Convenience translation into USD thousands (Note 1b) | | | | |
| **BALANCE AT DECEMBER 31, 2013** | 621 | 131,102 | 8,792 | (130,054) | 10,461 |
| **CHANGES IN 2014:** | | | | | |
| Issuance of share capital, net | 385 | 30,178 | - | - | 30,563 |
| Employee stock options exercised | * | 20 | (20) | - | - |
| Employee stock options forfeited and expired | - | 364 | (364) | - | - |
| Share-based compensation | - | - | 970 | - | 970 |
| Comprehensive loss for the year | - | - | - | (10,188) | (10,188) |
| **BALANCE AT DECEMBER 31, 2014** | 1,006 | 161,664 | 9,378 | (140,242) | 31,806 |

* Represents an amount less than $1,000.

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

**BioLineRx Ltd.**

CONSOLIDATED CASH FLOW STATEMENTS

| | Year ended December 31, | | | Convenience translation into USD (Note 1b) |
|---|---|---|---|---|
| | 2012 | 2013 | 2014 | 2014 |
| | NIS in thousands | | | In thousands |
| **CASH FLOWS - OPERATING ACTIVITIES** | | | | |
| Net loss | (76,270) | (61,438) | (39,620) | (10,188) |
| Adjustments required to reflect net cash used in operating activities (see appendix below) | 1,125 | (9,026) | (16,763) | (4,310) |
| Net cash used in operating activities | (75,145) | (70,464) | (56,383) | (14,498) |
| | | | | |
| **CASH FLOWS - INVESTING ACTIVITIES** | | | | |
| Investments in short-term deposits | (12,025) | (129,359) | (206,449) | (53,086) |
| Maturities of short-term deposits | 64,801 | 107,049 | 136,408 | 35,075 |
| Investments in restricted deposits | (775) | - | - | - |
| Maturities of restricted deposits | - | 2,900 | - | - |
| Purchase of property and equipment | (598) | (309) | (674) | (173) |
| Purchase of intangible assets | (61) | (99) | (21) | (5) |
| Net cash provided by (used in) investing activities | 51,342 | (19,818) | (70,736) | (18,189) |
| | | | | |
| **CASH FLOWS - FINANCING ACTIVITIES** | | | | |
| Issuance of share capital and warrants, net of issuance expenses | 59,207 | 55,306 | 117,816 | 30,295 |
| Repayments of bank loan | (300) | (127) | - | - |
| Proceeds from exercise of employee stock options | 2 | 10 | * | * |
| Net cash provided by financing activities | 58,909 | 55,189 | 117,816 | 30,295 |
| | | | | |
| **INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS** | 35,106 | (35,093) | (9,303) | (2,392) |
| **CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR** | 33,061 | 68,339 | 30,888 | 7,942 |
| **EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS** | 172 | (2,358) | 934 | 240 |
| **CASH AND CASH EQUIVALENTS - END OF YEAR** | 68,339 | 30,888 | 22,519 | 5,790 |

* Less than 1,000.

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

**BioLineRx Ltd.**

CONSOLIDATED CASH FLOW STATEMENTS

| | Year ended December 31, | | | Convenience translation into USD (Note 1b) |
|---|---|---|---|---|
| | 2012 | 2013 | 2014 | 2014 |
| | NIS in thousands | | | In thousands |
| **APPENDIX** | | | | |
| **Adjustments required to reflect net cash used in operating activities:** | | | | |
| **Income and expenses not involving cash flows:** | | | | |
| Depreciation and amortization | 1,524 | 1,147 | 960 | 247 |
| Write-off of intangible assets | - | 137 | 377 | 97 |
| Retirement benefit obligations | 60 | 9 | (152) | (39) |
| Long-term prepaid expenses | - | 35 | (21) | (6) |
| Exchange differences on cash and cash equivalents | (172) | 2,358 | (934) | (240) |
| Warrant issuance costs | 1,204 | 470 | - | - |
| Gain on adjustment of warrants to fair value | (7,265) | (5,169) | (12,354) | (3,177) |
| Commitment fee paid by issuance of share capital | 880 | - | 1,040 | 267 |
| Share-based compensation | 3,138 | 3,040 | 3,772 | 970 |
| Interest and exchange differences on short-term deposits | 1,547 | 1,424 | (9,968) | (2,563) |
| Interest and linkage differences on bank loan | 20 | (10) | - | - |
| Interest and exchange differences on restricted deposits | 8 | 40 | (71) | (18) |
| | 944 | 3,481 | (17,351) | (4,462) |
| **Changes in operating asset and liability items:** | | | | |
| Decrease in trade accounts receivable and other receivables | 1,454 | 913 | 286 | 74 |
| Increase (decrease) in accounts payable and accruals | (1,273) | (13,420) | 302 | 78 |
| | 181 | (12,507) | 588 | 152 |
| | 1,125 | (9,026) | (16,763) | (4,310) |
| **Supplementary information on investing and financing activities not involving cash flows:** | | | | |
| Credit received in connection with purchase of property and equipment | 10 | - | 554 | 142 |
| **Supplementary information on interest received in cash** | 1,720 | 503 | 348 | 90 |

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

## NOTE 1 – GENERAL INFORMATION

### a. General

BioLineRx Ltd. ("BioLineRx"), headquartered in Jerusalem, Israel, was incorporated and commenced operations in April 2003.

Since incorporation, BioLineRx and its consolidated entities (collectively, the "Company") have been engaged in the development of therapeutics, from pre-clinical-stage development to advanced clinical trials, for a wide range of medical needs.

In December 2004, BioLineRx registered a limited partnership, BioLine Innovations Jerusalem L.P. ("BIJ LP"), which commenced operations in January 2005. BioLineRx held a 99% interest in BIJ LP, with the remaining 1% held by a wholly owned subsidiary of BioLineRx, BioLine Innovations Ltd. ("BIJ Ltd."). BIJ LP was established to operate a biotechnology incubator located in Jerusalem (the "Incubator") under an agreement with the State of Israel. The agreement with the State of Israel relating to the Incubator terminated on December 31, 2013, and BIJ LP was liquidated in 2014. The Company expects to liquidate BIJ Ltd. during 2015. See Note 12a(1).

In February 2007, BioLineRx listed its securities on the Tel Aviv Stock Exchange ("TASE") and they have been traded on the TASE since that time. Since July 2011, BioLineRx's American Depositary Shares ("ADSs") have also been traded on the NASDAQ Capital Market. See Note 9.

The Company has been engaged in drug development since its incorporation. Although the Company has generated significant revenues from a number of out-licensing transactions, the Company cannot determine with reasonable certainty when and if it will have sustainable profits.

### b. Convenience translation into US dollars ("dollars", "USD" or "$")

For the convenience of the reader, the reported New Israeli Shekel (NIS) amounts as of December 31, 2014 and for the year then ended have been translated into dollars at the representative rate of exchange on December 31, 2014 ($1 = NIS 3.889). The dollar amounts presented in these financial statements should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated.

### c. Approval of consolidated financial statements

The consolidated financial statements of the Company for the year ended December 31, 2014 were approved by the Board of Directors on March 23, 2015, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer and the Chief Financial and Operating Officer.

## NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

### a. Basis of presentation

The Company's consolidated financial statements as of December 31, 2014 and 2013, and for each of the three years in the period ended December 31, 2014, have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). The significant accounting policies described below have been applied on a consistent basis for all years presented, unless noted otherwise.

The consolidated financial statements have been prepared on the basis of historical cost, subject to adjustment of financial assets and liabilities to their fair value through profit or loss and adjustment of assets and liabilities in connection with retirement benefit obligations.

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

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Company's accounting policies. Areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in Note 4. Actual results may differ materially from estimates and assumptions used by the Company's management.

### b. Consolidation of the financial statements

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

### c. Functional and presentation currency

Items included in the financial statements of each of the Company's entities are measured using the currency of the primary economic environment in which each entity operates (the "functional currency"). The consolidated financial statements are presented in NIS, which has been the Company's functional and presentation currency since inception through December 31, 2014. Effective January 1, 2015, as a result of a number of factors, including the strategic collaboration agreement with Novartis (see Note 16) that will be managed solely in U.S. dollars, as well as expectations regarding a significant increase in expenses denominated in U.S. dollars relating to advanced clinical trials, the Company's functional and presentation currency will be the U.S. dollar.

Transactions that are executed in currencies other than the Company's functional currency ("foreign currency transactions") are translated into the functional currency using the exchange rates prevailing at the date of each transaction. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in profit or loss within the relevant line items to which the gains and losses are related.

**NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES** (cont.)

**d. Property and equipment**

Property and equipment are stated at historical cost less depreciation and related grants received from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor (the "OCS") – see also 2g below. Historical cost includes expenditures that are directly attributable to the acquisition of the items. Assets are depreciated by the straight-line method over the estimated useful lives of the assets, provided that the Company's management believes the residual values of the assets to be negligible, as follows:

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

The assets' residual values, methods of depreciation and useful lives are reviewed and adjusted, if appropriate, at each balance sheet date. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Leasehold improvements are amortized by the straight-line method over the term of the lease, which is shorter than the estimated useful life of the improvements.

**e. Intangible assets**

The Company applies the cost method of accounting for initial and subsequent measurements of intangible assets. Under this method of accounting, intangible assets are carried at cost less any accumulated amortization and any accumulated impairment losses.

Intellectual property

The Company recognizes in its financial statements intangible assets developed by the Company to the extent that the conditions stipulated in p. below are met. Intellectual property acquired by the Company is initially measured at cost. Intellectual property acquired by the Company for development purposes is not amortized and is tested annually for impairment. See f. below.

Computer software

Acquired computer software licenses are capitalized on the basis of the costs incurred to acquire and bring to use the specific software. These costs are amortized over the estimated useful lives of the software (3-5 years).

**NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES** (cont.)

**f. Impairment of non-financial assets**

Impairment testing of intellectual property is required when the Company decides to terminate or suspend the development of a project based on such intellectual property. The Company performs impairment reviews on an annual basis, or more frequently if events or changes in circumstances indicate a potential impairment. Property and equipment, as well as computer software, are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized equal to the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and the asset's value in use to the Company.

**g. Government grants related to fixed assets**

Government grants related to fixed assets are recorded as a reduction in the book value of the related assets, and are charged to profit and loss in accordance with the straight-line method.

**h. Financial assets**

1) Classification

The Company classifies its financial assets in the following categories: (i) at fair value through profit or loss and (ii) loans and receivables. The classification depends on the purpose for which each financial asset was acquired. The Company's management determines the classification of financial assets at initial recognition.

a) Financial assets at fair value through profit or loss

The Company's investment policy with regard to its excess cash, as adopted by its Board of Directors, is composed of the following objectives: (i) preserving investment principal, (ii) providing liquidity and (iii) providing optimum yields pursuant to the policy guidelines and market conditions. The policy provides detailed guidelines as to the securities and other financial instruments in which the Company is allowed to invest. In addition, in order to maintain liquidity, investments are structured to provide flexibility to liquidate at least 50% of all investments within 15 business days. Information about these assets, including details of the portfolio and income earned, is provided internally on at least a quarterly basis to the Company's key management personnel and on a semi-annual basis to the Investment Monitoring Committee of the Board of Directors. Any divergence from this investment policy requires approval from the Board of Directors.

**NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES** (cont.)

**h. Financial assets** (cont.)

b) Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. These assets are included in current assets, except for installments which are due more than 12 months subsequent to the balance sheet date. Such installments are included in non-current assets. The Company's loans and receivables include "other receivable," "cash and cash equivalents", "bank deposits" and "restricted deposits" on the balance sheet. See Notes 2i and 2j.

2) Recognition and measurement

Investments are initially recognized at fair value plus transaction costs for all financial assets not carried at fair value through profit or loss. Financial assets carried at fair value through profit or loss are initially recognized at fair value, and transaction costs are expensed in profit or loss. Financial assets are de-recognized when the rights to receive cash flows from the investments have expired or have been transferred and the Company has transferred substantially all risks and rewards of ownership. Loans and receivables are subsequently carried at amortized cost using the effective interest method.

3) Offsetting financial instruments

Financial assets and liabilities are offset and the net amount reported in the balance sheet when there is a legally enforceable right to offset the recognized amounts and there is an intention to settle on a net basis or realize the asset and settle the liability simultaneously.

**i. Cash equivalents**

Cash and cash equivalents include cash on hand and short-term bank deposits (up to three months from date of deposit) that are not restricted as to withdrawal or use, and are therefore considered to be cash equivalents.

**j. Restricted deposits**

The Company has placed a lien on dollar deposits in bank to secure its liabilities and commitments to the lessor of its premises. Those deposits are presented separately as non-current assets, in accordance with the timing of the relevant restrictions. See Note 12b.

**NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES** (cont.)

**k. Warrants**

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

**l. Share capital**

BioLineRx's ordinary shares are classified as equity. Incremental costs directly attributable to the issuance of new shares are shown in equity as a deduction from the issuance proceeds.

**m. Trade payables**

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

**n. Deferred taxes**

Deferred taxes are recognized using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred income tax assets are recognized only to the extent that it is probable that future taxable income will be available against which the temporary differences can be utilized.

As the Company is currently engaged primarily in development activities and is not expected to generate taxable income in the foreseeable future, no deferred tax assets are included in the financial statements.

**NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES** (cont.)

**o. Revenue recognition**

The Company recognizes revenue in accordance with International Accounting Standard ("IAS") 18 – "Revenue," including guidance regarding arrangements with multiple deliverables. Pursuant to this guidance, the Company applies revenue recognition criteria to the separately identifiable components of a single transaction. The consideration from the arrangement is allocated among the separately identifiable components by reference to their fair value.

Revenues incurred in connection with out-licensing of the Company's patents and other intellectual property are recognized when all of the following criteria have been met as of the balance sheet date:

- The Company has transferred to the buyer the significant risks and rewards of ownership of the patents and intellectual property.
- The Company does not retain either the continuing managerial involvement to the degree usually associated with ownership or the effective control over the patent and intellectual property.
- The amount of revenue can be measured reliably.
- It is probable that the economic benefits associated with the transaction will flow to the Company.
- The costs incurred or to be incurred in respect of the sale can be measured reliably.

Revenues in connection with rendering of services are recognized by reference to the stage of completion of the transaction as of the balance sheet date, if and when the outcome of the transaction can be estimated reliably.

Revenues from royalties are recognized on an accrual basis in accordance with the substance of the relevant agreement.

**NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES** (cont.)

**p. Research and development expenses**

Research expenses are charged to profit or loss as incurred.

An intangible asset arising from development (or from the development phase of an internal project) is recognized if all of the following conditions are fulfilled:

- technological feasibility exists for completing development of the intangible asset so that it will be available for use or sale.
- it is management's intention to complete development of the intangible asset for use or sale.
- the Company has the ability to use or sell the intangible asset.
- it is probable that the intangible asset will generate future economic benefits, including existence of a market for the output of the intangible asset or the intangible asset itself or, if the intangible asset is to be used internally, the usefulness of the intangible asset.
- adequate technical, financial and other resources are available to complete development of the intangible asset, as well as the use or sale thereof.
- the Company has the ability to reliably measure the expenditure attributable to the intangible asset during its development.

Other development costs that do not meet the foregoing conditions are charged to profit or loss as incurred. Development costs previously expensed are not recognized as an asset in subsequent periods. As of December 31, 2014, the Company has not yet capitalized development expenses.

**q. Government participation in research and development expenses**

The Company has received participation in research and development expenses from the State of Israel through the OCS, both in the form of loans extended to the Incubator for research and development, as described in Note 12a(1), and in the form of grants, as described in Note 12a(2). The agreement with the State of Israel relating to the Incubator terminated on December 31, 2013; accordingly, the Company does not expect to receive additional funding in the form of loans extended to the Incubator.

Despite the formal difference between the two types of support from the OCS, there is no material financial difference between them. Each loan and grant qualifies as a "forgivable loan" in accordance with IAS 20, "Accounting for Government Grants and Disclosure of Government Assistance," since the loans and grants are repayable only if the Company generates revenues related to the project that is the subject of the loan or grant.

**NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES** (cont.)

**q. Government participation in research and development expenses** (cont.)

The Company recognizes each forgivable loan on a systematic basis at the same time the Company records, as an expense, the related development costs for which the grant/loan is received, provided that there is reasonable assurance that (a) the Company complies with the conditions attached to the grant/loan, and (b) the grant/loan will be received. The amount of the forgivable loan is recognized based on the participation rate approved by the OCS.

The Company accounts for each forgivable loan as a liability unless it is more likely than not that the Company will meet the terms of forgiveness, in which case the forgivable loan is accounted for as a government grant and carried to income as a reduction of research and development expenses.

If forgivable loans are initially carried to income, as described above, and, in subsequent periods, it appears more likely than not that the project will be successful and that the loans will be repaid or royalties paid to the OCS, the Company recognizes a liability which is measured based on the Company's best estimate of the amount required to settle the Company's obligation at the end of each reporting period.

**r. Employee benefits**

1) Pension and severance pay obligations

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

With respect to the remaining employees, the Company records a liability on its balance sheet for defined benefit plans that represents the present value of the defined benefit obligation as of each reporting date, net of the fair value of plan assets. The present value of the defined benefit liability is determined by discounting the anticipated future cash outflows, using interest rates that are denominated in the currency in which the benefits will be payable.

The amounts recorded as an employee benefit expense in respect of pension and severance pay obligation for the years 2012, 2013 and 2014 were NIS 1,997,000, NIS 1,746,000 and NIS 1,662,000, respectively.

**NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES** (cont.)

**r. Employee benefits** (cont.)

2) Vacation days and recreation pay

Labor laws in Israel entitle every employee to vacation days and recreation pay, both of which are computed annually. The entitlement with respect to each employee is based on the employee's length of service at the Company. The Company recognizes a liability and an expense in respect of vacation and recreation pay based on the individual entitlement of each employee.

3) Share-based payments

The Company operates an equity-settled, share-based compensation plan, under which it receives services from employees as consideration for equity instruments (options) of the Company. The fair value of the employee services received in exchange for the grant of the options is recognized as an expense. The total amount to be expensed is determined by reference to the fair value of the options granted:

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

- excluding the impact of any service and non-market performance vesting conditions (for example, profitability, sales growth targets and the employee remaining with the entity over a specified time period).

Non-market performance and service conditions are included in assumptions about the number of options that are expected to vest. The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied.

When the options are exercised, the Company issues new shares. The proceeds received, net of any directly attributable transaction costs, are credited to share capital (at par value) and share premium when the options are exercised.

**s. Loss per share**

1) Basic

The basic loss per share is calculated by dividing the loss attributable to the holders of ordinary shares by the weighted average number of ordinary shares outstanding during the year.

2) Diluted

The diluted loss per share is calculated by adjusting the weighted average number of outstanding ordinary shares, assuming conversion of all dilutive potential shares. The Company's dilutive potential shares consist of warrants issued to investors, as well as options granted to employees and service providers. The dilutive potential shares were not taken into account in computing loss per share in 2012, 2013 and 2014, as their effect would not have been dilutive.

**NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES** (cont.)

**t. Changes in accounting policy and disclosures**

New and amended standards adopted by the Company

The following standards have been adopted by the Company for the first time for the fiscal year beginning January 1, 2014:

Amendment to IAS 32, "Financial Instruments: Presentation", on asset and liability offsetting, which clarifies some of the requirements for offsetting financial assets and financial liabilities on the balance sheet.

New standards and interpretations not yet adopted

A number of new standards and amendments to standards and interpretations are effective for annual periods beginning after January 1, 2014, and have not been applied in preparing these consolidated financial statements. None of these is expected to have a significant effect on the Company's consolidated financial statements, except the following set out below, for which the impact has not yet been fully assessed.

IFRS 15, "Revenue from Contracts with Customers", which is the converged standard on revenue recognition. It replaces IAS 11, "Construction Contracts", IAS 18,"Revenue" and related interpretations. Revenue is recognized when a customer obtains control of a good or service. A customer obtains control when it has the ability to direct the use of and obtain the benefits from the good or service. The core principle of IFRS 15 is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. An entity recognizes revenue in accordance with that core principle by applying the following steps: Step 1: identify the contract(s) with a customer; Step 2: identify the performance obligations in the contract; Step 3: determine the transaction price; Step 4: allocate the transaction price to the performance obligations in the contract; and Step 5: recognize revenue when (or as) the entity satisfies a performance obligation. IFRS 15 also includes a cohesive set of disclosure requirements that will result in an entity providing users of financial statements with comprehensive information about the nature, amount, timing and uncertainty of revenue and cash flows arising from the entity's contracts with customers.

IFRS 9, "Financial Instruments", which replaces most of the guidance in IAS 39. IFRS 9 retains but simplifies the mixed measurement model and establishes three primary measurement categories for financial assets: amortized cost, fair value through other comprehensive income (OCI) and fair value through P&L. The basis of classification depends on the entity's business model and the contractual cash flow characteristics of the financial asset. Investments in equity instruments are required to be measured at fair value through profit or loss with the irrevocable option at inception to present changes in fair value in OCI. There is now a new expected credit loss model that replaces the incurred loss impairment model used in IAS 39. For financial liabilities there were no changes to classification and measurement except for the recognition of changes in own credit risk in other comprehensive income, for liabilities designated at fair value, through profit or loss. IFRS 9 relaxes the requirements for hedge effectiveness by replacing the bright line hedge effectiveness tests. It requires an economic relationship between the hedged item and hedging instrument and for the "hedged ratio" to be the same as the one management actually use for risk management purposes. Contemporaneous documentation is still required but is different to that currently prepared under IAS 39.

## NOTE 3 – FINANCIAL RISK MANAGEMENT

Based on assessments by Company management, the Company's exposure to credit risk as of December 31, 2014 is immaterial (see Note 3b). The activities of the Company expose it to market risk, particularly as a result of currency risk.

The Company's Finance Department is responsible for carrying out risk management activities in accordance with policies approved by its Board of Directors. In this regard, the Finance Department identifies, defines and assesses financial risks in close cooperation with other Company departments. The Board of Directors provides written guidelines for overall risk management, as well as written policies dealing with specific areas, such as exchange rate risk, interest rate risk, credit risk, use of financial instruments, and investment of excess cash.

### a. Market risk

1) Concentration of currency risk

The Company's activities are partly denominated in foreign currency, which exposes the Company to risks resulting from changes in exchange rates (primarily the dollar).

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

| | December 31, 2014 | | | | |
|---|---|---|---|---|---|
| | Income (loss) | | Value on balance sheet | Income (loss) | |
| Sensitive instrument | 10% increase | 5% increase | | 5% decrease | 10% decrease |
| | NIS in thousands | | | | |
| Dollar-linked balances: | | | | | |
| Cash and cash equivalents | 1,331 | 666 | 13,313 | (666) | (1,331) |
| Short-term bank deposits | 11,235 | 5,618 | 112,354 | (5,618) | (11,235) |
| Restricted deposits* | 64 | 32 | 644 | (32) | (64) |
| Trade payables | (323) | (162) | (3,231) | 162 | 323 |
| Total dollar-linked balances | 12,307 | 6,154 | 123,080 | (6,154) | (12,307) |
| Euro-linked trade payables | (81) | (40) | (809) | 40 | 81 |
| **Total** | 12,226 | 6,114 | 122,271 | (6,114) | (12,226) |

* See also Note 12b.

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

| | December 31, 2013 | | | | |
|---|---|---|---|---|---|
| | Income (loss) | | Value on balance sheet | Income (loss) | |
| Sensitive instrument | 10% increase | 5% increase | | 5% decrease | 10% decrease |
| | NIS in thousands | | | | |
| Dollar-linked balances: | | | | | |
| Cash and cash equivalents | 2,239 | 1,119 | 22,388 | (1,119) | (2,239) |
| Short-term bank deposits | 3,235 | 1,617 | 32,345 | (1,617) | (3,235) |
| Restricted deposits* | 57 | 29 | 573 | (29) | (57) |
| Trade payables | (612) | (306) | (6,117) | 306 | 612 |
| Total dollar-linked balances | 4,919 | 2,459 | 49,189 | (2,459) | (4,919) |
| Euro-linked trade payables | (22) | (11) | (225) | 11 | 22 |
| **Total** | 4,897 | 2,448 | 48,964 | (2,448) | (4,897) |

* See also Note 12b.

**NOTE 3 – FINANCIAL RISK MANAGEMENT** (cont.)

**a. Market risk** (cont.)

1) Concentration of currency risk (cont.)

Set forth below is data regarding exchange rates and the Israeli CPI:

| | Exchange rate of $1 | Exchange rate of € 1 | Israeli CPI* |
|---|---|---|---|
| | NIS | NIS | Points |
| As of December 31: | | | |
| 2013 | 3.471 | 4.782 | 133.04 |
| 2014 | 3.889 | 4.725 | 132.78 |
| | | | |
| Percentage increase (decrease) in: | | | |
| 2013 | (7.0)% | (2.8)% | 1.8% |
| 2014 | 12.0% | (1.2)% | (0.2)% |

* Based on the CPI index for the month ending on each balance sheet date, on the basis that the average for year 2000 = 100.

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

| | December 31, 2013 | | | December 31, 2014 | | |
|---|---|---|---|---|---|---|
| | Dollar | Other currencies | NIS | Dollar | Other currencies | NIS |
| | NIS in thousands | | | | | |
| **Assets:** | | | | | | |
| Current assets: | | | | | | |
| Cash and cash equivalents | 22,388 | 37 | 8,463 | 13,313 | 29 | 9,177 |
| Short term bank deposits | 32,345 | - | - | 112,354 | - | - |
| Other receivables | - | - | 896 | - | - | 859 |
| Non-current assets: | | | | | | |
| Restricted deposits | 573 | - | - | 644 | - | - |
| Total assets | 55,306 | 37 | 9,359 | 126,311 | 29 | 10,036 |
| | | | | | | |
| **Liabilities:** | | | | | | |
| Current liabilities: | | | | | | |
| Accounts payable and accruals: | | | | | | |
| Trade | 6,117 | 350 | 1,478 | 3,231 | 1,029 | 2,171 |
| Other | - | - | 2,499 | - | - | 4,869 |
| Total liabilities | 6,117 | 350 | 3,977 | 3,231 | 1,029 | 7,040 |
| **Net asset value** | 49,189 | (313) | 5,382 | 123,080 | (1,000) | 2,996 |

**NOTE 3 – FINANCIAL RISK MANAGEMENT** (cont.)

**a. Market risk** (cont.)

2) Fair value of financial instruments

As of December 31, 2014, the financial instruments of the Company consist of non-derivative assets and liabilities (primarily working capital items and restricted deposits), as well as a liability on account of warrants.

With regard to non-derivative assets and liabilities, in view of their nature, the fair value of the financial instruments included in working capital is generally close or identical to their carrying amount. The fair value of the restricted cash in long-term deposits also approximates the carrying amount, as these financial instruments bear interest at a rate approximating the prevailing interest rate.

With regard to the liability on account of warrants, see Note 9c(1), 9c(2).

3) Exposure to market risk and the management thereof

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

4) Interest rate risk

Company management does not consider interest rate risk to be material, as the Company holds deposits and short-term government bonds whose fair value and/or cash flows are not materially affected by changes in interest rates.

**b. Credit risk**

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

The Company's cash, cash equivalents and short-term bank deposits at December 31, 2013 and 2014 were mainly deposited with highly-rated major Israeli and U.S. banks. In the Company's opinion, the credit risk in respect of these balances is remote.

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

| | December 31, | |
|---|---|---|
| | 2013 | 2014 |
| | NIS in thousands | |
| **Assets:** | | |
| Cash and cash equivalents | 30,888 | 22,519 |
| Short-term bank deposits | 32,345 | 112,354 |
| Other receivables | 1,249 | 1,000 |
| Restricted deposits | 573 | 644 |
| **Total** | 65,055 | 136,517 |

**c. Liquidity risk**

Company management monitors rolling forecasts of the Company's liquidity reserves on the basis of anticipated cash flows and maintains the liquidity balances at a level that is sufficient to meet its needs.

**NOTE 3 – FINANCIAL RISK MANAGEMENT** (cont.)

**c. Liquidity risk** (cont.)

Although the Company has succeeded in generating significant revenues from number of out-licensing transactions, it cannot determine with reasonable certainty if and when it will become profitable on a current basis. Management believes that the Company's current cash and other resources, including the proceeds from the public offering completed in March 2015 (see Note 20), will be sufficient to fund its projected cash requirements into 2018. Accordingly, in the event that the Company does not continue to generate cash from its operating activities, the Company will need to raise additional capital in the future. Inability to raise additional capital would have a material adverse effect on the financial condition of the Company.

**d. Financial instruments**

As of December 31, 2013 and 2014, the Company's financial instruments consisted of loans and receivables, and a liability on account of warrants.

**e. Fair value estimations**

In February 2012 and 2013, BioLineRx completed financing transactions in which it issued ADSs and warrants to purchase additional ADSs – see Note 9c. The fair value of the warrants, which are not traded on an active market, is determined by using valuation techniques. These valuation techniques maximize the use of observable market data where it is available and rely as little as possible on entity specific estimates.

**NOTE 4 – CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS**

As part of the financial reporting process, Company management is required to make estimates that affect the value of assets, liabilities, income, expenses and certain disclosures included in the Company's consolidated financial statements. By their very nature, such estimates are subjective and complex and consequently may differ from actual results.

The accounting estimates used in the preparation of the financial statements are continually evaluated and adjusted based on historical experience and other factors, including expectation of future events that are believed to be reasonable under the circumstances.

Described below are the critical accounting estimates used in the preparation of the financial statements, the formulation of which required Company management to make assumptions as to circumstances and events that involve significant uncertainty. In using its judgment to determine the accounting estimates, the Company takes into consideration, as appropriate, the relevant facts, past experience, the effect of external factors and reasonable assumptions under the circumstances.

**a. Development expenses**

Development expenses are capitalized in accordance with the accounting policy described in Note 2p. The capitalization of costs is based on management's judgment of technological and economic feasibility, which is usually achieved when a development project reaches a predefined milestone, or when the Company enters into a transaction to sell the know-how that resulted from the development process. In determining the amount to be capitalized, management makes assumptions as to the future anticipated cash inflows from the assets, and the anticipated period of future benefits. Company management has concluded that, as of December 31, 2014, the foregoing conditions have not been met and therefore development expenses have not been capitalized for any project.

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

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

**b. Grants/loans from the OCS**

In accordance with the accounting treatment prescribed in Note 2q, Company management is required to evaluate whether there is reasonable assurance that the grant/loan received will be paid or repaid. Additionally, whenever the grant/loan is initially recognized as income, management is required to evaluate whether the payment of royalties/repayment of loans to the OCS is considered more likely than not.

See Notes 12a(1) and 12a(2) with regard to the potential amount repayable to the OCS as of December 31, 2014.

**NOTE 5 – CASH AND CASH EQUIVALENTS**

| | December 31, | |
|---|---|---|
| | **2013** | **2014** |
| | **NIS in thousands** | |
| Cash on hand and in bank | 12,822 | 8,685 |
| Short-term bank deposits | 18,066 | 13,834 |
| | 30,888 | 22,519 |

The short-term bank deposits included in cash and cash equivalents bear interest at annual rates of between 0.10% and 0.95%. The carrying amount of cash and cash equivalents approximates their fair value, since they bear interest at rates similar to prevailing market interest rates.

**NOTE 6 – SHORT-TERM BANK DEPOSITS**

The short-term bank deposits are linked to the dollar and bear interest at annual rates of between 0.42% and 0.65%.

**NOTE 7 – PROPERTY AND EQUIPMENT**

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

| | Cost | | | | Accumulated depreciation | | | | Net book value | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Balance at beginning of year | Additions during year | Deletions during year | Balance at end of year | Balance at beginning of year | Additions during year | Deletions during year | Balance at end of year | December 31, 2011 | December 31, 2012 |
| | NIS in thousands | | | | NIS in thousands | | | | NIS in thousands | |
| **Composition in 2012** | | | | | | | | | | |
| Office furniture and equipment | 879 | 27 | - | 906 | 254 | 52 | - | 306 | 625 | 600 |
| Computers and communications equipment | 1,569 | 111 | - | 1,680 | 961 | 310 | - | 1,271 | 608 | 409 |
| Laboratory equipment, net* | 5,111 | 198 | - | 5,309 | 2,648 | 689 | - | 3,337 | 2,463 | 1,972 |
| Leasehold improvements | 4,266 | 7 | - | 4,273 | 3,751 | 331 | - | 4,082 | 515 | 191 |
| | 11,825 | 343 | - | 12,168 | 7,614 | 1,382 | - | 8,996 | 4,211 | 3,172 |
| *Item is net of OCS grants received - see 12a(1) | 2,250 | - | - | 2,250 | 1,826 | 311 | - | 2,137 | 424 | 113 |

| | Cost | | | | Accumulated depreciation | | | | Net book value | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Balance at beginning of year | Additions during year | Deletions during year | Balance at end of year | Balance at beginning of year | Additions during year | Deletions during year | Balance at end of year | December 31, 2012 | December 31, 2013 |
| | NIS in thousands | | | | NIS in thousands | | | | NIS in thousands | |
| **Composition in 2013** | | | | | | | | | | |
| Office furniture and equipment | 906 | - | - | 906 | 306 | 51 | - | 357 | 600 | 549 |
| Computers and communications equipment | 1,680 | 142 | (467) | 1,355 | 1,271 | 288 | (467) | 1,092 | 409 | 263 |
| Laboratory equipment, net* | 5,309 | 157 | (3,273) | 2,193 | 3,337 | 606 | (3,273) | 670 | 1,972 | 1,523 |
| Leasehold improvements | 4,273 | - | (3,531) | 742 | 4,082 | 55 | (3,531) | 606 | 191 | 136 |
| | 12,168 | 299 | (7,271) | 5,196 | 8,996 | 1,000 | (7,271) | 2,725 | 3,172 | 2,471 |
| *Item is net of OCS grants received – see 12a(1) | 2,250 | - | - | 2,250 | 2,137 | 92 | - | 2,229 | 113 | 21 |

**NOTE 7 – PROPERTY AND EQUIPMENT** (cont.)

| | Cost | | | | Accumulated depreciation | | | | Net book value December 31, | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Balance at beginning of year | Additions during year | Deletions during year | Balance at end of year | Balance at beginning of year | Additions during year | Deletions during year | Balance at end of year | 2013 | 2014 |
| | NIS in thousands | | | | NIS in thousands | | | | NIS in thousands | |
| **Composition in 2014** | | | | | | | | | | |
| Office furniture and equipment | 906 | - | - | 906 | 357 | 53 | - | 410 | 549 | 496 |
| Computers and communications equipment | 1,355 | 158 | - | 1,513 | 1,092 | 208 | - | 1,300 | 263 | 213 |
| Laboratory equipment, net* | 2,193 | 243 | - | 2,436 | 670 | 607 | - | 1,277 | 1,523 | 1,159 |
| Leasehold improvements | 742 | 827 | - | 1,569 | 606 | 27 | - | 633 | 136 | 936 |
| | 5,196 | 1,228 | - | 6,424 | 2,725 | 895 | - | 3,620 | 2,471 | 2,804 |
| *Item is net of OCS grants received – see 12a(1) | 2,250 | - | - | 2,250 | 2,229 | 19 | - | 2,248 | 21 | 2 |

**NOTE 8 – INTANGIBLE ASSETS**

| | Cost | | | | Accumulated depreciation | | | | Net book value | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Balance at beginning of year | Additions during year | Deletions during year | Balance at end of year | Balance at beginning of year | Additions during year | Deletions during year | Balance at end of year | December 31, 2011 | December 31, 2012 |
| | NIS in thousands | | | | NIS in thousands | | | | NIS in thousands | |
| **Composition in 2012** | | | | | | | | | | |
| Intellectual property | 1,643 | - | - | 1,643 | 751 | - | - | 751 | 892 | 892 |
| Computer software | 1,140 | 61 | - | 1,201 | 888 | 142 | - | 1,030 | 252 | 171 |
| | 2,783 | 61 | - | 2,844 | 1,639 | 142 | - | 1,781 | 1,144 | 1,063 |

| | Cost | | | | Accumulated depreciation | | | | Net book value | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Balance at beginning of year | Additions during year | Deletions during year | Balance at end of year | Balance at beginning of year | Additions during year | Deletions during year | Balance at end of year | December 31, 2012 | December 31, 2013 |
| | NIS in thousands | | | | NIS in thousands | | | | NIS in thousands | |
| **Composition in 2013** | | | | | | | | | | |
| Intellectual property | 1,643 | - | (137) | 1,506 | 751 | - | - | 751 | 892 | 755 |
| Computer software | 1,201 | 99 | (243) | 1,057 | 1,030 | 147 | (243) | 934 | 171 | 123 |
| | 2,844 | 99 | (380) | 2,563 | 1,781 | 147 | (243) | 1,685 | 1,063 | 878 |

| | Balance at beginning of year | Additions during year | Deletions during year | Balance at end of year | Balance at beginning of year | Additions during year | Deletions during year | Balance at end of year | Net book value December 31, 2013 | Net book value December 31, 2014 |
|---|---|---|---|---|---|---|---|---|---|---|
| | NIS in thousands | | | | NIS in thousands | | | | NIS in thousands | |
| **Composition in 2014** | | | | | | | | | | |
| Intellectual property | 1,506 | - | (753) | 753 | 751 | - | (376) | 375 | 755 | 378 |
| Computer software | 1,057 | 21 | - | 1,078 | 934 | 65 | - | 999 | 123 | 79 |
| | 2,563 | 21 | (753) | 1,831 | 1,685 | 65 | (376) | 1,374 | 878 | 457 |

During 2013, the Company wrote-off intellectual property in the total amount of NIS 137,000 in respect of the termination of BL-5040. During 2014, the Company wrote-off intellectual property in the total amount of NIS 377,000 in respect of the out-licensing of BL-5010.

Depreciation in respect of computer software for all years presented, as well as the impairment of intellectual property for 2013, was included in research and development expenses.

## NOTE 9 – EQUITY

### a. Share capital

As of December 31, 2014 and 2013, share capital is composed of ordinary shares, as follows:

| | Number of Ordinary Shares | |
|---|---|---|
| | December 31, | |
| | 2013 | 2014 |
| Authorized share capital | 750,000,000 | 750,000,000 |
| Issued share capital | 241,487,049 | 391,150,507 |
| Paid-up share capital | 241,487,049 | 391,150,507 |

| | In NIS | |
|---|---|---|
| | December 31, | |
| | 2013 | 2014 |
| Authorized share capital | 7,500,000 | 7,500,000 |
| Issued share capital | 2,414,870 | 3,911,505 |
| Paid-up share capital | 2,414,870 | 3,911,505 |

As of December 31, 2014, the market price on NASDAQ of BioLineRx's ADSs was $1.62, and the market price on the Tel Aviv Stock Exchange of BioLineRx's ordinary shares was NIS 0.644. Each ADS represents 10 ordinary shares.

### b. Rights related to shares

The ordinary shares confer upon their holders voting and dividend rights and the right to receive assets of the Company upon its liquidation. As of December 31, 2014 and 2013, all outstanding share capital consisted of ordinary shares.

**NOTE 9 – EQUITY** (cont.)

**c. Changes in the Company's equity**

1) In February 2012, BioLineRx completed a private placement to healthcare-focused U.S. institutional investors, pursuant to which it issued an aggregate of 5,244,301 ADSs, at a purchase price of $2.86 per ADS, and warrants to purchase up to 2,622,157 additional ADSs, at an exercise price of $3.57 per ADS. The offering raised a total of $15,000,000, with net proceeds of approximately $14,100,000, after deducting fees and expenses.

The warrants are exercisable over a period of five years from the date of their issuance. Since the exercise price was not deemed to be fixed, the warrants did not qualify for classification as an equity instrument and have therefore been classified as a non-current derivative financial liability.

The amount of the private placement consideration allocated to the warrants was approximately $4,800,000, as calculated on the basis of the Black-Scholes model, which reflected their fair value as of the issuance date. The portion of total issuance costs allocable to the warrants, in the amount of approximately $300,000, was recorded as non-operating expense on the statement of comprehensive loss. The changes in fair value from the date of issuance through December 31, 2012, and for the years ended December 31, 2013 and 2014, of approximately $1,900,000, $100,000 and $2,000,000, respectively, have been recorded as non-operating income on the statement of comprehensive loss.

2) In February 2013, the Company completed a direct placement to leading healthcare investor, OrbiMed Israel Partners Limited Partnership, an affiliate of OrbiMed Advisors LLC. The placement consisted of 2,666,667 ADSs and 1,600,000 warrants to purchase an additional 1,600,000 ADSs, at a unit price of $3.00. The warrants have an exercise price of $3.94 per ADS and are exercisable for a term of five years. The offering raised a total of $8,000,000, with net proceeds of approximately $7,700,000, after deducting fees and expenses.

**NOTE 9 – EQUITY** (cont.)

**c. Changes in the Company's equity** (cont.)

The warrants are exercisable over a period of five years from the date of their issuance. Since the exercise price was not deemed to be fixed, the warrants did not qualify for classification as an equity instrument and have therefore been classified as a non-current derivative financial liability.

The amount of the direct placement consideration allocated to the warrants was approximately $3,400,000, as calculated on the basis of the Black-Scholes model, which reflects their fair value as of the issuance date. The portion of total issuance costs allocable to the warrants, in the amount of approximately $130,000, was recorded as a non-operating expense on the statement of comprehensive loss. The change in fair value from the date of issuance through December 31, 2013, and for the year ended December 31, 2014, amounting to approximately $1,600,000 and $1,100,000, has been recorded as non-operating income on the statement of comprehensive loss.

3) In March 2014, the Company completed an underwritten public offering of 9,660,000 ADSs at a public offering price of $2.50 per ADS. The offering raised a total of $24.2 million, with net proceeds of approximately $22.3 million.

**d. Share purchase agreement**

In September 2012, BioLineRx and Lincoln Park Capital Fund, LLC, an Illinois limited liability company ("LPC"), entered into a $15 million purchase agreement, together with a registration rights agreement, whereby LPC agreed to purchase, from time to time, up to $15 million of BioLineRx's ADSs, subject to certain limitations, during the 36-month term of the Purchase Agreement.

In consideration for entering into the $15 million agreement, BioLineRx paid to LPC an initial commitment fee of $225,000, paid via the issuance of 98,598 ADSs, as well as an initial finder's fee, in cash, to Oberon Securities, LLC of $150,000. These initial fees, in the total aggregate amount of $375,000, as well as other one-time expenses associated with the initial set-up of the facility, were recorded as a non-operating expense in the statement of comprehensive loss for the year ended December 31, 2012. Additional commitment and finder's fees associated with the agreement, payable only upon the issuance of shares, have been recorded as issuance expenses against share premium on the statement of financial position.

During the year ended December 31, 2014, BioLineRx sold a total of 151,164 ADSs to LPC for aggregate gross proceeds of $400,000. In connection with these issuances, a total of 3,779 ADSs was issued to LPC as an additional commitment fee and a total of $8,000 was paid to Oberon Securities as an additional finder's fee.

On a cumulative basis, from the effective date of the $15,000,000 purchase agreement through its termination in May 2014, BioLineRx sold a total of 3,793,209 ADSs to LPC for aggregate gross proceeds of $9,731,000. In connection with these issuances, a total of 94,832 ADSs was issued to LPC as an additional commitment fee and a total of $195,000 was paid to Oberon Securities as an additional finder's fee.

**NOTE 9 – EQUITY** (cont.)

**d. Share purchase agreement** (cont.)

In May 2014, BioLineRx and LPC entered into a new $20 million, 36-month purchase agreement, and terminated the previous $15 million agreement. The terms of the new purchase agreement are substantially identical to the terms of the previous purchase agreement. Through the approval date of these financial statements, no sales of ADSs to LPC have been made under the new purchase agreement.

In consideration for entering into the new $20 million purchase agreement, BioLineRx paid to LPC an initial commitment fee of $300,000, paid via the issuance of 150,000 ADSs, and will pay a further commitment fee of up to $500,000, pro rata, as the facility is used over time, which will be paid in ADSs valued based on the prevailing market prices of BioLineRx's ADSs at such time. The new purchase agreement may be terminated by BioLineRx at any time, at its sole discretion, without any cost or penalty.

In connection with the new purchase Agreement, BioLineRx agreed to pay an initial cash finder's fee to Oberon Securities of $50,000, and will pay an additional cash finder's fee equal to 2.0% of the dollar amount of ADSs sold under the new agreement, up to an aggregate additional finder's fee of $200,000. BioLineRx has no other obligations to Oberon Securities with respect to this or any other potential future agreement.

The initial commitment fee payable to LPC and the initial finder's fee payable to Oberon Securities, in the total aggregate amount of $350,000, were recorded as a non-operating expense in the statement of comprehensive loss for the year ended December 31, 2014. Future commitment and finders fees payable, if and when the facility is used over time, will be recorded as issuance expenses against share premium on the statement of financial position.

**e. Share-based payments**

1) Stock option plan – general

In 2003, BioLineRx adopted the 2003 Share Option Plan (the "Plan"). The Plan provides for the granting of options and ordinary shares to the Company's employees, directors, consultants and other service providers. Options are issued at the determination of the Board of Directors in accordance with applicable law. The options are generally exercisable for a seven-year period and the grants generally vest over a four-year period - 50% after the first two years of service, and 25% for each subsequent additional year of service. During 2013, the Company's Board of Directors approved amendments to the Plan to take into account changes in laws and regulations that had occurred since its adoption and to extend the term of the plan until November 2023. As of December 31, 2014, there were 32,450,718 ordinary shares issuable upon the exercise of outstanding options under the Plan.

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

**NOTE 9 – EQUITY** (cont.)

**e. Share-based payments** (cont.)

1) Stock option plan – general (cont.)

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

During 2012, the Board of Directors approved a two-year extension to the exercise period for 3,867,910 previously issued and outstanding employee stock options. This extension brought the total exercise period of such options in line with the seven-year exercise period generally used for most employee stock options that were previously granted. The total compensation cost associated with this extension was approximately NIS 680,000, and has been recorded as an expense over the vesting period of the options.

In May 2012 and November 2014, the Company's Board of Directors approved increases of 16 million shares each to the total pool of authorized but unissued ordinary shares reserved for purposes of the Plan and any other present or future share incentive plans of the Company, bringing the pool to an aggregate of 46 million shares. As of December 31, 2014, there were 5,780,782 remaining authorized but unissued ordinary shares in the pool reserved for future share-based incentive grants.

**NOTE 9 – EQUITY** (cont.)

**e. Share-based payments** (cont.)

2) Employee stock options (cont.)

The following table contains additional information concerning options granted to employees and directors under the existing stock-option plans.

| | Year ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2012 | 2013 | | 2014 | | |
| | Number of options | Weighted average exercise price (in NIS) | Number of options | Weighted average exercise price (in NIS) | Number of options | Weighted average exercise price (in NIS) |
| Outstanding at beginning of year | 5,557,720 | 1.87 | 12,936,019 | 1.32 | 18,612,802 | 1.20 |
| Granted | 8,122,000 | 1.07 | 7,558,000 | 0.97 | 14,782,000 | 0.57 |
| Forfeited and expired | (687,895) | 2.83 | (1,629,755) | 1.35 | (1,509,850) | 1.30 |
| Exercised | (55,806) | 0.04 | (251,462) | 0.04 | (14,028) | 0.04 |
| Outstanding at end of year | 12,936,019 | 1.32 | 18,612,802 | 1.20 | 31,870,924 | 0.91 |
| Exercisable at end of year | 1,526,437 | 2.04 | 2,737,797 | 2.04 | 6,419,595 | 1.51 |

The total consideration received from the exercise of stock options during 2012, 2013 and 2014 was NIS 2,000, NIS 10,000 and NIS 500, respectively.

The weighted average prices of BioLineRx's shares on the dates of exercise were NIS 1.21, NIS 0.78 and NIS 0.77 for 2012, 2013 and 2014, respectively.

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

| | Year ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2012 | | 2013 | | 2014 | |
| Range of exercise prices (in NIS) | Number of options outstanding | Weighted average remaining contractual life (in yrs.) | Number of options outstanding | Weighted average remaining contractual life (in yrs.) | Number of options outstanding | Weighted average remaining contractual life (in yrs.) |
| Up to 1.00 | 1,108,879 | 5.34 | 2,508,892 | 6.12 | 17,176,864 | 6.61 |
| 1.01-2.00 | 11,119,315 | 6.18 | 15,475,935 | 5.78 | 14,066,085 | 4.84 |
| 2.01-3.00 | 109,025 | 3.82 | 109,025 | 2.82 | 109,025 | 1.82 |
| 3.01-4.00 | 151,100 | 4.10 | 111,250 | 1.56 | 111,250 | 2.36 |
| Over 4.00 | 447,700 | 3.19 | 407,700 | 2.24 | 407,700 | 1.34 |
| | 12,936,019 | 5.90 | 18,612,802 | 5.70 | 31,870,924 | 5.73 |

**NOTE 9 – EQUITY** (cont.)

**e. Share-based payments** (cont.)

2) Employee stock options (cont.)

The fair value of all options granted to employees through December 31, 2014 has been determined using the Black-Scholes option-pricing model. These values are based on the following assumptions as of the applicable grant dates:

| | 2012 | 2013 | 2014 |
|---|---|---|---|
| Expected dividend yield | 0% | 0% | 0% |
| Expected volatility | 68% | 69% | 65% |
| Risk-free interest rate | 3% | 2% | 2% |
| Expected life of options (in years) | 7 | 7 | 5 |

3) Stock options to consultants

From inception through December 31, 2006, the Company issued to consultants options for the purchase of 210,990 ordinary shares at an average exercise price of NIS 0.04 per share. In 2007, the Company issued options to consultants for the purchase of 144,242 ordinary shares at an average exercise price of NIS 2.13 per share. The options vest over four years and may be exercised for a period of ten years.

In 2010, the Company issued options to consultants for the purchase of 300,000 ordinary shares at an average exercise price of NIS 4.03 per share. The options vest over four years and may be exercised for a period of five years.

In 2012, the Company issued options to consultants for the purchase of 110,000 ordinary shares at an average exercise price of NIS 1.115 per share. The options vest over four years and may be exercised for a period of seven years.

In 2013 and 2014, no options were issued to consultants.

Company management estimates the fair value of the options granted to consultants based on the value of services received over the vesting period of the applicable options. The value of such services (primarily in respect of clinical advisory services) is estimated based on the additional cash compensation the Company would need to pay if such options were not granted. The value of services recorded in 2012, 2013 and 2014 amounted to NIS 906,000, NIS 140,000 and NIS 156,000, respectively.

## NOTE 10 – TAXES ON INCOME

### a. Corporate taxation in Israel

The income of BioLineRx and BIJ Ltd. is taxed at standard Israeli corporate tax rates, which were 25% in 2012 and 2013, and 26.5% for 2014 and thereafter.

Capital gains recorded through December 31, 2013 were subject to a tax rate of 25%. Beginning 2014 and thereafter, capital gains are subject to a tax rate of 26.5%.

During its existence, BIJ LP was not subject to tax under Israeli tax law; rather, each of the partners thereof (BioLineRx and BIJ Ltd.) was liable for the tax applicable to the operations of BIJ LP in proportion to their respective share in BIJ LP's results.

### b. Approved enterprise benefits

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

Subject to compliance with the applicable requirements, the portion of undistributed income derived from Benefited Enterprise programs will be entitled to a tax exemption for a period of ten years commencing in the first year in which BioLineRx generates taxable income after setting off losses for Israeli tax purposes from prior years (see c. below). The ten-year period may not extend beyond 14 years from the beginning of the Benefited Enterprise's election year. BioLineRx received Benefited Enterprise status with respect to Eligible Projects beginning in the 2009 tax year, so depending on when the Benefited Enterprise programs begin to generate taxable income, the benefit period could continue through 2022. However, any distribution of income derived from Benefited Enterprise programs will result in such income being subject to a rate of corporate tax of 26.5%.

BioLineRx has the option to transition to a "Preferred Enterprise" regime under the Investments Law, according to which all income which is eligible for benefits under the regime would be subject to a flat corporate tax rate of 9%, whether or not distributed. If BioLineRx were to move its operations to a different part of Israel, these rates may be increased. A transition to a Preferred Enterprise regime may not be reversed.

In addition, the ITA approved BioLineRx's operations as an "Industrial Enterprise" under the Investments Law, meaning that BioLineRx is eligible for accelerated depreciation with respect to certain tangible assets belonging to its Benefited Enterprise. Should BioLineRx not meet the requirements for maintaining these benefits, they may be reduced or cancelled and, among other things, income deriving from the Eligible Projects would be subject to Israeli corporate tax at the standard rate of 26.5%.

**NOTE 10 – TAXES ON INCOME** (cont.)

**c. Tax loss carryforwards**

As of December 31, 2013 and 2014, the tax loss carryforwards of BioLineRx were approximately NIS 467,000,000 and NIS 523,000,000, respectively; and the tax loss carryforwards of BIJ Ltd. were approximately NIS 2,000,000 at both dates. The tax loss carryforwards of both BioLineRx and the BIJ Ltd. have no expiration date.

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

**d. Tax assessments**

In accordance with Israeli tax regulations, the tax returns filed by BioLineRx and its Israeli subsidiary through the 2009 tax year are considered final. BioLineRx USA has not yet been assessed for tax purposes.

**e. Theoretical taxes**

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

| | Year ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2012 | | 2013 | | 2014 | |
| | | NIS in thousands | | NIS in thousands | | NIS in thousands |
| Loss before taxes | 25% | (76,270) | 25% | (61,438) | 26.5% | (39,620) |
| Theoretical tax benefit | | (19,068) | | (15,360) | | (10,499) |
| Disallowed deductions (tax exempt income): | | | | | | |
| Gain on adjustment of warrants to fair value | | (1,816) | | (1,292) | | (3,274) |
| Share-based compensation | | 785 | | 760 | | 1,000 |
| Other | | 75 | | 66 | | 53 |
| Increase in taxes for tax losses and timing differences incurred in the reporting year for which deferred taxes were not created | | 20,024 | | 15,826 | | 12,720 |
| Taxes on income for the reported year | | - | | - | | - |

**f. Value-added tax (VAT)**

BioLineRx is jointly registered for VAT purposes together with its Israeli subsidiaries.

## NOTE 11 – LOSS PER SHARE

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

| | Year ended December 31, | | |
|---|---|---|---|
| | 2012 | 2013 | 2014 |
| | NIS in thousands | | |
| Loss attributed to ordinary shares | (76,270) | (61,438) | (39,620) |
| Number of shares used in basic calculation (in thousands) | 169,405 | 224,885 | 324,339 |
| | NIS | | |
| Basic loss per ordinary share | (0.45) | (0.27) | (0.12) |
| Diluted loss per ordinary share | (0.45) | (0.27) | (0.12) |

## NOTE 12 – COMMITMENTS AND CONTINGENT LIABILITIES

### a. Commitments

1) Agreement with the State of Israel for operation of the Incubator

The Company originally entered into a six-year agreement with the State of Israel to operate the Incubator, effective January 1, 2005 and expiring on December 31, 2010. In accordance with approval certificates subsequently received from the OCS, the Incubator agreement was extended for two additional periods, through December 31, 2013. Following expiration of the agreement on December 31, 2013, the Company terminated the activities of the incubator and applied to the courts for a formal liquidation of BIJ LP, which took effect on December 31, 2014.

As part of the Incubator agreement between BIJ LP and the State of Israel, represented by the OCS, the State of Israel agreed to grant loans to BIJ LP to partially finance projects approved by the OCS. As security for such loans, the Incubator registered first-ranking pledges in favor of the OCS on a project-specific basis, which included a restriction on the transfer of, and/or licensing rights in, technologies which originated from the project, and on any equipment purchased for use in the project. In addition, the Incubator agreement contained various restrictions regarding compliance with the Israel R&D Law (the Encouragement of Research and Development in Industry Law) related to maintaining the intellectual property and manufacturing rights relating to each OCS-funded project in Israel.

The proceeds from the sale or use of project-related intellectual property serve as the exclusive source for repayment of OCS loans financing such projects, and the sole collateral for the repayment of project loans are pledges on project-related intellectual property and assets purchased with loan proceeds. Upon termination of a project, loan amounts are forgiven in their entirety by the OCS.

During 2012 and 2013, the Company received loans of NIS 2,048,000 and NIS 50,000, respectively, from the OCS in the framework of the Incubator, the entire amounts of which were in respect of projects subsequently terminated by the Company. As of December 31, 2014, the Company has no further liabilities to the OCS in respect of loans received under the Incubator.

With respect to the accounting treatment of State loans, see Note 2q.

**NOTE 12 – COMMITMENTS AND CONTINGENT LIABILITIES** (cont.)

**a. Commitments** (cont.)

2) Obligation to pay royalties to the State of Israel – regular OCS funding

The Company is required to pay royalties to the State of Israel (represented by the OCS), computed on the basis of proceeds from the sale or license of products whose development was supported by State grants. This obligation relates solely to the State's financial participation in the development of products by the Company outside the framework of the Incubator that was operated by BIJ LP through December 31, 2013.

In accordance with the terms of the grants provided by the OCS, the State is entitled to royalties on the sale or license of any product whose development was supported with State participation. These royalties are generally 3% in the first three years from initial repayment, 4% of sales in the three subsequent years and 5% of sales in the seventh year until repayment of 100% of the grants (linked to the dollar) received by the Company, plus annual interest at the LIBOR rate. Under certain circumstances, the royalty rate is calculated according to a formula based on the ratio of the participation by the OCS in the project to the total project costs incurred by the Company. As of December 31, 2014, the contingent liability for potential royalties payable by the Company for OCS grants received (other than BL-8040 – see below) amounts to NIS 13.2 million ($3.4 million), of which NIS 12.5 million ($3.2 million) are attributed to projects recorded by the Company as terminated for repayment purposes (as a result of the actual termination of the license agreements with the relevant licensors) but which still require a formal termination process with the OCS.

In connection with the in-licensing of BL-8040 from Biokine Therapeutics Ltd. ("Biokine"), and as a condition to OCS consent to the transaction, the Company agreed to abide by any obligations resulting from funds previously received by Biokine from the OCS. The contingent liability to the OCS assumed by the Company relating to this transaction amounts to approximately NIS 10.6 million ($2.7 million) as of December 31, 2014. The Company has a full right of offset for amounts payable to the OCS from payments due to Biokine in the future. Therefore, in the opinion of management, the likelihood of any future Company payment obligation to the OCS with regard to this matter is remote.

3) Licensing agreements

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

**NOTE 12 – COMMITMENTS AND CONTINGENT LIABILITIES** (cont.)

**a. Commitments (cont.)**

3) Licensing agreements (cont.)

The licenses that have been granted to the Company are broad and comprehensive, and generally include various provisions and usage rights as follows: (i) territorial scope of the license (global); (ii) term of the license (unrestricted but not shorter than the life of the patent); and (iii) development of the therapeutic compound (allowing the Company to perform all development activities on its own, or by outsourcing under Company supervision, as well as out-licensing development under the license to other companies, subject to the provisions of the licensing agreements).

According to the provisions of the licensing agreements, the intellectual property rights in the development of any licensed technology, through the date the applicable license agreement is effective, remain with the licensor, while the rights in products and/or other deliverables developed by the Company after the license is granted belong to the Company. In cases where the licensor has a claim to an invention that was jointly developed with the Company, the licensor also co-owns the related intellectual property. In any event, the scope of the license also covers these rights.

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

The consideration paid pursuant to the licensing agreements generally includes several components that may be payable over the license period and that relate, inter alia, to the progress made in research and development activities, as well as commercial success, as follows: (a) one-time payment of up to $200,000 and/or periodic payments of up to $30,000 per year; (b) royalties on amounts the Company receives from an out-licensing transaction that generally range from 20% to 29.5% of net consideration, although in specific instances the royalty rate has been higher or lower than this range; (c) payments through the early stages of development ( i.e. through the end of phase 2) of up to $150,000; (d) payments of up to $2,000,000 upon the achievement of milestones necessary for advancing to phase 3; (e) payments of up to $5,000,000 from the end of a successful phase 3 trial through approval of the therapeutic compound; and f) royalties on sales of the final product resulting from development under the license or including any component thereof, ranging between 3%-5% of the Company’s net sales of the product, although in specific instances the royalty rate has been higher or lower than this range.

**NOTE 12 – COMMITMENTS AND CONTINGENT LIABILITIES** (cont.)

**a. Commitments** (cont.)

3) Licensing agreements (cont.)

The license agreements may be cancelled by the licensor only in specific circumstances, generally upon the occurrence of one of the following events: (a) the Company's failure to meet certain milestones stipulated in the applicable license agreement and appended timetables; (b) default, insolvency, receivership, liquidation, etc. of the Company that is not imposed and/or lifted within the timeframe stipulated in the license agreement; and (c) fundamental breach of the license agreement that is not corrected within the stipulated timeframe. The Company may generally cancel a license agreement with prior notice of 30 to 90 days, due to unsuccessful development or any other cause.

The Company has undertaken to indemnify certain licensors, their employees, officers, representatives or anyone acting on their behalf for any damage and/or expense that they may incur in connection with the Company's use of a license granted to it, all in accordance with the terms stipulated in the applicable license agreements.

Some of the license agreements are accompanied by consulting, support and cooperation agreements, pursuant to which the Company is committed to pay the various licensers a fixed monthly amount over the period stipulated in the agreement for their assistance in the continued research and development under the license.

4) Lease agreements

a) The Company is a party to an existing operating lease agreement in connection with the lease of its current premises. The existing agreement (after taking into account a short-term extension agreed with the lessor) will expire on April 30, 2015. The monthly lease fees are linked to the dollar and amount to approximately NIS 70,000.

In August 2014, the Company entered into a new operating lease agreement in connection with the lease of new premises. Payments under the new lease will commence in June 2015 and the new lease will expire in June 2020. The new monthly lease fees will amount to approximately NIS 73,000. The Company has the option to extend the lease for 4 additional lease periods totaling up to an additional 10 years, each option at a 5% increase to the preceding lease payment amount.

As to bank deposits pledged to secure the Company's liability under the lease agreements, see Note 12b.

b) The Company has entered into operating lease agreements in connection with a number of vehicles. The lease periods are generally for three years. The annual lease fees, linked to the CPI, are approximately NIS 890,000. To secure the terms of the lease agreements, the Company has made certain prepayments to the leasing companies, representing approximately two months of lease payments. These amounts have been recorded as prepaid expenses. See also Note 14b.

**NOTE 12 – COMMITMENTS AND CONTINGENT LIABILITIES** (cont.)

**a. Commitments** (cont.)

5) Early Development Program ("EDP") agreement

On the signature date of an investment agreement with Pan Atlantic Bank and Trust Limited ("Pan Atlantic") in 2007, BioLineRx also entered into an agreement with Pan Atlantic for the funding of an early development program (the "EDP Agreement"). According to the EDP Agreement, Pan Atlantic undertook to provide grants for the promotion of drug-development projects in the preliminary stages of research in an aggregate amount of up to $5,000,000, in semi-annual "calls" of up to $625,000 each. In parallel, for every dollar of EDP project funding provided by Pan Atlantic, BioLineRx committed to provide twenty cents of funding (i.e., a funding ratio of 5:1). Pan Atlantic's undertakings under the EDP agreement were not subject to Pan Atlantic being a lender to, or a shareholder of, BioLineRx. During 2012, Pan Atlantic fulfilled its entire $5,000,000 funding commitment under the EDP agreement, and during 2013, the Company utilized the remaining funds available under the program.

In consideration for the EDP funding commitment, BioLineRx granted to Pan Atlantic the right to participate in a future public offering of BioLineRx outside of Israel, at the public offering price, in an amount of up to $5,000,000. This right was exercised by Pan Atlantic in the Company's March 2014 underwritten public offering (see Note 9c(3)) and is no longer relevant for future Company financings.

During 2012, funding under the EDP agreement by Pan Atlantic amounted to NIS 1,867,000. The amounts recognized as a reduction of research and development expenses in 2012 and 2013 were NIS 3,955,000 and NIS 2,415,000, respectively.

**b. Contingent liabilities**

Guarantees and liens:

To secure the Company's liability to the lessor of its premises, the Company has pledged several dollar-denominated bank deposits in the aggregate amount of $164,000 (NIS 640,000), which are presented under non-current assets.

## NOTE 13 – TRANSACTIONS AND BALANCES WITH RELATED PARTIES

### Transactions with related parties

Expenses (income):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2012 | 2013 | 2014 |
| | NIS in thousands | | |
| Participation in EDP project funding* | (3,955) | (2,415) | - |
| Benefits to related parties: | | | |
| Compensation and benefits to senior management, including benefit component of option grants | 5,354 | 5,738 | 7,455 |
| Number of individuals to which this benefit related | 5 | 5 | 5 |
| Compensation and benefits to directors, including benefit component of option grants | 549 | 692 | 778 |
| Number of individuals to which this benefit related | 5 | 6 | 7 |

* This amount relates to a grant received from Pan Atlantic, in accordance with the EDP Agreement as detailed in Note 12a(5).

### Key management compensation

Key management includes directors (executive and non-executive), executive officers and the internal auditor. The compensation paid or payable to key management for services during each of the years indicated is presented below.

| | Year ended December 31, | | |
|---|---|---|---|
| | 2012 | 2013 | 2014 |
| | NIS in thousands | | |
| Salaries and other short-term employee benefits | 4,448 | 4,589 | 6,095 |
| Post-employment benefits | 441 | 436 | 465 |
| Other long-term benefits | 57 | 57 | 106 |
| Share-based compensation | 957 | 1,348 | 1,567 |
| | 5,903 | 6,430 | 8,233 |

## NOTE 14 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

### a. Other receivables

| | December 31, | |
|---|---|---|
| | 2013 | 2014 |
| | NIS in thousands | |
| Institutions | 1,227 | 973 |
| Grants receivable from the OCS | 6 | - |
| Other | 16 | 27 |
| | 1,249 | 1,000 |

### b. Long-term prepaid expenses

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

### c. Accounts payable and accruals

| | December 31, | |
|---|---|---|
| | 2013 | 2014 |
| | NIS in thousands | |
| 1) Trade: | | |
| Accounts payable: | | |
| In Israel | 1,672 | 2,171 |
| Overseas | 6,273 | 4,260 |
| | 7,945 | 6,431 |
| 2) Other: | | |
| Payroll and related expenses | 714 | 1,403 |
| Accrual for vacation and recreation pay | 974 | 1,079 |
| Accrued expenses | 801 | 2,371 |
| Other | 10 | 16 |
| | 2,499 | 4,869 |

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

**NOTE 14 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION** (cont.)

**d. Research and development expenses – net**

| | Year ended December 31, | | |
|---|---|---|---|
| | **2012** | **2013** | **2014** |
| | **NIS in thousands** | | |
| Payroll and related expenses, including vehicles | 14,283 | 12,794 | 13,490 |
| Depreciation and amortization | 1,433 | 817 | 903 |
| Write-off of intellectual property | - | 137 | 377 |
| Research and development services | 43,940 | 25,545 | 21,642 |
| Professional fees | 7,344 | 3,905 | 2,439 |
| Materials | 148 | 60 | 65 |
| Overseas travel | 115 | 48 | 41 |
| Lab, occupancy and telephone | 3,457 | 3,168 | 3,361 |
| Other | 338 | 227 | 125 |
| | 71,058 | 46,701 | 42,443 |
| Less – OCS participation in research and development costs - see also Notes 12a(1) and (2) | (2,799) | (229) | - |
| Less – participation in research and development costs by a related party - see Note 13 | (3,955) | (2,415) | - |
| | 64,304 | 44,057 | 42,443 |

**e. Sales and marketing expenses**

| | Year ended December 31, | | |
|---|---|---|---|
| | **2012** | **2013** | **2014** |
| | **NIS in thousands** | | |
| Payroll and related expenses, including vehicles | 1,841 | 1,752 | 2,389 |
| Marketing | 1,044 | 2,001 | 2,859 |
| Overseas travel | 342 | 348 | 437 |
| | 3,227 | 4,101 | 5,685 |

**NOTE 14 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION** (cont.)

**f. General and administrative expenses**

| | Year ended December 31, | | |
|---|---|---|---|
| | **2012** | **2013** | **2014** |
| | **NIS in thousands** | | |
| Payroll and related expenses, including vehicles | 6,664 | 6,855 | 8,166 |
| Professional fees | 4,708 | 4,183 | 3,160 |
| Office supplies and telephone | 79 | 53 | 50 |
| Office maintenance | 78 | 66 | 61 |
| Insurance | 618 | 513 | 522 |
| Depreciation | 91 | 330 | 57 |
| Other | 1,788 | 1,225 | 1,575 |
| | 14,026 | 13,225 | 13,591 |

**g. Non-operating income, net**

| | Year ended December 31, | | |
|---|---|---|---|
| | **2012** | **2013** | **2014** |
| | **NIS in thousands** | | |
| Issuance costs | (1,204) | (978) | (366) |
| Changes in fair value of warrants | 7,265 | 5,169 | 12,354 |
| Initial commitment and finder's fees associated with LPC agreement | (2,103) | - | (1,040) |
| | 3,958 | 4,191 | 10,948 |

**h. Financial income**

| | Year ended December 31, | | |
|---|---|---|---|
| | **2012** | **2013** | **2014** |
| | **NIS in thousands** | | |
| Income from interest and exchange differences on deposits | 8,819 | 2,600 | 12,754 |
| | 8,819 | 2,600 | 12,754 |

**i. Financial expenses**

| | Year ended December 31, | | |
|---|---|---|---|
| | **2012** | **2013** | **2014** |
| | **NIS in thousands** | | |
| Exchange differences | 7,393 | 6,774 | 1,533 |
| Bank commissions | 97 | 72 | 70 |
| | 7,490 | 6,846 | 1,603 |

## NOTE 15 – BELLEROPHON AGREEMENT

During the third quarter of 2009, the Company entered into an out-licensing agreement with Bellerophon BCM, LLC ("Bellerophon") (f/k/a Ikaria Development Subsidiary One LLC), pursuant to which the Company granted Bellerophon an exclusive, worldwide license to develop, manufacture and commercialize BL-1040 – a compound for the treatment of patients that have suffered an acute myocardial infarction ("AMI").

In accordance with the agreement, Bellerophon is obligated to use commercially reasonable efforts to complete clinical development of and to commercialize BL-1040, and will bear all subsequent costs involved in the continued development of the product, the conduct and funding of its commercialization, and the prosecution and maintenance of patents.

Total payments to the Company under the agreement (not including royalties) are up to $282,500,000, subject to the achievement of certain milestones. Upon the closing of the agreement, the Company became entitled to the first payment in the amount of $7,000,000, which was received in October 2009. In connection with this payment, the Company undertook to indemnify Bellerophon for any obligations it may have had to withhold taxes on such payment. In April 2010, the first milestone payment of $10,000,000 was received, in respect of which withholding tax of 15% was deducted. The Company received a full refund of the tax withheld in 2011. Approximately 50% of the remaining payments are subject to certain development and regulatory milestones and the rest are subject to commercialization milestones. The abovementioned first two payments were recognized as revenues in 2009, and future milestone payments will be recognized as revenues if and when their receipt will become probable and their amount can be reliably measured.

The Company is also entitled to royalties on the net sales of any product developed under the agreement, ranging from 11% to 15%, depending on annual net sales levels.

The out-licensing agreement with Bellerophon terminates on the date that the last patent rights in respect of BL-1040 are still valid (through at least 2029).

During 2014, the Company conducted a number of discussions with Bellerophon about alleged breaches relating to Bellerophon's performance under the BL-1040 license agreement and about the timing of a $12.5 million milestone payment that Bellerophon would owe to the Company in the future based upon progress in the BL-1040 clinical development program. In January 2015, the Company and Bellerophon entered into an amendment to the BL-1040 license agreement, which resolved the disputes and provided for a release of the Company's claims against Bellerophon. The amendment resulted in changes to certain milestones and related payments; however, the total potential milestone payments to be paid under the license agreement remain the same.

The Company is required to pay to the licensors of the BL-1040 compound 28% of all consideration received under the agreement.

**NOTE 16 – STRATEGIC COLLABORATION AGREEMENT WITH NOVARTIS**

In December 2014, the Company entered into a multi-year strategic collaboration agreement with Novartis Pharma AG ("Novartis") designed to facilitate development and commercialization of Israeli-sourced drug candidates. Novartis will evaluate projects identified and presented by the Company for co-development and future licensing under the collaboration. The parties intend to co-develop a number of pre-clinical and clinical therapeutic projects up to clinical proof of concept.

Under the terms of the agreement, Novartis acquired an initial 5,000,000 of the Company's ADSs, representing 12.8% of the Company's then outstanding share capital, in a private transaction at a price of $2.00 per ADS, for a total equity investment of $10 million. Novartis will not have any governance rights and has agreed to certain standstill provisions. Novartis and the Company will jointly evaluate both clinical and pre-clinical stage projects presented by the Company via a Joint Steering Committee, which will determine which projects to advance further in development and on what terms. Projects at or reaching the clinical stage will be eligible for selection by Novartis. Upon selection of a project, Novartis will pay the Company an option fee of $5 million, as well as fund 50% of the anticipated remaining development costs associated with establishing clinical proof-of-concept, in the form of an additional equity investment in the Company. Novartis will have an exclusive right of first negotiation to license from the Company each selected project upon establishment of clinical proof-of-concept. The companies intend to develop up to three programs through clinical proof-of-concept pursuant to this collaboration.

**NOTE 17 – AGREEMENT WITH OMEGA PHARMA**

In December 2014, the Company entered into an exclusive out-licensing arrangement with a subsidiary of Omega Pharma NV ("Omega Pharma") for the rights to BL-5010 for OTC indications in the territory of Europe, Australia and additional selected countries. The Company will retain the rights to BL-5010 in the United States and the rest of the world. Under the out-licensing arrangement with Omega Pharma, Omega Pharma is obligated to use commercially reasonable best efforts to obtain regulatory approval in the licensed territory for at least two OTC indications and to commercialize BL-5010 for those two OTC indications. In addition, Omega Pharma will sponsor and manufacture BL-5010 in the relevant regions. Omega Pharma will pay the Company an agreed amount for each unit sold, and the Company will be entitled to certain commercial milestone payments. In addition, the Company will have full access to all clinical and development data generated during the performance of the development plan and may use these data in order to develop or license the product in other territories and fields of use where the Company retains the rights.

**NOTE 18 – CYPRESS AGREEMENT**

In June 2010, the Company entered into an exclusive, royalty-bearing out-licensing agreement with Cypress Bioscience, Inc. for the United States, Canada and Mexico (the "territories"), with regard to BL-1020, a therapeutic candidate for the treatment of schizophrenia. Under the agreement, Cypress Bioscience was obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and to commercialize BL-1020 in the territories, and was to bear all subsequent costs involved in the continued development of the product, the conduct and funding of its commercialization, and the prosecution and maintenance of patents in the territories. The agreement became effective in August 2010, upon receipt of the consent of the Office of the Chief Scientist of Israeli Ministry of Industry, Trade and Labor (“OCS”).

The Company received an upfront fee of $30,000,000 from Cypress Bioscience upon the effectiveness of the agreement. Upon receipt of this fee, the Company became obligated to repay grants received from the OCS regarding the BL-1020 project, in accordance with the Israeli R&D Law and as agreed with the OCS. Accordingly, during 2010, the Company recorded a liability to the OCS for the full amount of the grants received in respect of the project, in the total amount of $4,500,000. The Company paid $3,000,000 of this liability to the OCS in August 2010, leaving a remaining balance of $1,500,000, which was reflected in current liabilities through December 31, 2012.

In May 2011, the Company signed an agreement, effective June 1, 2011, to reacquire all development and commercialization rights to BL-1020 granted to Cypress Bioscience pursuant to the license agreement signed in June 2010, as well as to terminate the license agreement. In consideration for the reacquisition of such rights, including substantially all materials required for timely commencement of the CLARITY clinical trial for BL-1020 that commenced in June 2011, the Company was obligated to pay Cypress Bioscience a 1% royalty on worldwide net sales of BL-1020 up to an aggregate cumulative amount of $80,000,000. In addition, the Company was obligated to pay Cypress Bioscience 10% of all future one-time payments received in respect of BL-1020, not to exceed an aggregate cumulative amount of $10,000,000, as reimbursement for costs that Cypress Bioscience incurred in developing the intellectual property portfolio, designing the CLARITY trial and conducting substantially all preparations to launch the trial.

In March 2013, the Company decided to terminate the CLARITY study. Following the study termination, as of March 31, 2013, the Company reversed the remaining $1,500,000 liability to the OCS in respect of BL-1020, since it became more likely than not that such liability would not be repaid.

Following further analyses performed on the CLARITY study data during the second half of 2013, the Company announced the termination of the BL-1020 project in March 2014.

**NOTE 19 – AGREEMENT WITH CTTQ**

In June 2013, the Company signed an out-licensing agreement with Jiangsu Chia-tai Tianqing Pharmaceutical Co., Ltd. ("CTTQ"), the leading Chinese pharmaceutical company in the liver disease therapeutic area, for the development and commercialization of BL-8030, an orally available treatment for HCV in the pre-clinical stages of development. Under the terms of the agreement, the Company granted CTTQ exclusive rights to develop, manufacture and commercialize BL-8030 in China and Hong Kong. Pursuant to the agreement, CTTQ paid a small upfront license fee, and may pay future development, regulatory and commercialization milestones, for a total potential deal value of approximately $30 million. In addition, the Company has the right to receive high single-digit royalties on future sales of the drug. The Company has retained the right to develop and commercialize BL-8030 in other parts of the world.

**NOTE 20 – EVENT SUBSEQUENT TO THE BALANCE SHEET DATE**

In March 2015, the Company completed an underwritten public offering of 14,375,000 ADSs at a public offering price of $2.00 per ADS. The offering raised a total of $28.8 million, with net proceeds of approximately $26.4 million.

**EXHIBIT 4.17**

CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. ASTERISKS DENOTE OMISSIONS.

**EXECUTION VERSION**

# AMENDED AND RESTATED

# LICENSE AND COMMERCIALIZATION AGREEMENT

BY AND AMONG

IKARIA DEVELOPMENT SUBSIDIARY ONE LLC

AND

BIOLINERX LTD.

AND

BIOLINE INNOVATIONS JERUSALEM L.P.

AUGUST 26, 2009

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AMENDED AND RESTATED
LICENSE AND COMMERCIALIZATION AGREEMENT

This Amended and Restated License and Commercialization Agreement (the "Agreement") is entered into this 26th day of August, 2009, by and among **Ikaria Development Subsidiary One LLC**, a Delaware limited liability company having a principal place of business at 6 State Route 173, Clinton, NJ 08809, USA ("Ikaria"), **BioLineRx Ltd.**, a corporation organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel ("BioLineRx Ltd."), and **BioLine Innovations Jerusalem L.P.**, a limited partnership organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel ("BioLine Innovations"; together with BioLineRx Ltd., "BioLineRx").

INTRODUCTION

WHEREAS, BioLineRx owns or controls certain intellectual property rights covering a liquid polymer composed of Sodium Alginate and Ca-D-Gluconate (designated by BioLineRx as "BL-1040");

WHEREAS, BioLineRx is currently developing the Product (as defined below) as a medical device for the direct treatment of cardiac tissue following acute myocardial infarction;

WHEREAS, BioLineRx is concluding the safety and clinical trials of the Product that were initiated by BioLineRx prior to the Effective Date (as defined below);

WHEREAS, BioLineRx desires to grant to Ikaria the worldwide exclusive rights to Develop, Manufacture, and Commercialize Products (as such capitalized terms are defined below); and

WHEREAS, Ikaria desires to obtain such exclusive rights in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, BioLineRx and Ikaria agree as follows:

Article I

Definitions; Interpretation

When used in this Agreement, each of the following capitalized terms has the meaning set forth in this Article I:

Section 1.1 "Affiliate" shall mean, with respect to a Party, any Person that controls, is controlled by, or is under common control with such Party. For purposes of this Section 1.1, "control" shall refer to (a) in the case of a Person that is a corporate entity, direct or indirect ownership of more than fifty percent (50%) of the stock, shares or membership units having the right to vote for the election of a majority of the directors of such Person, and (b) in the case of a Person that is an entity, but is not a corporate entity, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

Section 1.2 "BGN License Agreement" shall mean that certain License Agreement, dated January 10, 2005, as amended, by and among BioLine Jerusalem L.P. and B.G. Negev Technologies and Applications Ltd. ("BGN") on behalf of Ben Gurion University.

Section 1.3 "BioLineRx Know-How" shall mean all Know-How that is (a) necessary or useful for the Development, Manufacture, or Commercialization of any Product and (b) either (i) is Controlled by BioLineRx as of the Effective Date or (ii) BioLineRx comes to Control during the term of this Agreement.

Section 1.4 "BioLineRx Patent Rights" shall mean Patent Rights that claim or disclose BioLineRx Know-How, including the Patent Rights listed in Exhibit B.

Section 1.5 "BioLineRx Intellectual Property" shall mean BioLineRx Patent Rights (including Patent Rights in the Sublicensed IP), and BioLineRx Know-How (including Know-How in the Sublicensed IP).

Section 1.6 "Business Day" shall mean a day that is not a Saturday, a Sunday or a day on which banking institutions in New York, New York, USA are authorized by law to remain closed.

Section 1.7 "Commercialization" or "Commercialize" shall mean any activities directed to marketing, promoting, distributing, importing, exporting, or selling a product.

Section 1.8 "Commercially Reasonable Efforts" shall mean the efforts, expertise and resources normally used by a Party to Develop, Manufacture and Commercialize a product owned by it or to which it has rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety and efficacy, product profile, difficulty in developing the product, competitiveness of the marketplace for the product, the proprietary position of the product, the regulatory structure involved, the availability and level of reimbursement for such treatment by Third Party payors or health insurance plans, the potential total profitability of the applicable product(s) marketed or to be marketed and other relevant factors affecting the cost, risk and timing of Development and the total potential reward to be obtained if a product is Commercialized. The Parties agree that Commercially Reasonable Efforts shall require a Party to expend efforts, expertise and resources that such Party would normally expend to Develop, use, Manufacture and Commercialize a product owned by it or to which it has rights, taking into account the foregoing factors.

Section 1.9 "Confidential Information" shall mean, with respect to a disclosing Party, all Know-How or other information (whether or not patentable) regarding such Party's technology, products, business information or objectives (whether disclosed before or after the Effective Date) that is of a confidential and proprietary nature, including reports and audits under Section 4.3, the Development Plan, the Commercialization Plan, the terms of this Agreement, and all proprietary tangible materials (and data and information associated therewith) of such Party. Notwithstanding the foregoing, Confidential Information shall not include Know-How or other information that:

(a) was rightfully known or used by the receiving Party or its Affiliates without an obligation of confidentiality prior to its date of disclosure to the receiving Party as demonstrated by contemporaneous written records; or

(b) either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party or its Affiliates by sources other than the disclosing Party rightfully in possession of such information and not bound by confidentiality obligations to the disclosing Party; or

(c) either before or after the date of the disclosure to the receiving Party or its Affiliates is or becomes published or otherwise is or becomes part of the public domain through no breach hereof on the part of the receiving Party or its Affiliates; or

(d) is independently developed by or for the receiving Party or its Affiliates without reference to or use of the Confidential Information of the disclosing Party as demonstrated by contemporaneous written records.

Section 1.10 "Control" shall mean the legal authority or right of a Party or its Affiliates to grant a license or sublicense of intellectual property rights to the other Party, or to provide tangible material to or otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party. For the avoidance of doubt, BioLineRx Controls the Sublicensed IP.

Section 1.11 "Cover" or "Covered" shall mean, with respect to a Patent Right and a product, that, in the absence of ownership of (with a retained right to exploit), or a license granted under, a Valid Claim included in such Patent Right, the Manufacture, Development, Commercialization, use, sale, import, or offer for sale, as applicable, of such product would infringe such Valid Claim in the country where such activity occurs.

Section 1.12 "Development" or "Develop" shall mean development activities, including test method development and stability testing, toxicology, formulation, optimization, quality assurance/quality control development, statistical analysis, clinical studies, regulatory affairs, product approval, and registration.

Section 1.13 "Development Term" shall mean the term of development of Products by Ikaria.

Section 1.14 "EU" shall mean the European Union and all the member states thereof, as it may be comprised from time to time.

Section 1.15 "EU Milestone Conditions" shall mean (a) satisfaction of all requirements for [***], (b) [***] set forth therein, **and** (c) [***].

**[***] Redacted pursuant to a confidential treatment request.**

Section 1.16 "Executive Officers" shall mean the Chief Executive Officer of Ikaria (or a senior executive officer of Ikaria designated by Ikaria) and the Chief Executive Officer of BioLineRx (or a senior executive officer of BioLineRx designated by BioLineRx).

Section 1.17 "FDA" shall mean the United States Food and Drug Administration or any successor agency thereof.

Section 1.18 "Field" shall mean any and all uses described or claimed in the BioLineRx Patent Rights.

Section 1.19 "First Commercial Sale" shall mean, with respect to a Product in a country, the first commercial sale of such Product by Ikaria, its Affiliates, distributors, agents or Licensees in such country. Sales for clinical trial purposes or compassionate or similar use shall not be considered to constitute a First Commercial Sale.

Section 1.20 Intentionally Omitted

Section 1.21 Intentionally Omitted

Section 1.22 Intentionally Omitted

Section 1.23 Intentionally Omitted.

Section 1.24 Intentionally Omitted."

Section 1.25 "Know-How" shall mean any tangible or intangible know-how, expertise, information, inventions, discoveries, documents and other works of authorship, copyrights, trade secrets, data, or materials, whether proprietary or not, including ideas, concepts, formulas, methods, procedures, designs, technologies, compositions, plans, applications, technical data, data generated in clinical trials, samples, chemical compounds and biological materials and all derivatives, modifications and improvements thereof.

Section 1.26 "Knowledge" shall mean, with respect to a Party, the Party's actual knowledge together with any knowledge of any of the Party's officers or director-level employees, that a Person in such party's position would be expected to obtain given the exercise of reasonably prudent scientific and business diligence in accordance with the standards of companies of such Party's size in such Party's industry.

Section 1.27 "Licensee" shall mean any Person to whom Ikaria licenses its rights under this Agreement in the manner provided in Section 2.1, including any Third Party contractors.

Section 1.28 "Manufacturing" or "Manufacture" shall mean any activities associated with the production, manufacture, supply, processing, filling, packaging, labeling, shipping, or storage of a product or any components thereof, including process and formulation development, process validation, stability testing, manufacturing scale-up, development and commercial manufacture and analytical development, product characterization, quality assurance and quality control development, testing, and release.

Section 1.29 "Net Sales" shall mean, with respect to a Product, the gross amounts billed by Ikaria, its Affiliates, or Licensees in respect of sales of such Product by Ikaria and its Affiliates or Licensees to unrelated Third Parties, in each case less the following deductions:

(a) Trade, cash, or quantity discounts (including amounts incurred in connection with government mandated rebate programs) actually allowed and taken with respect to such sales;

(b) Tariffs, duties, excises, sales taxes or other taxes imposed upon and paid with respect to the production, sale, delivery, or use of the Product (excluding national, state, or local taxes based on income);

(c) Amounts repaid or credited by reason of billing corrections, rejections, defects, recalls, or returns (due to spoilage, damage, expiration of useful life or otherwise) or because of chargebacks, refunds or retroactive price reductions and allowances for wastage replacement and bad debts;

(d) Portions of invoices sales amounts included in Net Sales in prior periods that are actually written off by Ikaria, its Affiliates, or licenses as uncollectible; and

(e) Postage, freight, shipping, insurance, and other transportation related charges incurred in shipping a Product to Third Parties.

Such amounts shall be determined from the books and records of Ikaria, its Affiliates, or Licensees, maintained in accordance with generally accepted accounting principles, consistently applied. For the avoidance of doubt, in no event will fines, penalties or other monetary damages assessed against Ikaria, its Affiliates or Licensees by any governmental authority for violation of any applicable law, result in an appropriate deduction to Net Sales.

If one or more Products is sold as part of a Combination Product (as defined below), the Net Sales from the Combination Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales (as determined above) of the Combination Product, during the applicable royalty reporting period, by the fraction, A/(A+B), where A is the average sale price of the Product(s) when sold separately in finished form and B is the average sale price of the other components included in the Combination Product when sold separately in finished form, in each case in the applicable country during the applicable royalty reporting period or, if sales of both the Product(s) and the other components did not occur in such country in such period, then in the most recent royalty reporting period in which sales of both occurred. If such average sale price cannot be determined for both the Product(s) and all other components included in such Combination Product, Net Sales for the purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the fraction of C/(C+D) where C is the fair market value of the Product(s) and D is the fair market value of all other components included in the Combination Product. In such event, the Parties shall negotiate in good faith to arrive at a determination of the respective fair market values of the Product(s) and all other components included in the Combination Product. If the Parties are unable to agree on such determination within sixty (60) days, then such matter shall be resolved as provided in Article IX.

As used above, the term "Combination Product" means any therapeutic medical product that includes both (i) one or more Product(s) and (ii) other component(s).

Section 1.30 "On-Going Phase I/II Trial" shall mean that certain clinical trial of a Product that was initiated by BioLineRx prior to and that is ongoing as of the Effective Date, the protocol for which is attached hereto as Schedule 1.30.

Section 1.31 "Other On-Going Trials" shall mean those pre-clinical and CMC trials (other than the On-Going Phase I/II Trial) that were initiated by BioLineRx prior to, and that are ongoing as of, the Effective Date, descriptions of which are attached hereto as Schedule 1.31.

Section 1.32 "Party" shall mean BioLineRx or Ikaria; "Parties" shall mean BioLineRx and Ikaria.

Section 1.33 "Patent Rights" shall mean United States and foreign patents and patent applications (including provisional applications) and all substitutions, divisionals, continuations, continuations-in-part, reissuances, reexaminations, registrations, renewals, confirmations, supplementary protection certificates and extensions thereof.

Section 1.34 "Person" shall mean any natural person or any corporation, company, partnership, joint venture, firm, university, other entity, governmental authority, or subdivision thereof.

Section 1.35 "Pivotal Clinical Trial" shall mean a randomized, controlled clinical trial of a Product designed to demonstrate statistically significant clinical efficacy and safety in human patients (in conjunction with performance of a therapeutic procedure) pursuant to a clinical study agreed with the FDA, which trial the FDA accepts as a pivotal clinical trial necessary for Regulatory Approval of such Product. An outline of the structure of the initial Pivotal Clinical Trial is attached as Schedule 1.35.

Section 1.36 "Primary Indication" shall mean the diagnosis, prevention, mitigation, or treatment of injury to myocardial tissue via the administration of a Product to a human patient.

Section 1.37 "Product" shall mean a liquid polymer composed of Sodium Alginate and Ca-D-Gluconate (designated by BioLineRx as "BL-1040"), or any back-ups or second-generation polymers or polymer combinations thereof that is Developed under the Development Program.

Section 1.38 "Regulatory Approval" shall mean, with respect to a jurisdiction, the approval of the applicable Regulatory Authority required to market and sell a Product in such jurisdiction. For clarity, Regulatory Approval for a Product shall occur:

(a) in the United States, on the date when the FDA approves a Premarket Approval (PMA) application;

(b) in Europe, on the date when such Product may first be placed on the market as a medical device (as such terms are defined in Art. 1 Paragraphs 2(a) and (h) of Directive 93/42/EEC, as amended) bearing the CE marking according to Art. 17 of Directive 93/42/EEC, as amended, in any member state of the EU; and

(c) in Japan, on the date when the Ministry of Health approves a marketing authorization.

Section 1.39 "Regulatory Authority" shall mean any national (*e.g.*, the FDA), supra-national or other regulatory agency or governmental entity involved in the granting of Regulatory Approval for, or in the regulation of human clinical studies of, therapeutic medical devices.

Section 1.40 "Royalty Term" shall mean, with respect to a Product in a country of the Territory, the period of time commencing on the First Commercial Sale of such Product in such country and ending upon the earlier of (a) the expiration of the last-to-expire Valid Claim in the BioLineRx Patent Rights that Covers the sale or use of such Product in the Field in such country, or (b) the date of a judicial determination from which no appeal can be taken of invalidity of a set of claims in the BioLineRx Patent Rights that Cover the sale or use of such Product in the Field in such country and that are asserted through litigation (whether in an infringement action, a declaratory judgment action, or otherwise) to exclude a Third Party from selling or using a product in the Field in such country.

Section 1.41 "Sublicensed IP" shall mean that portion of the BioLineRx Intellectual Property licensed to BioLineRx pursuant to the BGN License Agreement.

Section 1.42 "Successful Completion" shall mean:

(a) with respect to the On-Going Phase I/II Trial, no treatment-related safety findings during the treatment period and the six (6) month follow up period, that were considered by the Independent Safety Monitoring Board for the On-Going Phase I/II Trial (in accordance with and subject to the Independent Safety Monitoring Board Charter attached hereto as Schedule 1.42(a)) to be of sufficient concern to discontinue the On-Going Phase I/II Trial;

(b) with respect to the Interim Analysis of the Pivotal Clinical Trial/Phase IIb Proof of Concept, safety and efficacy data from completion of all patients at the [***] follow up demonstrates more than a [***]probability of meeting pre-specified endpoints at [***] in the Pivotal Clinical Trial, and no apparent safety signal in the treatment group for the entire cohort at all times;

(c) with respect to the Pivotal Clinical Trial for the Primary Indication, safety and efficacy data from completion of all patients at the [***] follow up meets the primary endpoint and demonstrates a positive benefit-to-risk ratio to enable FDA submission; and

(d) with respect to all other clinical trials of a Product, that the JDC has determined that the final results of such clinical trial have achieved the success criteria established by the JDC with respect to such clinical trial.

Section 1.43 "Territory" shall mean the entire world.

**[***] Redacted pursuant to a confidential treatment request**

Section 1.44 "Third Party" shall mean any Person other than a Party or any of its Affiliates or Licensees.

Section 1.45 "Valid Claim" shall mean a claim of any issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, reexamination, disclaimer, or otherwise.

Section 1.46 Additional Definitions. Each of the following terms is defined in the section of this Agreement indicated below:

| Term | Section |
|---|---|
| "Agreement" | Preamble |
| "Bankruptcy Code" | Section 2.5 |
| "BGN" | Section 1.2 |
| "BioLineRx" | Preamble |
| "BL-1040" | Section 1.37 |
| "Breaching Party" | Section 8.2 |
| "Combination Product" | Section 1.29 |
| "Commercialization Plan" | Section 3.7 |
| "Competitive Infringement" | Section 5.3(a) |
| "Effective Date" | Section 2.1 |
| "Existing Product Agreements" | Section 2.3 |
| "Ikaria" | Preamble |
| "Development Plan" | Section 3.1 |
| "Development Program" | Section 3.1 |
| "Force Majeure Event" | Section 10.7 |
| "Indemnified Party" | Section 10.1(c) |
| "Indemnifying Party" | Section 10.1(c) |
| "Invalidity Claim" | Section 5.3(d) |
| "Joint Development Committee" or "JDC" | Section 3.2 |
| "Joint Manufacturing Committee" or "JMC" | Section 3.6(c) |
| "Lead Party" | Section 5.3(e) |
| "Losses" | Section 10.1(a) |
| "New Indication" | Section 2.4 |
| "New Indication Invention" | Section 5.1(a) |
| "Non-Breaching Party" | Section 8.2 |
| "OCS" | Section 2.1 |
| "SEC" | Section 6.1 |
| "Severed Clause" | Section 10.11 |
| "Technology Exchange" | Section 3.5 |
| "Technology Exchange Plan" | Section 3.5 |
| "Third Party Payment" | Section 4.2(b) |

Section 1.47 Interpretation. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine, and neuter forms. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation". The word "will" shall be construed to have the same meaning and effect as the word "shall". The word "or" shall be construed to have the same meaning and effect as "and/or". This Agreement has been prepared jointly with the assistance of counsel and shall not be strictly construed against either Party. The captions or headings of the sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and shall have no effect on the meaning of the provisions hereof. Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument, or other document herein shall be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements, or modifications set forth herein or therein), (b) any reference to any laws herein shall be construed as referring to any law, statute, rule, regulation, ordinance, or other pronouncement having the effect of law of any federal, national, multinational, state, provincial, county, city, or other political subdivision, domestic or foreign, as they from time to time may be enacted, repealed, or amended, (c) any reference herein to any Person shall be construed to include the Person's successors and assigns, (d) the words "herein", "hereof", and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) any reference herein to the words "mutually agree" or "mutual written agreement" shall not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as such Party may determine in such Party's sole discretion, and (f) all references herein to Articles, Sections, Exhibits, or Schedules shall be construed to refer to Articles, Sections, Exhibits, and Schedules of this Agreement.

## Article II

## Grant of Rights

Section 2.1 BioLineRx License Grant to Ikaria; Consent of OCS. Subject to the terms and conditions of this Agreement, including the consent of the Office of the Chief Scientist of the State of Israel ("OCS"), BioLineRx hereby grants to Ikaria the exclusive, royalty-bearing right and license in the Territory under the BioLineRx Intellectual Property (including, for clarity, a sublicense under the Sublicensed IP) to Develop, Manufacture and Commercialize Products for use in the Field. Subject to the consent of BioLineRx, which consent shall not be unreasonably withheld, conditioned or delayed, the foregoing license includes the right to grant sublicenses under the BioLineRx Intellectual Property, provided that, with respect to sublicenses granted under the Sublicensed IP, Ikaria shall (a) grant such sublicenses only for consideration and at arm's-length transactions, and (b) grant such sublicenses only pursuant to written agreements that contain such terms and conditions as may be required for Ikaria to comply with this Agreement. BioLineRx shall use its best efforts to obtain the written consent of the OCS to this Agreement within [***] days after August 26th, 2009, which consent must be in a form that is satisfactory to each Party. If the OCS has still not provided such consent during such [***] days, Ikaria shall have the right to require BioLineRx to continue to use best efforts to obtain such consent within the subsequent [***] day period. In addition, (i) Ikaria shall have the right to have a representative present at all interactions between BioLineRx's representatives and the OCS relating to such consent, (ii) BioLineRx shall (A) provide Ikaria with a reasonable opportunity to review and approve the request for consent submitted to the OCS and (B) keep Ikaria fully informed as to the progress of such request for consent and shall consult with Ikaria in good faith with respect thereto, (iii) BioLineRx shall not engage in any activities or discussions with any Third Party relating to the subject matter of this Agreement, including pursuing any other transactions relating to the BioLineRx Intellectual Property, without Ikaria's consent, and (iv) Ikaria shall have the right, prior to the Effective Date, to unilaterally modify this Agreement to comply with the specific, formal, written requests of the OCS, provided that such modifications have no detrimental financial impact on BioLineRx under this Agreement. Notwithstanding BioLineRx's obligation to exercise best efforts to obtain the consent from the OCS as described above, BioLineRx shall not be required to (y) agree to any request by the OCS that would require BioLineRx to pay to the OCS an aggregate amount of more than [***] or (z) obtain a consent based on the characterization of this Agreement as a "transfer of know-how outside of Israel" under Section 19B of the Israeli Law for the Encouragement of Industrial Research & Development, 1984. Notwithstanding anything herein to the contrary, subject to Section 8.6, the provisions of this Agreement other than this Section 2.1, Section 2.2, Article VII, Section 8.6 and Article X shall not be effective until such consent has been obtained and each Party has delivered the certificate set forth in Section 7.8 (the "Effective Date").

Section 2.2 Non-Competition. During the term of this Agreement, BioLineRx shall not, within the Territory, directly or indirectly (including through its Affiliates), conduct research or discovery activities, Develop, Manufacture (except as set forth in Section 3.6), Commercialize, or grant any rights or options or provide assistance to any Third Party to conduct research or discovery activities, Develop, Manufacture (except as set forth in Section 3.6) or Commercialize, (a) the Product or (b) any compound, substance, polymer, or product (whether pharmaceutical or device in nature) the method of action or effect of which is similar to any Product.

Section 2.3 Existing Product Agreements. BioLineRx hereby agrees that, upon the written request of Ikaria, BioLineRx shall assign to Ikaria each of the agreements listed in Schedule 2.3 attached hereto (the "Existing Product Agreements"), and all of its rights, title, and interest therein. BioLineRx shall cooperate with Ikaria, including by executing and recording documents, as may be necessary to effectuate such assignments and the exercise by Ikaria of its rights under the Existing Product Agreements.

Section 2.4 Intentionally Omitted.

**[***] Redacted pursuant to a confidential treatment request.**

Section 2.5 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any Section of this Agreement, including under this Article II and with respect to any BioLineRx Intellectual Property subject to Technology Exchange under Section 3.5, are rights to "intellectual property" (as defined in Section 101(35A) of Title 11 of the United States Code (such Title, the "Bankruptcy Code")). Each of Ikaria and BioLineRx hereby acknowledges "embodiments" of such intellectual property for purposes of Section 365(n) of the Bankruptcy Code shall include (a) copies of research data, (b) laboratory samples, (c) product samples, (d) formulas, (e) laboratory notes and notebooks, (f) data and results related to clinical studies, (g) regulatory filings and approvals, (h) rights of reference in respect of regulatory filings and approvals, (i) research data and results, and (j) marketing, advertising, and promotional materials, in each case, that relate to such intellectual property. Each Party shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code or analogous legislation in any other jurisdiction. Upon the institution by or against BioLineRx of any assignment for the benefit of creditors, composition, or any bankruptcy, reorganization, arrangement, insolvency, or similar proceedings under the laws of any jurisdiction, Ikaria shall further be entitled to a complete duplicate of, or complete access to, as appropriate, any such intellectual property (including embodiments thereof), and such intellectual property and embodiments, if not already in its possession, shall be promptly delivered to Ikaria, unless BioLineRx elects to continue, and continues, to perform all of its obligations under this Agreement.

Section 2.6 Retained Rights. Except as otherwise specifically provided for in this Agreement, each Party retains all rights and licenses to exploit its own intellectual property.

## Article III

## Development; Manufacturing; Commercialization

Section 3.1 General. Ikaria shall be solely responsible for conducting and funding all Development activities pursuant to the Development Plan, and shall have the sole right to Develop, Manufacture, and Commercialize Products in the Field in the Territory. Subject to its obligations under Section 3.8, Ikaria shall prepare a non-binding plan (the "Development Plan") for the Development of Product(s) (the "Development Program"). The Development Plan shall include an estimated budget setting forth Ikaria's anticipated development costs. Ikaria shall provide BioLineRx with a copy of its then-current Development Plan at least [***] per year, but no later than [***]days following the beginning of each year. The initial Development Plan is attached hereto as Schedule 3.1, which shall be non-binding, including any timelines or milestones that may be included therein. In addition, Ikaria shall, within [***] days after the Effective Date, provide BioLineRx with a revised draft protocol for the Interim Analysis of the Pivotal Clinical Trial/Phase IIb Proof of Concept and the Pivotal Clinical Trial, after taking into account any comments BioLineRx may wish to provide based on the initial draft of the protocol attached hereto as Schedule 1.35, that would include modifications designed to maximize the likelihood of obtaining reasonable reimbursement for one or more Products in any one or more of the following countries: [***]. Upon the Successful Completion of the Interim Analysis of the Pivotal Clinical Trial/Phase IIb Proof of Concept, or, failing that, upon the Successful Completion of the Pivotal Clinical Trial, Ikaria shall, within [***] days thereafter, submit a formal written request for a reimbursement price for one or more Product(s) to the applicable governmental agency in one or more of the following countries: [***].

**[***] Redacted pursuant to a confidential treatment request.**

Section 3.2 Joint Development Committee.

(a) The Parties shall establish a Joint Development Committee (the "Joint Development Committee" or "JDC"), comprised of [***] representatives of Ikaria and [***] representatives of BioLineRx, to oversee the Development of Products. Each Party shall make its initial designation of its representatives not later than [***] days after the Effective Date. Each Party may change any one or more of its representatives to the Joint Development Committee at any time upon notice to the other Party.

(b) The JDC shall meet at least [***] during the Development Term or more or less frequently as the JDC may agree. The JDC may meet in person or by means of a telephone or video conference call. One meeting of the JDC per year shall be held in person at Ikaria's headquarters in Clinton, NJ and one meeting of the JDC per year shall be held in person at BioLineRx's headquarters in Israel, provided, that the Parties' representatives may participate in person, via telephone, or video conference in their discretion. Each Party shall use reasonable efforts to cause its representatives to attend the meetings of the JDC. If a representative of a Party is unable to attend a meeting, such Party may designate an alternate to attend such meeting in place of the absent representative. Each Party shall bear its own costs with respect to its participation on the JDC. Prior to every meeting of the JDC, Ikaria will provide to the JDC detailed reports describing Ikaria's current clinical and development activities and plans.

(c) The JDC shall be the vehicle by which BioLineRx may offer insight and guidance to Ikaria with respect to (i) establishing the Development Plan setting forth the Development Program's objectives and the activities to be conducted, (ii) reviewing and updating the Development Plan from time to time, (iii) monitoring the progress and results of the Development Program, (iv) determining future Development Program activities, including Development activities relating to Manufacturing, to be conducted during the Development Term, and (v) establishing success criteria for the clinical trials (other than those for which success criteria are set forth in this Agreement), and determining whether the results of such clinical trials have achieved the applicable success criteria.

(d) The JDC shall only act unanimously, with each Party given one (1) vote regardless of the number of representatives. If, however, the JDC is unable to reach agreement with respect to any matter within [***] days, the matter shall be referred to the Parties' respective Executive Officers for resolution. If the Executive Officers are not able to resolve any such matter by consensus within [***] days following referral, Ikaria's Executive Officer shall have the right to decide the matter taking into account Ikaria's obligation to use Commercially Reasonable Efforts under Section 3.8.

**[***] Redacted pursuant to a confidential treatment request.**

Notwithstanding anything in this Section 3.2, neither Party shall have a unilateral right to resolve any dispute involving the breach or alleged breach of this Agreement, to amend or modify this Agreement or the Parties' respective rights and obligations hereunder or, except as expressly provided in this Section 3.2, any Development Plan or the Parties' respective rights and obligations thereunder.

Section 3.3 On-Going Trials. BioLineRx shall retain control of, bear all costs relating to the On-Going Phase I/II Trial and the Other On-Going Trials, and shall exercise Commercially Reasonable Efforts to continue and complete the On-Going Phase I/II Trial and the Other On-Going Trials, which shall be managed by BioLineRx. BioLineRx may modify the On-Going Phase I/II Trial and the Other On-Going Trials, including any changes to the protocols therefor, only with the prior written consent of Ikaria, which consent shall not be unreasonably withheld, conditioned or delayed.

Section 3.4 Regulatory Matters. Ikaria shall prepare and submit all filings with Regulatory Authorities relating to Products, which filings shall be in Ikaria's name, provided that Ikaria shall provide BioLineRx [***] days prior notice to enable BioLineRx to review and provide any comments on such submissions. With respect to regulatory matters concerning Products, BioLineRx shall cooperate with Ikaria in the preparation and support of each application for Regulatory Approval and shall provide Ikaria with such reasonable assistance as Ikaria may request. For example, upon Ikaria's request, BioLineRx shall describe the materials in sufficient and reasonable detail as requested by Ikaria, the Manufacturing techniques and other appropriate characteristics of Products (and the components thereof), and provide Ikaria with such other information related to the Products, including materials, chemistry, Manufacturing, technical dossier and controls data, batch records, analytical and quality control, device master files (if applicable), data from the On-Going Phase I/II Trial or Other On-Going Trials, or other information as Ikaria may reasonably request.

Section 3.5 Technology Exchange.

(a) As soon as reasonably practicable after Ikaria's written request, BioLineRx shall complete the activities assigned to BioLineRx as set forth on the technology exchange plan attached hereto as Exhibit A (the "Technology Exchange Plan"), to effect the transfer to Ikaria (or Ikaria's designee(s)) of all embodiments of and information relating to BioLineRx Intellectual Property reasonably necessary for the exercise of Ikaria's rights under the license granted pursuant to Section 2.1, including the Manufacturing of Products ("Technology Exchange"). BioLineRx shall make available to Ikaria (or Ikaria's designee(s)) such number of technical personnel as may be set forth in the Technology Exchange Plan to answer any questions or provide instruction as reasonably requested by Ikaria (or Ikaria's designee(s)) concerning the items delivered pursuant to this Section 3.5, in connection with the Development, Manufacture and Commercialization of Products hereunder. Each Party shall bear its own costs with respect to the Technology Exchange.

**[***] Redacted pursuant to a confidential treatment request.**

(b) The Joint Development Committee shall be responsible for coordinating the technology exchange activities under the Technology Transfer Plan. Each Party shall cooperate with the other Party in such other Party's conduct of technology exchange activities under the Technology Exchange Plan.

(c) If Ikaria desires that BioLineRx provide technology exchange services beyond the scope of the Technology Exchange Plan, BioLineRx shall provide such services on terms to be agreed upon in good faith by the Parties. Notwithstanding the foregoing, BioLineRx shall provide Ikaria with reasonable access to BioLineRx's employees and consultants involved prior to the Effective Date and during the term of this Agreement with the Development of any Product.

Section 3.6 Manufacturing.

(a) Ikaria shall be solely responsible for the Manufacture of Products for Development or for Commercialization in the Field in the Territory, which Ikaria may conduct itself or through Affiliates or Licensees.

(b) BioLineRx Ltd. shall have the option (either directly or through an Affiliate), exercisable in its sole discretion no later than [***] months prior to the date on which Ikaria intends to file for Regulatory Approval in the U.S., to Manufacture Product pursuant to the terms of a supply agreement to be negotiated in good faith by the Parties, provided that (i) BioLineRx may exercise the foregoing option only to the extent that it has the demonstrated ability to manufacture the Product, including compliance with cGMP and all applicable laws and regulations, including those of the FDA and EMEA, (ii) BioLineRx shall bear all expenses required to establish and qualify the BioLineRx manufacturing site, including the costs of scale-up batches, process validation batches and stability batches, (iii) BioLineRx shall not be entitled to assign such option or to utilize subcontract manufacturing, and (iv) neither Party shall have any obligation to enter into such agreement unless all of the terms and conditions thereof are acceptable to both Parties. If BioLineRx Ltd. exercises such option and the Parties enter into a supply agreement, (x) Ikaria shall be required to purchase no less than twenty percent (20%) of its requirements for the Product from BioLineRx, and (y) the per unit price for the Product shall be the [***], provided that the price shall not exceed [***]%) of the Net Sales price per unit of Product; provided, further, that if BioLineRx at any time shall fail to supply Product on time or such supply is otherwise disrupted, the minimum purchase requirement set forth in the preceding clause (x) shall no longer apply. Any clinical supply provided to Ikaria by BioLineRx would be provided at cost.

**[***] Redacted pursuant to a confidential treatment request.**

(c) The Parties will discuss the most efficient structure for the Manufacture and supply of Product for Development and Commercialization purposes. If the Parties determine that coordination in Manufacturing is appropriate, the Parties will establish a Joint Manufacturing Committee (the "Joint Manufacturing Committee" or "JMC") to coordinate Manufacturing efforts. If established, the JMC would be comprised of [***] representatives of Ikaria and [***] representatives of BioLineRx, to oversee the Manufacturing of Products. Each Party would make its initial designation of its representatives not later than [***] days after the Parties agreed to establish the JMC. Each Party shall designate as its representatives individuals who have the requisite experience and knowledge to discuss the Manufacturing of Products. Each Party would be permitted to change any one or more of its representatives to the JMC at any time upon notice to the other Party.

(d) The JMC would meet at least [***] or more or less frequently as the JMC may agree. The location of such meetings shall be as mutually agreed by the Parties. The JMC may also meet by means of a telephone or video conference call. Each Party shall use reasonable efforts to cause its representatives to attend the meetings of the JMC. If a representative of a Party is unable to attend a meeting, such Party may designate an alternate to attend such meeting in place of the absent representative. Each Party would bear its own costs with respect to its participation on the JMC.

(e) The JMC would only act unanimously. If, however, the JMC is unable to reach agreement with respect to any matter within [***] days, the matter shall be referred to the Parties' respective Executive Officers for resolution. If the Executive Officers are not able to resolve any such matter by consensus within [***] days following referral, Ikaria's Executive Officer shall have the right to decide the matter taking into account Ikaria's obligation to use Commercially Reasonable Efforts under Section 3.8.

Section 3.7 Commercialization. Ikaria shall be solely responsible for conducting, itself or through Affiliates or Licensees, the Commercialization of Products in the Field in the Territory, including (a) contracting with customers and booking sales, (b) setting the price and terms and conditions under which a Product may be sold to customers, and (c) handling of managed care accounts, and, subject to Section 1.29, Section 4.2(b), Section 5.2(d), Section 5.3(e) and Section 10.1(b), as between the Parties, Ikaria shall bear all costs associated therewith. Ikaria shall produce and update from time to time a comprehensive Commercialization plan (the "Commercialization Plan"), which shall include plans for Commercializing Product in each major market in which Ikaria does not then have a presence. The Commercialization Plan shall include a preliminary timeline for the initial Commercialization of Products, which is intended as a planning and informational tool and shall not constitute a binding obligation on Ikaria, and shall be subject to adjustment by Ikaria from time to time, provided, that, Ikaria shall provide BioLineRx with prior written notice of any material proposed change to a timeline. The most recent preliminary Commercialization Plan is attached hereto as Schedule 3.7.

Section 3.8 Efforts. Ikaria shall use Commercially Reasonable Efforts, either itself or through Affiliates or Licensees, (a) to Develop at least one Product in the Territory and (b) to Commercialize at least one Product in the Territory.

**[***] Redacted pursuant to a confidential treatment request.**

Article IV

Financial Provisions

Section 4.1 Milestone Payments.

(a) Development and Regulatory Milestones. With respect to each of the following milestones, Ikaria shall pay BioLineRx the corresponding payment set forth below within [***] days after the achievement by Ikaria, its Affiliates or Licensees of such milestone:

| MILESTONE | PAYMENT |
|---|---|
| 1. Effective Date | $ 7,000,000 |
| 2. Successful Completion of On-Going Phase I/II Trial | $ 10,000,000 |
| 3. [***] | |
| 4. [***] | |
| 5. [***] | |
| 6. [***] | |
| **Total Development and Regulatory Milestone Payments** | $ 132,500,000 |

(b) Commercialization Milestones. Ikaria shall pay each of the following milestone payments to BioLineRx within [***] days after the achievement of such milestone:

| MILESTONE | PAYMENT |
|---|---|
| 7. Annual Net Sales in Territory exceed $[***] in a Calendar Year | $ [***] |
| 8. Annual Net Sales in Territory exceed $[***] in a Calendar Year | $ [***] |
| 9. Annual Net Sales in Territory exceed $[***] in a Calendar Year | $ [***] |

Each of the milestones set forth in Section 4.1(a) and Section 4.1(b) shall be paid only once regardless of the number of Products that achieve such milestone.

**[***] Redacted pursuant to a confidential treatment request.**

Section 4.2 Royalties on Net Sales of Products. During the Royalty Term applicable to each Product, and subject to adjustment as set forth in Section 4.2(b), Ikaria shall pay to BioLineRx royalties on a Product-by-Product basis, with the amount of such royalties calculated as a percentage of Net Sales in a calendar year for such Product as set forth below:

| Net Sales | Royalty |
|---|---|
| [***] | |
| [***] | |
| [***] | |

(a) Royalties Payable Only Once. The obligation to pay royalties is imposed only once with respect to Net Sales of the same unit of a Product.

(b) Royalty Reductions for Third Party Payments. Ikaria shall use Commercially Reasonable Efforts to avoid any Third Party Payments. Ikaria shall provide BioLineRx written notice within [***] days of its receipt of any request or demand that Ikaria, its Affiliates or any Licensee obtain a license or immunity from suit from any Third Party in order for Ikaria, its Affiliates, or any Licensee to exercise or use the rights granted to Ikaria herein. If Ikaria is required to obtain a license or immunity from suit from any Third Party in order for Ikaria, its Affiliates, or any Licensee to exercise or use the rights granted to Ikaria herein, and Ikaria, its Affiliates, or any Licensee pays any Third Party any up-front fee, milestone, royalty, or other payment (each, a "Third Party Payment") in connection with such license or immunity from suit, Ikaria shall have the right to set off against any amounts payable to BioLineRx under this Article IV [***]%) of any Third Party Payments provided that in no event will the royalty paid to BioLineRx on Net Sales in the applicable country fall below [***]%). If the amount of Third Party Payments that Ikaria is entitled to set off exceeds the amount otherwise payable to BioLineRx at any given time, or is limited by the foregoing [***]%), Ikaria shall be entitled to carry over the excess for set off against amounts payable to BioLineRx in subsequent periods until Ikaria has been credited for the full amount it is entitled to set off. Prior to paying any Third Party Payment, the Parties shall obtain an analysis from their respective counsel in respect of the validity of the claim of any Third Party seeking Third Party Payments. If the Parties are unable to agree on an assessment of the claim, the Parties shall jointly engage mutually acceptable independent patent counsel not regularly employed by either Party to assess such claims. Ikaria shall substitute the decision of such independent patent counsel for that of its own counsel with respect to deciding whether to obtain a license or immunity from suit from any Third Party in order for Ikaria, its Affiliates, or any Licensee to exercise or use the rights granted to Ikaria herein.

(c) Duration of Payments. The amounts payable to BioLineRx under Section 4.2 shall be paid on a Product-by-Product and country-by-country basis until the expiration of the Royalty Term for such Product in such country.

**[***] Redacted pursuant to a confidential treatment request.**

(d) Price Concessions. Ikaria shall not, and shall ensure that its Affiliates and Licensees do not, sell or distribute the Product at a discount (including in the form of government mandated rebates) (with or without consideration) in return substantially for (i) concessions or consideration received in transactions involving products or services other than the Product or (ii) concessions from any government or governmental authority relating to products or services other than the Product.

Section 4.3 Reports and Accounting.

(a) Reports; Payments. Ikaria shall deliver to BioLineRx, within [***] days after the end of each calendar quarter, reasonably detailed written accountings of Net Sales of Products that are subject to payment obligations to BioLineRx for such calendar quarter. Such quarterly reports shall indicate (i) gross sales and Net Sales on a country-by-country basis, (ii) the calculation of payment amounts owed to BioLineRx from such gross sales and Net Sales, and (iii) any amounts set off pursuant to Section 4.2(b) against payments owed to BioLineRx. When Ikaria delivers such accounting to BioLineRx, Ikaria shall also deliver all amounts due under Section 4.2 to BioLineRx for the calendar quarter. All payments shall be made by wire transfer to the account specified in Schedule 4.3(a).

(b) Audits by BioLineRx. Ikaria shall keep, and shall require its Affiliates and Licensees to keep, complete and accurate records of the most recent [***] years relating to gross sales and Net Sales and all information relevant under Section 4.1 and Section 4.2. For the sole purpose of verifying amounts payable to BioLineRx, BioLineRx shall have the right no more than [***] per calendar year, at BioLineRx's expense, to engage independent accountants to review such records in the location(s) where such records are maintained by Ikaria, its Affiliates, and its Licensees upon reasonable notice and during regular business hours. Prior to any review conducted pursuant to this Section 4.3(b), BioLineRx's accountants shall have entered into a written agreement with Ikaria limiting the use of such records to verification of the accuracy of payments due under this Agreement and prohibiting the disclosure of any information contained in such records to a Third Party and to BioLineRx for a purpose other than as set forth in this Section 4.3(b). The right to audit any royalty report or quarterly report or payment shall extend for [***] years from the end of the calendar year in which such royalty report or quarterly report was delivered or such payment made. Results of such review shall be made available to Ikaria. If the review reflects an underpayment to BioLineRx, such underpayment shall be promptly remitted to BioLineRx. Likewise, if the review reflects an overpayment, Ikaria shall be entitled to reduce any subsequent payments by the amount of the overpayment. If the underpayment to BioLineRx is equal to or greater than [***] %) of the amount that was otherwise due, BioLineRx shall be entitled to have Ikaria reimburse BioLineRx's reasonable out-of-pocket costs of such review.

**[***] Redacted pursuant to a confidential treatment request.**

Section 4.4 Currency Amounts. All dollar ($) amounts specified in this Agreement are United States Dollar amounts.

Section 4.5 Currency Exchange. With respect to sales of Products invoiced in U.S. Dollars and other amounts received or paid by Ikaria, its Affiliates or Licensees in U.S. Dollars, such amounts and the amounts payable hereunder shall be expressed in U.S. Dollars. With respect to sales of Products invoiced in a currency other than U.S. Dollars and other amounts received or paid by Ikaria, its Affiliates or Licensees in a currency other than U.S. Dollars, such amounts and the amounts payable hereunder shall be expressed in their U.S. Dollar equivalent calculated using the applicable rate of exchange reported by *The Wall Street Journal* (Eastern U.S. edition) on the last Business Day of the calendar quarter to which the report under Section 4.3(a) relates. All payments hereunder shall be made in U.S. Dollars.

Section 4.6 Tax Withholding. The Parties shall use all reasonable and legal efforts to reduce tax withholding on payments made to BioLineRx. The Parties agree to cooperate in good faith to provide one another with such documents and certifications as are reasonably necessary to enable Ikaria to minimize any withholding tax obligations. Ikaria shall promptly provide to BioLineRx documentation of the payment of any withholding taxes that are paid pursuant to this Section 4.6, including copies of receipts or other evidence reasonably required and sufficient to allow BioLineRx to document such tax withholdings adequately for purposes of claiming foreign tax credits and similar benefits.

Section 4.7 Upfront Payments Received Under Sublicenses. If Ikaria receives an upfront payment consideration under a sublicense granted to a Third Party under this Agreement, Ikaria shall pay to BioLineRx [***]%) of any such payment within 30 days after actual receipt thereof from the Third Party.

## Article V

## Intellectual Property Ownership, Protection and Related Matters

Section 5.1 Ownership of Inventions.

(a) Intentionally Omitted.

(b) Intentionally Omitted.

(c) Inventorship. Questions of inventorship shall be resolved in accordance with United States patent laws. In the event of a dispute regarding inventorship, if the Parties are unable to resolve the dispute, the Parties shall jointly engage mutually acceptable independent patent counsel not regularly employed by either Party to resolve such dispute. The decision of such independent patent counsel shall be binding on the Parties with respect to the issue of inventorship.

**[***] Redacted pursuant to a confidential treatment request.**

(d) Further Actions and Assignments. Each Party shall take all further actions and execute all assignments requested by the other Party and reasonably necessary or desirable to vest in the other Party the ownership rights set forth in this Section 5.1.

Section 5.2 Prosecution and Maintenance of Patent Rights.

(a) Intentionally Omitted.

(b) BioLineRx Intellectual Property. Upon the Effective Date, Ikaria shall assume responsibility for the management of the preparation, filing prosecution and maintenance of any and all patent applications, including any interference proceedings related thereto, included in the BioLineRx Intellectual Property (including, for clarity, the Sublicensed IP, BioLineRx Patent Rights and patents and patent applications that claim or disclose BioLineRx Know-How).

(c) BioLineRx Step-in Right. If Ikaria, on a country-by-country basis, declines to file and prosecute, or elects not to take actions necessary to avoid abandonment of, any patent applications or maintain any patent in any country, in each case for which it has responsibility under Section 5.2(a) or Section 5.2(b), it shall give BioLineRx reasonable notice to this effect sufficiently in advance to permit BioLineRx to undertake such filing and prosecution without a loss of rights, and thereafter BioLineRx may, upon written notice to Ikaria, file and prosecute such patent applications and maintain such patents in such country. If BioLineRx files, prosecutes or maintains any such patent application or patent in such country and any resulting Valid Claim of BioLineRx Patent Rights constitutes the only BioLineRx Patent Rights Covering the Product in such country (*i.e.*, there are no other BioLineRx Patent Rights Covering the Product in such country), then Ikaria shall reimburse BioLineRx for all patent filing, prosecution and maintenance costs incurred by BioLineRx pursuant to the exercise of the foregoing step-in right.

If BioLineRx exercises the foregoing step-in right following the election by Ikaria to abandon all existing BioLineRx Patent Rights in a given country, Ikaria shall, within [***] days following BioLineRx's written request, notify BioLineRx in writing whether Ikaria intends to Commercialize a Product in the Field in such country. If Ikaria notifies BioLineRx that Ikaria has no intent to Commercialize a Product in the Field in such country, BioLineRx may, upon written notice to Ikaria within [***] days of receipt of Ikaria's notice of lack of intent, exercise a right to directly Commercialize a Product in the Field in such country. If BioLineRx provides Ikaria with such notice:[***]

(d) Costs and Expenses. [***]

**[***] Redacted pursuant to a confidential treatment request.**

(e) Cooperation Between Parties. Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of Patent Rights pursuant to this Section 5.2, including the execution of all such documents and instruments and the performance of such acts as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of such Patent Rights, including Patent Rights that such Party has elected not to pursue, as provided for in subsections (a), (b) and (c) above. In addition, the filing, prosecuting and maintaining Party in subsections (a), (b) and (c) above shall promptly forward to the other Party copies of any substantive correspondence and actions prepared for or received from the U.S. Patent and Trademark Office or any foreign patent office that may materially affect the Patent Rights being prosecuted or maintained. The other Party's patent counsel may provide comments to the filing, prosecuting and maintaining Party. If any comments by the other Party's patent counsel are provided in sufficient time for the filing, prosecuting and maintaining Party to reflect such comments in its correspondence or response, and such comments are reasonably directed to maximizing the coverage of the claims of the Patent Rights being prosecuted or maintained, the filing, prosecuting and maintaining Party shall reflect such comments in its correspondence or response, if its patent counsel deems it prudent to do so.

(f) Coordination with BioLineRx pursuant to the Sublicensed IP. With respect to any Sublicensed IP which Ikaria is responsible for filing, prosecuting, and maintaining, Ikaria shall:

(i) consult with BioLineRx regarding the preparation, filing, and prosecution of all patent applications, and the maintenance of all patents, included within such Sublicensed IP, including the content, timing, and jurisdiction of the filing of such patent applications and their prosecution, and other details and overall global strategy pertaining to the procurement and maintenance of Patent Rights in such Sublicensed IP, and shall file, prosecute, and maintain all such Patent Rights through a law or patent attorney firm selected by Ikaria and approved by BioLineRx (and BioLineRx shall exercise its rights under the BGN License Agreement as may be necessary to obtain BGN's approval); and

(ii) provide BioLineRx with copies of all patent applications that claim or disclose such Sublicensed IP, and BioLineRx shall exercise its rights under the BGN License Agreement to ensure that BGN cooperates in a timely manner with Ikaria's efforts to register such Patent Rights, including by causing BGN to execute any documents as may be required for such purpose.

BioLineRx shall take all actions required to remain in compliance with the BGN License Agreement in connection with the foregoing.

Section 5.3 Third Party Infringement.

(a) Notice. Each Party shall promptly report in writing to the other Party during the term of this Agreement any (i) known or suspected infringement of any of the BioLineRx Patent Rights or (ii) unauthorized use of any of the BioLineRx Know-How of which such Party becomes aware, including, in the case of either clause (i) or clause (ii) involving, or that may reasonably lead to, the Development, Manufacture, use or Commercialization of a product or product candidate that is or may be competitive with a Product in the Field ("Competitive Infringement"), and shall provide the other Party with all available evidence supporting such infringement, suspected infringement, unauthorized use or suspected unauthorized use.

(b) BioLineRx Intellectual Property; Step-in Rights.

(i) Ikaria shall have the first right, but not the obligation, to initiate a suit or take other appropriate action that either Party reasonably believes is required to protect BioLineRx Intellectual Property from Competitive Infringement. Ikaria shall give BioLineRx sufficient advance notice of its intent to file any such suit or take any such action, and the reasons therefor, and shall provide BioLineRx with an opportunity to make suggestions and comments regarding such suit or action. Thereafter, Ikaria shall keep BioLineRx informed, and shall from time to time consult with BioLineRx regarding the status of any such suit or action and shall provide BioLineRx with copies of all material documents (*i.e.*, complaints, answers, counterclaims, material motions, orders of the court, memoranda of law and legal briefs, interrogatory responses, depositions, material pre-trial filings, expert reports, affidavits filed in court, transcripts of hearings and trial testimony, trial exhibits and notices of appeal) filed in, or otherwise relating to, such suit or action. Any recovery obtained as a result of any proceeding pursuant to this subsection (b)(i), by settlement or otherwise, shall be applied in the following order of priority: (A) first, each Party shall be reimbursed, on a pro rata basis, for all costs incurred by such Party in connection with such suit; and (B) second, [***]

(ii) If Ikaria chooses not to initiate a suit or take other appropriate action under subsection (b)(i) above to protect BioLineRx Intellectual Property from Competitive Infringement, Ikaria will so notify BioLineRx of its intention, in which case BioLineRx shall have the right to initiate such suit or take such other appropriate action. BioLineRx shall give Ikaria sufficient advance notice of its intent to file any such suit or take any such action, and the reasons therefor, and shall provide Ikaria with an opportunity to make suggestions and comments regarding such suit or action. Thereafter, BioLineRx shall keep Ikaria informed, and shall from time to time consult with Ikaria regarding the status of any such suit or action and shall provide Ikaria with copies of all material documents (*i.e.*, complaints, answers, counterclaims, material motions, orders of the court, memoranda of law and legal briefs, interrogatory responses, depositions, material pre-trial filings, expert reports, affidavits filed in court, transcripts of hearings and trial testimony, trial exhibits and notices of appeal) filed in, or otherwise relating to, such suit or action. Any recovery obtained as a result of any proceeding pursuant to this subsection (b)(ii), by settlement or otherwise, shall be applied in the following order of priority: (A) first, each Party shall be reimbursed, on a pro rata basis, for all costs incurred by such Party in connection with such suit; and (B) second, any remainder shall be shared [***]% for BioLineRx and [***] % for Ikaria.

**[***] Redacted pursuant to a confidential treatment request.**

(iii) If BioLineRx chooses not to initiate a suit or take other appropriate action under subsection (b)(ii) above to protect Sublicensed IP from Competitive Infringement and BGN exercises its rights under the BGN License Agreement to prosecute, prevent, or terminate such Competitive Infringement, any amount received by BioLineRx in connection therewith, whether by settlement or otherwise, [***].

(c) Claimed Infringement. If a Party becomes aware of any claim that the Development, Manufacture, or Commercialization of Products for use in the Field in the Territory infringes Patent Rights or any other intellectual property rights of any Third Party, such Party shall promptly notify the other Party. In any such instance, Ikaria shall have the exclusive right to settle such claim.

(d) Patent Invalidity Claim. If a Third Party at any time asserts a claim that any BioLineRx Patent Rights is invalid or otherwise unenforceable (an "Invalidity Claim"), whether (i) as a defense in an infringement action brought by Ikaria or BioLineRx pursuant to subsection (b) above, or (ii) in an action brought against Ikaria or BioLineRx referred to in subsection (c) above, or (iii) otherwise, the Parties shall cooperate with each other in preparing and formulating a response to such Invalidity Claim. Neither Party shall settle or compromise any Invalidity Claim without the consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed.

(e) Conduct of Certain Actions; Costs. Ikaria shall have the sole and exclusive right to select counsel for any suit initiated by it referenced in subsection (b)(i) above or against it referenced in subsection (c) above, and BioLineRx shall have the sole and exclusive right to select counsel for any suit initiated by it referenced in subsection (b)(ii) above. If required under applicable law in order for a Party (the "Lead Party") to initiate or maintain such suit, the other Party shall join as a party to the suit. Such other Party shall offer reasonable assistance to the Lead Party in connection therewith at no charge to the Lead Party except for reimbursement of such other Party's reasonable out-of-pocket expenses incurred in rendering such assistance. The Lead Party shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings referenced in the first sentence of this subsection (e), including the fees and expenses of the counsel selected by it. Subject to applicable law, the other Party shall have the right to participate and be represented in any such suit by its own counsel at its own expense.

(f) Coordination with BGN. With respect to any suit to protect Sublicensed IP from infringement for which Ikaria is the Lead Party, notwithstanding anything to the contrary in this Section 5.3:

**[***] Redacted pursuant to a confidential treatment request.**

(i) if required under applicable law in order for Ikaria to initiate or maintain such suit, BioLineRx shall (A) exercise its rights under the BGN License Agreement to cause BGN to join as a party to such suit, (B) exercise its rights under the BGN License Agreement to obtain BGN's approval of counsel selected by Ikaria to represent Ikaria and BGN in such suit, and (C) [***];

(ii) Ikaria shall not compromise or settle such suit without the prior written consent of BGN, which consent BioLineRx shall exercise its rights under the BGN License Agreement to obtain; and

(iii) any recovery obtained by Ikaria as a result of such suit, by settlement or otherwise, shall be applied in the following order of priority: (A) first, each Party shall be reimbursed, on a pro rata basis, for all costs incurred by such Party in connection with such suit (for clarity, BioLineRx shall be reimbursed for any costs of BGN paid by BioLineRx in accordance with clause (i)(C) above); (B) second, [***]%) of any remainder shall paid to BioLineRx for remittance to BGN as provided in Section 10.1.2 of the BGN License Agreement ; and (C) third, the remaining [***]%) shall be retained by Ikaria; [***].

Article VI

Confidentiality; Non-Solicitation; Standstill

Section 6.1 Confidential Information. Each Party agrees that all Confidential Information disclosed to it or its Affiliates by the other Party (a) shall not be used by the receiving Party or its Affiliates except to fulfill its obligations or exercise its rights under this Agreement, (b) shall be maintained in confidence by the receiving Party and its Affiliates, and (c) shall not be disclosed by the receiving Party or its Affiliates to any Third Party who is not a consultant of, or an advisor to, the receiving Party or its Affiliates without the prior written consent of the disclosing Party, which consent the disclosing Party may withhold in its sole discretion. Notwithstanding the foregoing, either Party may disclose Confidential Information of the other Party if such Party is required to make such disclosure by applicable law, regulation or legal process, including by Israeli securities laws, the rules or regulations of the United States Securities and Exchange Commission (the "SEC") or any similar regulatory agency in a country other than the United States or of any stock exchange, including the Tel Aviv Stock Exchange, in which event such Party shall provide prior notice of such intended disclosure to such other Party, if possible under the circumstances, and shall disclose only such Confidential Information of the other Party as is required to be disclosed. If this Agreement shall be included in any report, statement or other document filed by either Party or an Affiliate of either Party pursuant to the preceding sentence, such Party shall use, or shall cause its Affiliate, as the case may be, to use, reasonable efforts to obtain confidential treatment from the SEC, similar regulatory agency or stock exchange of any financial information or other information of a competitive or confidential nature, and shall include in such confidentiality request such provisions of this Agreement as may be reasonably requested by the other Party.

**[***] Redacted pursuant to a confidential treatment request.**

Section 6.2 Disclosures to Employees, Consultants, Advisors, Etc. Each Party agrees that it and its Affiliates shall provide Confidential Information received from the other Party only to the receiving Party's respective employees, consultants, advisors, Licensees and potential Licensees, and to the employees, consultants and advisors of the receiving Party's Affiliates, who have a need to know such Confidential Information to assist the receiving Party in fulfilling its obligations under this Agreement and only under conditions of confidentiality and non-use at least as stringent as the conditions imposed by this Agreement, provided that BioLineRx and Ikaria shall each remain responsible for any failure by its and its Affiliates' respective employees, consultants, advisors, Licensees and potential Licensees to treat such information and materials as required under Section 6.1. For clarity, (a) Ikaria is permitted to disclose Confidential Information to actual or potential Licensees, acquirors or financing sources; and (b) BioLineRx is permitted to disclose this Agreement and the Development Plan to BGN, solely to the extent required under the BGN License Agreement; provided that any such disclosure subjects the receiving Third Party to conditions of confidentiality and non-use at least as stringent as the conditions imposed by this Agreement.

Section 6.3 Non-Solicitation. During the term of this Agreement and continuing for [***] months after the termination of this Agreement, neither Party shall directly or indirectly, for its own account or for the account of others, urge, induce, entice, or in any manner whatsoever solicit any employee directly involved in the activities conducted pursuant to this Agreement to leave the employment of the other Party or any of its Affiliates. For purposes of the foregoing, "urge", "induce", "entice" or "solicit" shall not be deemed to mean: (a) circumstances where an employee of a Party initiates contact with the other Party or any of its Affiliates with regard to possible employment; or (b) general solicitations of employment not specifically targeted at employees of a Party or any of its Affiliates, including responses to general advertisements.

Section 6.4 Standstill. Neither Ikaria nor any of its Affiliates shall directly or indirectly, for its own account or for the account of others, acquire more than [***]%) of the equity or debt securities of BioLineRx, or urge, induce, entice or solicit any Third Party to acquire the equity or debt securities of BioLineRx, in either case without the consent of BioLineRx, which may be withheld in its sole discretion. The obligations of Ikaria under this Section 6.4 shall terminate in the event that (a) any Third Party initiates a tender or exchange offer, or otherwise publicly proposes or agrees to acquire, a majority of the equity or debt securities of BioLineRx (provided that the restrictions set forth in this Section 6.4 shall be reinstated in the event that such tender or exchange offer, or proposal, is terminated or withdrawn), (b) it is publicly disclosed that voting securities representing at least [***] of the total voting power of BioLineRx have been acquired by any one or more Third Parties, (c) BioLineRx publicly announces that it intends to seek a Third Party acquirer (provided that the restrictions set forth in this Section 6.4 shall be reinstated in the event that BioLineRx publicly announces that it no longer is seeking a Third Party acquirer and so notifies Ikaria in writing), (d) BioLineRx enters into any agreement to merge with, or sell or dispose of [***] or more of its assets or securities, or (e) this Agreement is terminated pursuant to Article VIII. BioLineRx shall provide Ikaria with prompt written notice of the occurrence of any of the foregoing events to the extent permitted under applicable law. For clarity, the acquisition by any employee benefit plan of Ikaria or its Affiliates in any diversified index, mutual or pension fund, which fund in turn holds BioLineRx securities, shall not be deemed a breach of this Section 6.4.

**[***] Redacted pursuant to a confidential treatment request.**

Section 6.5 Term. All obligations of confidentiality imposed under this Article VI shall survive until the date that is [***] years after the expiration or termination of this Agreement.

Section 6.6 Publicity. During the term of this Agreement, the content of any press release or public announcement relating to this Agreement or a Product shall be mutually approved by the Parties, except that (a) a Party may issue such press release or public announcement if the contents of such press release or public announcement have previously been made public other than through a breach of this Agreement by the issuing Party, (b) a Party may issue such a press release or public announcement if it is advised by counsel that such press release or public announcement is required by applicable law, regulation or legal process, including by Israeli securities laws, the rules or regulations of the SEC or any similar regulatory agency in a country other than the United States or of any stock exchange, including the Tel Aviv Stock Exchange, and (c) Ikaria shall remain free to issue press releases and public announcements regarding the Development, Manufacturing, Commercialization and use of Products in the Field, provided that Ikaria shall provide BioLineRx with advance notice of at least [***] days prior to public disclosure of such releases and announcements or such shorter period as required to comply with any applicable law. In addition, BioLineRx shall reasonably implement any changes that Ikaria may recommend with respect to any filing to be made in accordance with the rules or regulations of the SEC or any similar regulatory agency in a country other than the United States or of any stock exchange, including the Tel Aviv Stock Exchange; provided that such Ikaria shall only have the right to comment upon portions of such filings that directly related to Ikaria or this Agreement. Nothing in the foregoing shall require BioLineRx to implement any change that Ikaria may recommend that is not consistent with the rules or regulations of the Israel Securities Authority, Tel Aviv Stock Exchange, the rules or regulations of the SEC, or any similar regulatory agency in a country other than the United States or Israel, as advised in writing by BioLineRx's legal counsel. BioLineRx's legal counsel will provide Ikaria confirmation of such advise.

Section 6.7 Publications. The results of the Development Program may be published by a Party as part of a scientific presentation or publication only after scientific review by and approval of the Joint Development Committee unless the other Party, acting reasonably, disapproves of the presentation or publication in writing within [***] days after receipt of the presentation or publication. Either Party may require that such Party's Confidential Information be redacted from such presentation or publication and may reasonably require that other information also be redacted. In addition, at the request of either Party, the date of submission for presentation or publication shall be delayed for a period of time sufficiently long to permit a Party to seek appropriate patent protection. Other than as provided for herein, BioLineRx shall not make any publication regarding any Product or containing any Confidential Information of Ikaria without the prior written consent of Ikaria. Notwithstanding the foregoing, to the extent necessary or appropriate as determined in Ikaria's discretion, Ikaria may disclose information otherwise covered by this Section 6.7 in documents filed with the SEC.

**[***] Redacted pursuant to a confidential treatment request.**

Article VII

Representations and Warranties

Section 7.1 Representations of Authority. BioLineRx and Ikaria each represents and warrants to the other Party that, except for the consent of the OCS, it has full corporate right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement and that it has the right to grant to the other Party the rights and licenses granted pursuant to this Agreement.

Section 7.2 Consents. BioLineRx and Ikaria each represents and warrants to the other Party that, except for the consent of the OCS, all necessary consents, approvals and authorizations of all government authorities and other Persons required to be obtained by it as of the date hereof in connection with the execution, delivery and performance of this Agreement have been obtained.

Section 7.3 No Conflict. BioLineRx and Ikaria each represents and warrants to the other Party that, notwithstanding anything to the contrary in this Agreement, except for the consent of the OCS, the execution and delivery of this Agreement, the performance of such Party's obligations in the conduct of the collaboration and the licenses and rights to be granted pursuant to this Agreement (a) do not conflict with or violate any requirement of applicable laws or regulations existing as of the date hereof and (b) do not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the date hereof.

Section 7.4 Enforceability. BioLineRx and Ikaria each represents and warrants to the other Party that this Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms.

Section 7.5 Additional BioLineRx Representations. BioLineRx represents and warrants to Ikaria that:

(a) BioLineRx has the right to grant the licenses granted to Ikaria on the terms set forth in this Agreement;

(b) BioLineRx is not engaged with any Third Party in any Development efforts directed to Products in the Field in the Territory other than with respect to the On-Going Phase I/II Trial, the Other On-Going Trials or the Existing Product Agreements;

(c) BioLineRx has provided Ikaria with true and complete copies of each of the Existing Product Agreements, each of which is in full force and effect in accordance with its terms as of the date hereof, and has obtained all consents necessary for the assignment to Ikaria of each of the Existing Product Agreements hereunder, and, following such assignment, Ikaria shall have the legal right to exercise all rights of BioLineRx that existed thereunder immediately prior to such assignment;

(d) to BioLineRx's Knowledge, the BioLineRx Patent Rights listed in Exhibit B are valid and enforceable and constitute all of the Patent Rights necessary or useful for Ikaria to fully exercise and enforce its rights hereunder;

(e) to BioLineRx's Knowledge, the BioLineRx Patent Rights are not being infringed and the BioLineRx Know-How is not being misappropriated by any Third Party;

(f) BioLineRx owns the entire right, title and interest in and to the BioLineRx Intellectual Property (other than the Sublicensed IP) free and clear of any liens, charges, claims and encumbrances, and no other Person has any claim of ownership or right to obtain compensation with respect to such BioLineRx Intellectual Property;

(g) to BioLineRx's Knowledge, the Products developed in the Development Program and the Development, Manufacture and Commercialization of such Products will not infringe or misappropriate any intellectual property rights not licensed to Ikaria hereunder; and

(h) BioLineRx has not received and has no Knowledge of any claim or demand of any Person pertaining to, or any proceeding which is pending or threatened that asserts, the invalidity, misuse or unenforceability of the BioLineRx Patent Rights or that challenges BioLineRx's ownership of the BioLineRx Intellectual Property or that makes any adverse claim with respect thereto, and, to the Knowledge of BioLineRx, there is no basis for any such claim, demand or proceeding.

Section 7.6 BGN License Agreement. BioLineRx represents, warrants and covenants to Ikaria that:

(a) BioLineRx has provided Ikaria with a true and complete copy of the BGN License Agreement, which is in full force and effect in accordance with its terms as of the date hereof;

(b) BioLineRx shall obtain and provide to Ikaria within ten (10) days of execution of this Agreement a written statement from BGN certifying that the terms of this Agreement are consistent with those of the BGN License Agreement, including in the context of Section 13.4.1(c) thereof;

(c) BioLineRx has (i) achieved by its designated performance date each Milestone (as that term is defined in the BGN License Agreement) having a designated performance date on or before the date hereof, or obtained a waiver in respect thereof, and (ii) neither (A) committed any material breach of the its obligations under the BGN License Agreement nor (B) received any notice from BGN of any alleged material breach thereof by BioLineRx or of any Failure (as that term is defined therein);

(d) BioLineRx shall upon receipt by BioLineRx promptly provide Ikaria with a copy of any notice from BGN described in the foregoing clause (c)(ii)(B);

(e) BioLineRx shall not terminate, amend, supplement or otherwise modify the BGN License Agreement without Ikaria's prior written consent;

(f) the rights and obligations of BioLine Jerusalem L.P. under the BGN License Agreement have been assigned and delegated, or otherwise transferred, to BioLineRx;

(g) as between BioLineRx and Ikaria, BioLineRx shall be responsible for any and all payments to be made under the BGN License Agreement;

(h) in the event of any termination of the BGN License Agreement, BioLineRx shall, at Ikaria's request, provide all reasonable assistance to Ikaria in Ikaria's efforts to obtain from BGN an exclusive license to the Sublicensed IP, including through enforcement of the provisions of Sections 5.2.3 and 13.4.1(c) of the BGN License Agreement.

Section 7.7 Employee, Consultant and Advisor Legal Obligations. BioLineRx and Ikaria each represents and warrants that each of its and its Affiliates' employees, consultants and advisors who is or will be involved in performing any obligations hereunder has executed or will have executed an agreement or have an existing obligation under law requiring assignment to such Party of all intellectual property made during the course of and as the result of his, her or its association with such Party or such Affiliate, and obligating such employee, consultant or advisor to maintain the confidentiality of Confidential Information to the extent required under Article VI. BioLineRx and Ikaria each represents and warrants that, to its Knowledge, none of its or its Affiliates' employees, consultants or advisors who is or will be involved in performing any obligations hereunder is, as a result of the nature of such obligations to be performed by the Parties, in violation of any covenant in any contract relating to non-disclosure of proprietary information, non-competition or non-solicitation.

Section 7.8 Accuracy of Representations and Warranties on Effective Date. The representations and warranties of each of the Parties set forth in the preceding sections of this Article VII remain true and accurate on and as of the Effective Date. Each Party shall promptly following receipt of acceptable consent from the OCS deliver to the other Party a certificate to such effect executed by its Chief Executive Officer.

Section 7.9 No Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING THAT ANY PRODUCTS WILL BE ECONOMICALLY OR TECHNICALLY UTILIZABLE, THAT ANY SALES OF ANY PRODUCTS WILL OCCUR, THAT THE DEVELOPMENT PROGRAM ACTIVITIES WILL BE COMPLETED IN THE EXPECTED TIMEFRAME, OR THAT ANY PRODUCT WILL BE FREE OF ANY THIRD PARTY RIGHTS.

## Article VIII

## Term and Termination

Section 8.1 Term. The term of this Agreement shall begin on the Effective Date, may be terminated as set forth in this Article VIII, and shall expire on a Product-by-Product and country-by-country basis upon the date of expiration of the Royalty Term for such Product in such country, and shall expire in its entirety upon the last-to-expire Royalty Term, unless earlier terminated as set forth in this Article VIII.

Section 8.2 Termination for Material Breach. Upon any breach of a material provision of this Agreement by a Party (the "Breaching Party"), the other Party (the "Non-Breaching Party") may terminate this Agreement by providing ninety (90) days written notice to the Breaching Party specifying the material breach. The termination shall become effective at the end of the notice period unless the Breaching Party cures such breach during such notice period. Ikaria may terminate this Agreement pursuant to this Section 8.2 immediately upon any termination of the BGN License Agreement.

Section 8.3 Development-Related Termination. Ikaria shall have the right to terminate this Agreement upon sixty (60) days prior written notice, if Ikaria at any time determines, in its sole judgment, that the results of the Development Program do not warrant further Development of Products.

Section 8.4 Effect of Certain Terminations and Expiration.

(a) If this Agreement is terminated by Ikaria under Section 8.2:

(i) The licenses granted by BioLineRx to Ikaria under Section 2.1 and, notwithstanding any other provision in this Agreement to the contrary, Ikaria's obligations under Section 4.2, shall survive;

(ii) Section 2.2 shall survive until Ikaria is no longer obligated to pay royalties to BioLineRx under Section 4.2; and

(iii) Section 5.1 and Section 5.3 shall survive.

(b) If this Agreement is terminated by either BioLineRx under Section 8.2, or by Ikaria under Section 8.3, the licenses granted under Section 2.1 shall terminate as of the effective date of such termination; provided, however, that Ikaria, its Affiliates, and its Licensees shall be afforded a commercially reasonable period of time (but no less than [***] months) to sell off any then existing or in process stocks of the Products, subject to the terms and conditions of this Agreement, including the payment of royalties thereon.

(c) Upon any termination or expiration of this Agreement, each Party shall return to the other Party any tangible property owned by the other Party, including any books and records and Confidential Information, in accordance with the reasonable instructions given by the other Party, with any shipping costs to be borne by the other Party, provided, however, that a Party may retain a copy of any regulatory records it is required to maintain in accordance with applicable law.

Section 8.5 Survival. In the event of any expiration or termination of this Agreement, (a) all financial obligations under Article IV and Article V owed as of the effective date of such expiration or termination shall remain in effect, including such obligations that have accrued, but have not been invoiced, as of such effective date, and (b) the obligations set forth in Section 5.1, Article VI, Article IX and Article X, and all other terms, provisions, representations, rights and obligations contained in this Agreement that by their express terms survive expiration or termination of this Agreement (including Section 8.4 and this Section 8.5), shall survive and all other terms, provisions, representations, rights and obligations contained in this Agreement shall terminate.

**[***] Redacted pursuant to a confidential treatment request.**

Section 8.6 Termination Prior to Effective Date. Notwithstanding anything to the contrary in this Article VIII, Ikaria may terminate this Agreement prior to the Effective Date, with no liability to BioLineRx, if the OCS does not consent to the Agreement in a form reasonably satisfactory to both Parties within forty-five (45) days after the execution of this Agreement. The provisions of Article X (except for Section 10.1(a)) and this Section 8.6 shall survive such termination, and all other terms, provisions, representations, rights and obligations contained in this Agreement shall terminate.

## Article IX

## Dispute Resolution

Section 9.1 Negotiation. Any controversy, claim or dispute arising out of or relating to this Agreement shall be settled, if possible, through good faith negotiations between the Parties.

Section 9.2 Escalation. If the Parties are unable to settle any dispute after good faith negotiations pursuant to Section 9.1 after [***] days, such dispute (except for any matter that by its express terms shall be resolved as provided in this Agreement, including any matter arising under Section 3.2 or Section 3.6) shall be referred to the Executive Officers to be resolved by negotiation in good faith as soon as is practicable but in no event later than [***] days after referral.

Section 9.3 Mediation. Solely with respect to a dispute as to whether Ikaria has breached its obligations to use Commercially Reasonable Efforts as set forth in Section 3.8, if the Executive Officers are unable to settle such dispute after good faith negotiations pursuant to Section 9.2 within [***] days after referral to the Executive Officers, the Parties shall, within [***] days thereof, engage a mutually agreeable Third Party mediator on a non-binding basis to assist the Parties in determining whether such a breach has occurred. The Parties agree that they will participate in good faith in an effort to resolve the dispute in an informal, inexpensive and expeditious manner and that any mediator selected shall agree to render any judgments in a timely manner, but no later than [***] days after the mediator is selected. All expenses of the mediator will be shared equally by the Parties.

Section 9.4 Litigation. If the Executive Officers are unable to settle any dispute after good faith negotiations pursuant to Section 9.2 (other than a dispute as to whether Ikaria has breached its obligations to use Commercially Reasonable Efforts as set forth in Section 3.8) within [***] days after referral, or if the Parties continue to dispute whether Ikaria has breached its obligations to use Commercially Reasonable Efforts as set forth in Section 3.8 following mediation pursuant to Section 9.3, then either Party may seek resolution of the dispute (except for any matter that by its express terms shall be resolved as provided in this Agreement, including any matter arising under Section 3.2 or Section 3.6) through remedies available at law or in equity from any court of competent jurisdiction as set forth in Section 10.3.

**[***] Redacted pursuant to a confidential treatment request.**

Section 9.5 Equitable Relief. Each Party acknowledges and agrees that the other Party would be damaged irreparably if any of the provisions of Article II, Article V and Article VI are not performed in accordance with their specific terms or otherwise are breached. Accordingly, each Party agrees that the other Party shall be entitled to an injunction or other equitable relief to prevent breaches of such provisions, to preserve status quo, and to enforce specifically such provisions in any action instituted in any court having jurisdiction over the Parties and the matter, in addition to any other remedy to which it may be entitled, at law or in equity.

## Article X

## Miscellaneous Provisions

Section 10.1 Indemnification.

(a) By Ikaria. Ikaria agrees to defend BioLineRx, its Affiliates and their respective directors, officers, employees and agents at Ikaria's cost and expense, and shall indemnify and hold harmless BioLineRx and its Affiliates and their respective directors, officers, employees and agents from and against any liabilities, losses, costs, damages, fees or expenses (collectively, "Losses") arising out of any Third Party claim to the extent relating to (i) any breach by Ikaria of any of its representations, warranties or obligations pursuant to this Agreement, or (ii) personal injury, property damage, product liability or other damage resulting from the Development, Manufacture, use or Commercialization of a Product by Ikaria or its Affiliates or Licensees, excluding any claim for which BioLineRx indemnifies Ikaria under subsection (b) below.

(b) By BioLineRx. BioLineRx agrees to defend Ikaria, its Affiliates and their respective directors, officers, employees and agents at BioLineRx's cost and expense, and shall indemnify and hold harmless Ikaria and its Affiliates and their respective directors, officers, employees and agents from and against any Losses arising out of any Third Party claim to the extent relating to (i) any breach by BioLineRx of any of its representations, warranties or obligations pursuant to this Agreement, (ii) personal injury, property damage or other damage resulting from the conduct of the On-Going Phase I/II Trial or the Other On-Going Trials by or on behalf of BioLineRx or its Affiliates, (iii) the BGN Agreement, or (iv) any allegation that the practice of the BioLineRx Intellectual Property rights in the Development Program infringes or misappropriates any Third Party intellectual property rights, to the extent BioLineRx had Knowledge that such practice would infringe or misappropriate such Third Party intellectual property rights on or before the Effective Date.

(c) Claims for Indemnification. A Person entitled to indemnification under this Section 10.1 (an "Indemnified Party") shall give prompt written notification to the Party from whom indemnification is sought (the "Indemnifying Party") of the commencement of any action, suit or proceeding relating to a Third Party claim for which indemnification may be sought or, if earlier, upon the assertion of any such claim by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third Party claim as provided in this Section 10.1(c) shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice). Within [***] days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such action, suit, proceeding or claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense. The Party not controlling such defense may participate therein at its own expense. The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which consent the Indemnifying Party shall not unreasonably withhold, condition or delay. The Indemnifying Party shall not agree, without the prior written consent of the Indemnified Party, which consent the Indemnified Party shall not unreasonably withhold, condition or delay, to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party.

Section 10.2 Governing Law. This Agreement shall be construed and the respective rights of the Parties determined in accordance with the laws of the State of New York, USA (other than any principle of conflict or choice of laws that would cause the application of the laws of any other jurisdiction).

Section 10.3 Submission to Jurisdiction. Each Party (a) submits to the jurisdiction of any state or federal court sitting in the State of New York, USA in any action or proceeding arising out of or relating to this Agreement, (b) agrees that all claims in respect of such action or proceeding may be heard and determined in any such court, (c) waives any claim of inconvenient forum or other challenge to venue in such court, and (d) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court, unless the state or federal courts sitting in the State of New York decline to exercise jurisdiction over any such action or proceeding or if those courts lack proper jurisdiction, then any action or proceeding arising out of or relating to this Agreement may be brought in any other U.S. court of competent jurisdiction. Each Party agrees to accept service of any summons, complaint or other initial pleading made in the manner provided for the giving of notices in Section 10.6, provided that nothing in this Section 10.3 shall affect the right of either Party to serve such summons, complaint or other initial pleading in any other manner permitted by law.

**[***] Redacted pursuant to a confidential treatment request.**

Section 10.4 Assignment. Ikaria may assign this Agreement or any right hereunder, or delegate any obligation hereunder, in its sole discretion, to (a) any Affiliate of Ikaria or (b) any entity acquiring all or substantially all of the assets of Ikaria Holdings, Inc. and its Affiliates. All other assignments by Ikaria, including (i) to any entity acquiring all or substantially all of the assets of Ikaria to which this Agreement relates or (ii) to any entity with which or into which Ikaria may consolidate or merge, are subject to BioLineRx's prior approval, which approval shall not be unreasonably withheld, conditioned or delayed. BioLineRx may assign its right to receive payments hereunder to a Third Party, in its sole discretion, but BioLineRx shall not otherwise be permitted to assign this Agreement, in whole or in part, without the prior written consent of Ikaria, which approval shall not be unreasonably withheld, conditioned or delayed. Any assignments in contravention of this Section 10.4 shall be null and void.

Section 10.5 Entire Agreement; Amendments. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes all previous arrangements between the Parties with respect to the subject matter hereof, whether written or oral, except for that certain Mutual Non Disclosure Agreement between the Parties dated February 25, 2009. Without limiting the generality of the foregoing, this Agreement hereby supersedes and replaces in its entirety the License and Commercialization Agreement by and among the parties dated as of July 5th, 2009. To the extent that any provision of this Agreement conflicts with any provisions of such Mutual Non Disclosure Agreement, the provision of this Agreement shall control. Except as set forth in Section 2.1(iv), any amendment or modification to this Agreement shall be made in writing signed by both Parties.

Section 10.6 Notices.

Notices to Ikaria shall be addressed to:

Ikaria Development Subsidiary One LLC
6 State Route 173
Clinton, NJ 08809, USA
Attention: Chief Executive Officer

with copy to:

Ikaria Holdings, Inc.
6 State Route 173
Clinton, NJ 08809, USA
Attention: General Counsel

Notices to BioLineRx Ltd. shall be addressed to:

BioLineRx Ltd.
19 Hartum Street
P.O. Box 45158
Jerusalem 91450, Israel
Attention: Chief Executive Officer

with copy to:

Arent Fox LLP
1050 Connecticut Avenue
Washington, DC 20036, USA
Attention: John Dwyer, Esq.

Notices to BioLine Innovations Jerusalem L.P. shall be addressed to:

BioLine Innovations Jerusalem L.P.
19 Hartum Street
P.O. Box 45158
Jerusalem 91450, Israel
Attention: Chief Executive Officer

with copy to:

Arent Fox LLP
1050 Connecticut Avenue
Washington, DC 20036, USA
Attention: John Dwyer, Esq.

Any Party may change its address by giving notice to the other Party in the manner herein provided. Any notice required or provided for by the terms of this Agreement shall be in writing and shall be (a) sent by registered or certified mail, return receipt requested, postage prepaid, (b) sent via a reputable international courier service, (c) sent by facsimile transmission, or (d) personally delivered, in each case properly addressed in accordance with the paragraph above. The effective date of notice shall be the actual date of receipt by the Party receiving the same.

Section 10.7 Force Majeure. No failure or omission by a Party in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from any cause or causes beyond the control of such Party, including the following: acts of God; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; and invasion (each such event, a "Force Majeure Event") and provided that such Party cures such failure or omission resulting from one of the above causes as soon as is practicable after the occurrence of one or more of the above-mentioned causes.

Section 10.8 Independent Contractors. It is understood and agreed that the relationship between the Parties hereunder is that of independent contractors and that nothing in this Agreement shall be construed as authorization for either BioLineRx or Ikaria to act as agent for the other.

Section 10.9 Limitations of Liability. NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, OR FOR LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 10.9 IS INTENDED TO LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY WITH RESPECT TO THIRD PARTY CLAIMS; (B) ANY LOSSES, INCLUDING LOST PROFITS, ARISING FROM ANY (I) BREACH OF A PARTY'S OBLIGATIONS WITH RESPECT TO THE OTHER PARTY'S CONFIDENTIAL INFORMATION, (II) BREACH BY BIOLINERX OF THE EXCLUSIVE RIGHTS GRANTED IN SECTION 2.1 OR THE COVENANT CONTAINED IN SECTION 2.2, OR (III) USE OF ANY PATENT RIGHTS OR KNOW-HOW LICENSED HEREUNDER BEYOND THE SCOPE OF SUCH LICENSE; OR (C) ANY LOSSES ARISING AS A RESULT OF A PARTY'S FRAUD, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

Section 10.10 No Implied Waivers; Rights Cumulative. No failure on the part of BioLineRx or Ikaria to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence thereto, nor shall any single or partial exercise of any such right, power, remedy or privilege preclude any further or other exercise thereof or the exercise of any other right, power, remedy or privilege.

Section 10.11 Severability. If, under applicable law or regulation, any provision of this Agreement is invalid, incomplete or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement (such invalid, incomplete or unenforceable provision, a "Severed Clause"), this Agreement shall endure except for the Severed Clause. The Parties shall consult one another and use reasonable efforts to agree upon a valid, complete and enforceable provision that is a reasonable substitute for the Severed Clause in view of the intent of this Agreement.

Section 10.12 Execution in Counterparts; Facsimile Signatures. This Agreement may be executed in counterparts, each of which, when so executed and delivered, shall be deemed to be an original, and all of which, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission shall be deemed to be original signatures.

REMAINDER OF PAGE LEFT EMPTY; NEXT PAGE IS THE SIGNATURE PAGE

IN WITNESS WHEREOF, the Parties have executed this License and Commercialization Agreement as of the Effective Date.

IKARIA DEVELOPMENT SUBSIDIARY ONE LLC

By: _____
Name: _____
Title: _____

BIOLINERX LTD.

By: _____
Name: _____
Title: _____

BIOLINE INNOVATIONS JERUSALEM L.P.
by its General Partner, BioLine Innovations Jerusalem, Ltd.

By: _____
Name: _____
Title: _____

SCHEDULE 1.30

PROTOCOL FOR ON-GOING PHASE I/II TRIAL

[*PROTOCOL IMMEDIATELY FOLLOWS*]

SCHEDULE 1.31

DESCRIPTIONS OF OTHER ON-GOING TRIALS

| Name of Study | Estimated Duration | Estimated End Date |
|---|---|---|
| [***] | [***] | [***] |
| [***] | [***] | [***] |
| [***] | [***] | [***] |

**[***] Redacted pursuant to a confidential treatment request.**

SCHEDULE 1.35

OUTLINE OF STRUCTURE FOR PIVOTAL CLINICAL TRIAL FOR PRIMARY INDICATION

(see Schedule 3.1)

SCHEDULE 1.42(a)

INDEPENDENT SAFETY MONITORING BOARD CHARTER

**Independent Safety Monitoring Board**

**Charter**

**For**

**Bioline Innovations Jerusalem**

**Protocol No. BL-1040**

**A Phase I, multi-center, open label study designed to assess the safety and feasibility of the injectable BL-1040 implant to provide scaffolding to infarcted myocardial tissue**

**[***]**

**[***] Redacted pursuant to a confidential treatment request.**

**[***] Redacted pursuant to a confidential treatment request.**

**[***] Redacted pursuant to a confidential treatment request.**

**[***] Redacted pursuant to a confidential treatment request.**

SCHEDULE 2.3

EXISTING PRODUCT AGREEMENTS

**[***]**

**[***] Redacted pursuant to a confidential treatment request.**

SCHEDULE 3.1

INITIAL DEVELOPMENT PLAN

**[***]**

**[***] Redacted pursuant to a confidential treatment request.**

SCHEDULE 3.7

PRELIMINARY COMMERCIALIZATION PLAN

**[***]**

**[***] Redacted pursuant to a confidential treatment request.**

SCHEDULE 4.3(a)

BIOLINERX WIRE TRANSFER INFORMATION

**[***]**

**[***] Redacted pursuant to a confidential treatment request.**

EXHIBIT A

TECHNOLOGY EXCHANGE PLAN

Upon Ikaria's request, the following will be provided by BioLineRx to Ikaria or its designee:

10. All materials (original or copies as appropriate) in BioLineRx's possession and Control relating to Product, including documentation relating to Development and all regulatory filings, clinical information, and data and other documents relating to the On-Going Phase I/II Trial and the Other On-Going Trials.

11. Copies of all documents and available information in BioLineRx's possession and Control necessary for Manufacturing of Product at the time of technology exchange. These documents will include information necessary to assist Ikaria or its designee in setting up Manufacturing operations for such things as:

- raw material test methods, specifications, qualification and justification for use
- raw material vendor lists with part numbers
- analytical methods stated purpose, development, qualification and validation reports
- process development reports, laboratory notebooks and associated electronically stored data
- Manufacturing summary including
    - detailed process description with process schematics, operating parameters and target ranges, flow charts outlining critical process controls and steps, cartoons, verbal description including abbreviations, process scale, yield, and standard process instructions
    - in-process controls/tests and acceptance criteria including stated purpose of in-process tests
    - master batch record(s)
    - filling/packaging process
    - aseptic and process development and validation documents
    - facility and equipment requirements and design documents
    - descriptions of process equipment, including suppliers, part numbers, and historic invoices
    - product test methods, specifications and justification of specifications
    - product stability, test methods and qualification/validation reports, stability reports, shelf life recommendations

As available and agreed upon by the JDC at the time of a technology exchange, BioLineRx will provide requested technical manufacturing or engineering advice to Ikaria or its designee. Ikaria will ensure designee has necessary expertise in place to exchange the documentation and expertise in an orderly fashion.

EXHIBIT B

BIOLINERX PATENT RIGHTS

Family 1

| INJECTABLE CROSS-LINKED POLYMER PREPARATIONS AND USES THEREOF | | | | | | |
|---|---|---|---|---|---|---|
| **Country** | **Earliest Priority** | **Entry Date** | **Filing Date**<br>**Application No.** | **Issue Date**<br>**Patent No.** | **Status** | **Owner** |

**[***]**

**[***] Redacted pursuant to a confidential treatment request.**

Family 2

| A METHOD OF TREATING MUSCLE TISSUES | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | |
| **Country** | **Earliest Priority** | **Entry Date** | **Filing Date Application No.** | **Issue Date Patent No.** | **Status** | **Owner** |

**[***]**

**[***] Redacted pursuant to a confidential treatment request.**

**PAYMENT DATE EXTENSION AMENDMENT**

Ikaria Development Subsidiary One LLC, a Delaware limited liability company having a principal place of business at 6 State Route 173, Clinton, NJ 08809, USA ("Ikaria"), BioLineRx Ltd., a corporation organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel ("BioLineRx Ltd."), and BioLine Innovations Jerusalem L.P., a limited partnership organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel ("BioLine Innovations"; together with BioLineRx Ltd., "BioLineRx") are party to an Amended and Restated License and Commercialization Agreement dated as of the 26th day of August, 2009 (the "Agreement"). Any defined terms used herein shall have them meaning ascribed thereto in the Agreement.

Pursuant to Section 4.1(a) the Agreement, Ikaria is required to make a milestone payment to BioLineRx of USD $10,000,000 upon the Successful Completion of the On-Going Phase I/II Trial (the "Second Milestone Payment") on or before [***]. BioLine and Ikaria are currently in discussions to determine whether Ikaria is required to withhold United States federal income taxes from the Second Milestone Payment. In order to enable the parties to complete those discussions, Ikaria and BioLine hereby agree that the due date for the Second Milestone Payment is hereby extended to [***].

Sections 10.2 ("*Governing Law*") and 10.3 ("*Submission to Jurisdiction*") of the Agreement are hereby incorporated herein by reference.

**Acknowledged, Agreed, and Confirmed**

/s/ Daniel Tassé
Daniel Tassé
Chief Executive Officer
Ikaria Development Subsidiary One LLC

/s/ Kinneret Savitsky
Kinneret Savitsky,
Chief Executive Officer
***On behalf of, and as authorized representative of, both BioLineRx Ltd. and BioLine Innovations Jerusalem L.P.***

**[***] Redacted pursuant to a confidential treatment request.**

**AMENDMENT TO THE AMENDED AND RESTATED LICENSE AND COMMERCIALIZATION AGREEMENT**

This Amendment (this "Amendment") is entered into this 21st day of April 2010 (the "Amendment Effective Date") by and between **Ikaria Development Subsidiary One LLC**, a Delaware limited liability company with a place of business at 6 Route 173, Clinton, NJ, 08809 USA ("Ikaria"), and **BiolineRx Ltd.**, a corporation organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, P.O. Box 45158, Jerusalem 91450, Israel ("BioLineRx Ltd."), and **BioLine Innovations Jerusalem L.P.**, a limited partnership organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, P.O. Box 45158 Jerusalem 91450, Israel ("BioLine Innovations"; together with BioLineRx Ltd., "BioLine Rx") . This Amendment amends the Amended and Restated License and Commercialization Agreement entered into by and between Ikaria and BioLineRx dated as of the 26th day of August 2009 (the "Agreement"). Any defined term used in this Amendment not expressly defined herein shall have the meaning ascribed thereto in the Agreement.

1. Modification of Payee. All payments to be made under the Agreement shall be made to BiolineRx Ltd. or any Third Party assignee of BioLineRx Ltd. permitted under Section 10.4 of the Agreement.

2. Modification of Assignment. The last two sentences of Section 10.4 of the Agreement are hereby amended and restated as follows:

"BioLineRx Ltd. may assign its right to receive payments hereunder to a Third Party, in its sole discretion, provided that BioLineRx Ltd. provides Ikaria with prior written notice of the assignment and the name and address of the assignee. Any such Third Party assignee may not further assign the right to receive payments hereunder without providing Ikaria with prior written notice of the assignment and the name and address of the assignee. Ikaria shall maintain a written record of any such assignments. The parties intend that this Agreement shall be considered to be in "registered form" as defined in United States Treasury Regulations Section 5f.103-1(c). BiolineRx shall not otherwise be permitted to assign this Agreement, in whole or in part, without the prior written consent of Ikaria, which approval shall not be unreasonably withheld, conditioned, or delayed. Any assignment in contravention of this Section 10.4 shall be null and void."

3. Ratification of Agreement. Except as set forth in this Amendment, all of the other terms and conditions of the Agreement are hereby ratified and confirmed to be of full force and effect, and shall continue in full force and effect. This Amendment is hereby integrated into and made a part of the Agreement.

4. Counterparts. This Amendment may be executed in two or more counterparts, each of which shall be effective as of the Amendment Effective Date, and all of which shall constitute one and the same instrument. Each such counterpart shall be deemed an original, and it shall not be necessary in making proof of this Amendment to produce or account for more than one such counterpart.

5. Execution and Delivery. This Amendment shall be deemed executed by the parties when any one or more counterparts hereof, individually or taken together, bears the signatures of each of the parties hereto.

**Acknowledged and Agreed to:**

**BIOLINERX LTD.**

By: /s/ Kinneret L. Savitsky /s/ Philip Serlin
Signature

Kinneret L. Savitsky Philip Serlin
Printed Name

CEO CFO
Title

April 21, 2010

**IKARIA DEVELOPMENT SUBSIDIARY ONE LLC**

By: /s/ Matthew M. Bennett
Signature

Matthew M. Bennett
Printed Name

Vice President and Secretary
Title

April 21, 2010

**BIOLINE INNOVATIONS JERUSALEM L.P.,**
**BY ITS GENERAL PARTNER BIOLINE INNOVATIONS JERUSALEM, LTD.**

By: /s/ Kinneret L. Savitsky /s/ Philip Serlin
Signature

Kinneret L. Savitsky Philip Serlin
Printed Name

CEO CFO
Title

April 21, 2010

AMENDMENT

TO

AMENDED AND RESTATED LICENSE AND COMMERCIALIZATION AGREEMENT

Amendment to Amended and Restated License and Commercialization Agreement (this "Amendment"), dated as of January 8, 2015 (the "Amendment Effective Date"), by and among Bellerophon BCM LLC, a Delaware limited liability company formerly known as Ikaria Development Subsidiary One LLC ("Bellerophon"), on the one hand, and BioLineRx Ltd., a corporation organized and existing under the laws of the State of Israel ("BioLineRx"), on the other hand. Each of Bellerophon and BioLineRx may be referred to herein as a "Party" and Bellerophon and BioLineRx may be referred to herein collectively as the "Parties."

WHEREAS, Bellerophon, BioLineRx and BioLine Innovations Jerusalem L.P., a limited partnership organized and existing under the laws of the State of Israel ("BioLine Innovations") entered into an Amended and Restated License and Commercialization Agreement as of August 26, 2009 (the "Agreement");

WHEREAS, BioLine Innovations has assigned all of its rights and obligations under the Agreement to BioLineRx, and BioLineRx has assumed such rights and obligations;

WHEREAS, Bellerophon has consented to the foregoing assignment and assumption in accordance with Section 10.4 of the Agreement;

WHEREAS, BioLineRx has alleged certain breaches or potential breaches of the Agreement in correspondence to Bellerophon, and Bellerophon has denied that any breach of the Agreement exists; and

WHEREAS, the Parties desire to amend certain provisions of the Agreement and to resolve all disputes relating to the Agreement that have arisen between them;

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, and for other good and valuable consideration, the Parties, intending to be legally bound, hereby agree as follows:

1. **Definitions.** Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement. For the avoidance of doubt, Bellerophon, as defined in this Amendment, and Ikaria, as defined in the Agreement, are one and the same entity.

2. **Amendment to Agreement Terms**. Section 4.1(a)(3) of the Agreement is hereby amended and restated to read as follows:

***[SIX WORDS REDACTED]*** $***

***[ELEVEN WORDS REDACTED]***

***[FIVE LINES REDACTED]***

***[FIVE LINES REDACTED]***

***[TWO LINES REDACTED]***

***[FOUR LINES REDACTED]***

***[TEN LINES REDACTED]***

***[SEVEN LINES REDACTED]***

3. **Release**. BioLineRx, on its own behalf and on behalf of its predecessors, successors, assigns, affiliates, agents and representatives, and each of them in all of their capacities, shall, and hereby does (in such capacity, the "Releasing Parties"), forever waive, release and discharge Bellerophon and Bellerophon's affiliates, and its and their predecessors, successors, assigns, affiliates, agents, representatives, officers, directors, employees, stockholders, attorneys and advisors, and each of them in all of their capacities (in such capacity, the "Released Parties"), of and from any and all claims, causes of action, demands, damages, debts, liabilities, obligations, equitable and provisional remedies, costs, expenses (including attorneys' and accountants' fees and expenses) actions and causes of action of any nature whatsoever, whether now known or unknown, suspected or unsuspected, that such Releasing Party now has or at any time previously had, based in any way, directly or indirectly, on the Agreement or the spin-out of Bellerophon from Ikaria Holdings, Inc. and its affiliates, or based on any act or failure to act, or on any disclosure or failure to disclose, by Bellerophon under or in connection with the Agreement (each, a "Claim"). Each Releasing Party irrevocably covenants and agrees not to assert directly or indirectly any Claim, or to commence, institute or cause to be commenced, any proceeding of any kind against any of the Released Parties, based upon, regarding, related to or arising out of any matters released in this release, and further covenants and agrees that this Amendment is a bar to any such Claim.

4. **Miscellaneous**. The Parties hereby confirm and agree that, as amended hereby, the provisions of the Agreement shall remain unchanged and in full force and effect and the Agreement remains a binding obligation of the Parties. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting the Agreement.

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their duly authorized representatives.

| | |
|---|---|
| **BELLEROPHON BCM LLC** | **BIOLINERX LTD.** |
| By: s/ BELLEROPHON BCM LLC | By: /s/ BIOLINERX LTD |

**Exhibit 4.37**

Summary of Lease Agreement dated August 7, 2014
between S.M.L. Solomon Industrial Buildings Ltd. and Infrastructure Management and Development Established by C.P.M. Ltd. (collectively, "Lessor")
and BioLineRx Ltd. ("Lessee"),
as amended December 9, 2014

Note: This Summary does not contain a full or direct translation of the terms of the original Hebrew-language agreement and is intended solely as a general summary of the lease document for the purposes of Registrant's annual report.

**Leased Premises**

The Lessee leases from the Lessor premises ("the Leased Premises") consisting of approximately 1,750 square meters (gross) on level -1 of a building known as "Atrium House" located in the Technological Park in Modi'in, Israel and 39 parking spaces.

**Lease Term**

The Lease Term will be for five years beginning June 15, 2015 and ending June 30, 2020 (hereinafter: the "**Lease Term**").

The Lessee has the right to extend the Lease Term for three additional periods as follows:

The first additional lease period: 5 years after the end of the Lease Term;

The second additional lease period: 3 years after the end of the first additional lease period;

The third additional lease period: 2 years after the end of the second additional lease period.

**Purpose of the Lease**

The purpose of the lease is offices and laboratories.

**Rental Payments**

1. The initial rental payment for the Leased Premises during the Lease Term will be NIS 72,341 per month.

2. The initial rental payment for the parking spaces will be NIS 7,000 per month.

3. The foregoing rental amounts (the "Basic Rent") will be linked to the Israeli Consumer Price Index. In addition, for each additional lease period as provided above, the Basic Rent will be increased by a rate of 5% of the rental payment that was paid in the last month of the lease period that preceded it.

3. The Lessor will, by means of a management company, be providing management services for the building for a monthly fee that will not, during the Lease Term, exceed NIS 15 per square meter of gross area of the Leased Premises.

**Taxes, Fees and Utilities**

The Lessee is required to pay all taxes, fees and utility costs associated with the possession and use of the Leased Premises.

**Insurance and Indemnity**

1. The Lessee agrees to maintain insurance for the Leased Premises of the following types: extended fire risk; consequential loss that may be caused to the Lessee by damage to the structure of the Leased Premises and/or their contents and/or the building, including its facilities, resulting from extended fire risks; third party liability; and employers' liability.

2. The Lessee will be liable for loss, injury, expense or damage (collectively, "Damages") of any type caused to the Lessor or third parties due to the acts or omissions of the Lessee in connection with the Leased Premises or the use of the common and public areas of the building. The Lessee will indemnify the Lessor for any such Damages.

3. The Lessor agrees to maintain insurance of the following types: extended fire risks for the building and loss of rent or management expenses that may be caused to the Lessor as a result of damage caused to the Leased Premises or because of demolition of the Leased Premises due to extended fire risks.

**Termination of the Lease Agreement**

The Lease Agreement may be terminated before the end of the Lease Term or any additional lease term upon the occurrence of any of the following events:

1. The Lessee commits a fundamental breach of the Lease Agreement and does not cure such breach within 14 days after delivery of the Lessor's first notice (and in the event of a repeated breach within seven days after delivery of the Lessor's first notice). The Lessor may in such event terminate the Lease Agreement with advance written notice of seven days.

3. The Lessee commits any other breach of the Lease Agreement and does not cure such breach within 30 days after delivery of the Lessor's first notice. The Lessor may in such event terminate the Lease Agreement with advance written notice of seven days.

2. The Lessee decided on voluntary liquidation or an order of liquidation was entered against the Lessee.

3. A petition for liquidation or for appointment of a receiver is filed against the Lessee or a liquidator and/or receiver, whether temporary or permanent, is appointed, when the grounds for such nomination is the inability of the Lessee to pay its debts, and such petition or appointment is not cancelled within 90 days.

**Exhibit 4.38**

# Investment and Collaboration Agreement

**by and between**

# BioLineRx Ltd.

**and**

# Novartis Pharma AG

December 16, 2014

**[*] 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.**

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

# INVESTMENT AND COLLABORATION AGREEMENT

**This Investment and Collaboration Agreement** (the **"Agreement"**) is entered into as of December 16, 2014 (the **"Effective Date"**) by and between **Novartis Pharma AG**, a corporation organized and existing under the laws of Switzerland and having its principal place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland (**"NVS"**), and **BioLineRx Ltd.**, a company organized and existing under the laws of the State of Israel and having a principal place of business at 19 Hartum Street, Jerusalem, 91450, Israel (**"BioLine"**).

## RECITALS

**Whereas**, BioLine is a clinical-stage biopharmaceutical company developing products for the pharmaceutical market satisfying unmet medical needs or exhibiting advantages over current therapies; and

**Whereas**, NVS is a leading, global pharmaceutical company with extensive experience in the research, development, manufacture, distribution, sales and marketing of pharmaceutical products; and

**Whereas**, NVS and BioLine desire to establish a framework pursuant to which BioLine will grant NVS access to BioLine's Israel-based drug development pipeline and project screening process with a view to enabling a collaborative approach to continued development of promising pharmaceutical candidates, in accordance with and subject to the terms and conditions set out herein (the "**Collaboration**"); and

**Whereas**, as an integral part of the Collaboration, NVS desires to make an equity investment in BioLine, all on the terms and conditions set forth herein.

**Now Therefore**, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

## ARTICLE 1
## Definitions

As used in this Agreement, the following initially capitalized terms, whether used in the singular or plural form, shall have the meanings set forth in this Article 1.

**"ADS"** has the meaning set out in Section 2.1.1.

**"Advisors"** has the meaning set out in Section 11.3.1.

**"Affiliate"** means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of 50% or more of the voting stock of such entity, or by contract or otherwise.

**"BioLine"** means BioLineRx Ltd., as further defined in the Preamble above.

**"Change of Control"** means a transaction which results in a change in the power to direct (directly or indirectly) the management and policies of BioLine through the ownership of voting capital, by which (i) any person or group becomes the beneficial owner of voting securities (including any options, rights or warrants to purchase, and any securities convertible into or exchangeable for, voting securities) of BioLine representing 50% or more of the voting power represented by all outstanding securities of BioLine; or (ii) a majority of the seats on the board of directors of BioLine shall at any time be occupied by persons who were not members of the board of directors prior to such transaction.

**"Clinical Proof of Concept"** means the conclusion of the first clinical study in healthy human volunteers or patients showing safety, tolerability, pharmacodynamic activity, pharmacokinetics, early evidence of efficacy, generally equivalent to a Phase I study pursuant to FDA regulations or foreign equivalents, as well as evidence of drug metabolism and mechanism of action, all as specifically agreed by the Parties during the process of establishing the Core Terms.

"**Closing Price Per ADS**" has the meaning set out in Section 2.1.

**"Collaboration"** has the meaning set out in the Preamble above.

**"Collaboration Quota"** means the presentation by BioLine to NVS at the Joint Steering Committee of seven projects, each of which is either: (a) an IND Project; or (b) a Pre-IND Project with respect to which NVS has exercised Matching Rights, where such project has been sublicensed by BioLine to NVS pursuant to the arrangements set out in Section 5.2.5.

**"Confidential Information"** means, with respect to a Party, all reports and other Information of such Party that is disclosed to the other Party pursuant to the arrangements set out in this Agreement, whether in oral, written, graphic, or electronic form. All Information disclosed by a Party pursuant to the Mutual Non-Disclosure Agreement between the Parties dated May 7, 2014, as amended through the Effective Date, shall be deemed to be such Party's Confidential Information disclosed hereunder.

**"Core Term Memorandum"** has the meaning set out in Section 6.3.3.

**"Core Terms"** has the meaning set out in Section 6.3.

**"CSR"** has the meaning set out in Section 6.8.

**"Development Budget Balance"** has the meaning set out in Section 6.5.1.

**"Dollar"** means the U.S. dollar, and "$" shall be interpreted accordingly.

**"Effective Date"** means the date on which this Agreement becomes effective, as set out in the Preamble above.

**"EMA"** means the European Medical Agency and any successors thereof.

**"Executive"** means a senior executive of a Party, such as, by way of example, a Party's Chief Executive Officer or the chairman of the Board of Directors of such Party.

**"FDA"** means the United States Food and Drug Administration and any successors thereof.

**"Flagged Project"** has the meaning set forth in Section 5.2.1.

**"Form 6-K"** shall mean that form administrated by the SEC and submitted by foreign private issuers of securities pursuant to certain rules promulgated under the Securities Exchange Act of 1934.

**"Form 20-F"** shall mean the most recent annual report filed by BioLine with the SEC on Form 20-F.

**"Governmental Authority"** means any multi-national, federal, state, local, municipal, provincial or other government authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

**"In-Person Meeting"** has the meaning set forth in Section 3.1.4.

**"IND"** means an Investigational New Drug Application pursuant to the regulations and guidelines of the FDA, or a comparable application pursuant to the regulations and guidelines of the EMA, the Israel Ministry of Health or another Regulatory Authority.

**"IND Project"** means a project that is included in the Collaboration and that (i) is IND-ready, or (ii) with respect to which human clinical data has been generated, whether by BioLine or a Third Party, or (iii) is otherwise deemed to be an IND Project in accordance with Section 5.3.

**"IND-ready"** means a project that is of such a stage of development that it is ready for IND submission pursuant to regulations of the Regulatory Authority to which it is to be submitted, as mutually agreed by the Parties.

**"Information"** means any data, results, technology, business information and information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, test data (including pharmacological, biological, chemical, biochemical, toxicological, preclinical and clinical test data), manufacturing know-how and data, analytical and quality control data, stability data, other study data and procedures.

**"Investment Date"** has the meaning set forth in Section 2.1.

**"JDT"** or **"Joint Discussion Team"** has the meaning set forth in Section 3.1.6.

**"Joint Steering Committee"** or **"JSC"** has the meaning set forth in Section 3.1.1.

**"Key Employee"** means a senior executive of BioLine.

**"Laws"** means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign, or of any Governmental Authority .

**"Matching Rights"** has the meaning set forth in Section 5.2.5.

**"Material Adverse Change"** has the meaning set forth in Section 2.1.4(c).

**"Matching Rights Notice"** has the meaning set forth in Section 5.2.4.

**"Net Consideration"** has the meaning set forth in Section 6.9.5.

**"NIBR"** means Novartis Institutes of BioMedical Research.

**"Non-Breaching Party"** has the meaning set forth in Section 12.2.1.

**"Non-Israel Sourced Projects"** has the meaning set forth in Section 4.1.

**"Notified Party"** has the meaning set forth in Section 12.2.1.

**"NVS"** means Novartis Pharma AG, as further defined in the Preamble above.

**"NVS Engagement Contributions"** has the meaning set forth in Section 5.2.1(i).

**"Option Fee"** has the meaning set forth in Section 6.4.

**"Option Fee Repayment Amount"** has the meaning set forth in Section 6.9.5.

**"Ordinary Shares"** has the meaning set forth in Section 2.1.1.

**"Partial Release Date"** has the meaning set forth in Section 2.3.1.

**"Party"** means either NVS or BioLine, and **"Parties"** means both NVS and BioLine, collectively.

**"POC Endpoints"** has the meaning set out in Section 6.3.1.

**"Pre-existing NVS IP"** means intellectual property and rights therein and thereto owned or controlled by NVS and/or its Affiliates prior to the Effective Date, and/or developed by NVS and/or its Affiliates subsequent to the Effective Date but outside the scope of the Collaboration.

**"Pre-IND Project"** means a project that is included in the Collaboration and (i) that is not IND-ready or (ii) with respect to which no human clinical data has been generated.

**"Project"** means either a Pre-IND Project or an IND Project, as the context requires, which is included in the Collaboration, and **"Projects"** means Pre-IND Projects and IND Projects, collectively.

**"Project IP"** has the meaning set out in Article 8.

**"Regulatory Approval"** means, with respect to a pharmaceutical product, all approvals, registrations, licenses or authorizations from the relevant Regulatory Authority, in any country or jurisdiction, that is specific to such product and necessary to manufacture, market and/or sell such product.

**"Regulatory Authority"** means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority responsible for granting Regulatory Approval. Without limiting the generality of the foregoing, the FDA, EMA and the Israel Ministry of Health are Regulatory Authorities in their respective jurisdictions.

**"Rejected Pre-IND Project"** has the meaning set out in Section 5.1.

**"Restricted Period"** has the meaning set out in Section 5.2.3.

**"ROFN"** has the meaning set out in Section 6.8.

**"ROFN Period"** has the meaning set out in Section 6.8.

**"Screen B Projects"** has the meaning set out in Section 4.1.

**"SEC"** means the U.S. Securities Exchange Commission.

**"Securities Act"** has the meaning set out in Section 2.1.2.

**"Selected Project"** has the meaning set out in Section 6.3.3.

"**Selected Project Selection Date**" has the meaning set out in Section 6.3.3.

**"Stand-Still Agreement"** has the meaning set out in Section 2.2.

**"Sublicense Agreement"** shall mean the agreement pursuant to which BioLine will grant to NVS, or another mutually agreed Affiliate of NVS, to the maximum extent possible, the exclusive, worldwide, sublicenseable right and license to exploit technology, know-how and other forms of intellectual property that BioLine has previously in-licensed from a Third Party (including by way of conducting further research and development of the licensed technology, and the manufacture, marketing, distribution and/or sale of products based on such technology, know-how and intellectual property) with respect to a Flagged Project or a Selected Project.

**"Term"** means the term of this Agreement, as determined in accordance with Section 12.1.

**"Third Party"** means any person or entity other than BioLine or NVS or an Affiliate of either of them.

**"Third Party Opportunity"** has the meaning set out in Section 5.2.4

**"Third Party Transaction"** has the meaning set out in Section 6.9.5.

**[*]**

**[*]**

has the meaning set out in Section 6.9.

**"VWAP"** means the volume-weighted average trading price of BioLine's ADSs on the Nasdaq.

## ARTICLE 2
### EQUITY INVESTMENT

2.1 **Equity Investment.** Within ten days of the Effective Date, NVS shall make an initial $10 million equity investment in American Depositary Shares ("**ADS**") of BioLine at a price per ADS based on the *higher* of (i) $2.00 per ADS; or (ii) a 20% premium over the VWAP, as reported on the Nasdaq, for the 30-day period ending on the day prior to the Effective Date; or (iii) a 10% premium over the closing price of BioLine's ADSs on the trading day immediately prior to the Effective Date (the "**Closing Price Per ADS**") as reported on the Nasdaq; *provided however*, that if the Closing Price Per ADS is less than $1.40, the price per ADS to be paid by NVS will be as set forth in the column captioned "Price per ADS to NVS" on the schedule set forth as **Exhibit 2.1**. The date upon which the equity investment is made shall be referred to as the "**Investment Date**". In connection with the equity investment:

2.1.1 **Authorization of Ordinary Shares**. BioLine has authorized the issuance and sale of (i) 50,000,000 ordinary shares, par value NIS 0.01 per share ("**Ordinary Shares**"), represented by 5,000,000 American Depositary Shares (the "**ADSs**"). For purposes of clarification, each ADS represents ten Ordinary Shares.

2.1.2 **Completion of Investment**. The completion of the equity investment shall occur on the Investment Date at the offices of Yigal Arnon & Co., One Azrieli Center, Tel Aviv, 6133701, Israel. At the completion, NVS shall deliver, in immediately available funds, the full amount of the purchase price for the ADSs being purchased hereunder by wire transfer to an account designated by BioLine, and BioLine shall, within three business days, deliver to NVS a certificate registered in the name of NVS, or in such nominee name as designated by NVS in writing, representing the number of ADSs set forth in Section 2.1.1 above. The issue and sale to NVS will comply with Rule 903 of Regulation S under the Securities Act of 1933, as amended (the "**Securities Act**") and the certificates will bear an appropriate legend referring to that fact.

2.1.3 **NVS Representations**. In connection with the purchase of the ADSs, NVS represents and warrants to, and covenants with BioLine that:

(a) Experience. (i) NVS is knowledgeable, sophisticated and experienced in financial and business matters, and is qualified to make decisions with respect to investments in shares representing an investment decision like that involved in the purchase of the ADSs, has the ability to bear the economic risks of an investment in the ADSs and has requested, received, reviewed and considered all information it deems relevant in making an informed decision to purchase the ADSs; (ii) NVS is acquiring the ADSs for its own account with no present (as of the Effective Date) intention of distributing any of such ADSs or entering into any arrangement or understanding with any other persons regarding the distribution of such ADSs; and (iii) NVS will not, directly or indirectly, offer, sell, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire or take a pledge of) any of the ADSs, nor will NVS engage in any short sale that results in a disposition of any of the ADSs by NVS, except in compliance with Sections 2.2 and 2.3 hereof, the Securities Act, the Israeli Securities Law, and the rules and regulations promulgated thereunder and any applicable state securities laws.

(b) U.S. exemption. (i) NVS is aware that the sale of the ADSs has not been registered under the Securities Act or any state securities laws or regulations in reliance upon Regulation S and similar exemptions under state law, (ii) NVS will not offer or sell the Shares unless they are registered or are exempt from registration under the Securities Act and any applicable state securities laws or regulation; (iii) NVS is not a U.S. Person (as that term is defined in Regulation S) nor acquiring the Shares for the account or benefit of any U.S. Person; and (iv) this Agreement has not been executed or delivered by NVS in the United States.

(c) Risk of Loss. NVS understands that its investment in the ADSs involves a significant degree of risk, including a risk of total loss of NVS's investment, and NVS has full cognizance of and understands all of the risk factors related to the NVS's purchase of the ADSs. NVS understands that the market price of the ADSs has been volatile and that no representation is being made as to the future value of any of the ADSs.

2.1.4 **BioLine Representations**. In connection with the equity investment, and in addition to the representations and warranties made by BioLine under Section 9.1 below, BioLine represents and warrants to, and covenants with NVS that:

(a) Authorization of the ADSs. The Ordinary Shares represented by the ADSs have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by BioLine pursuant to this Agreement, will be validly issued, fully paid, and non-assessable and free and clear of all liens, encumbrances, preemptive rights and other claims.

(b) Capitalization and Other Capital Stock Matters. The authorized, issued, and outstanding share capital of BioLine conformed in all material respects to the description thereof contained in the Form 20-F and any Forms 6-K filed or furnished subsequent thereto, in each case as of the date of such Form 6-K. All of the issued and outstanding Ordinary Shares have been duly authorized and validly issued, are fully paid and non-assessable and have been issued in compliance with applicable Israeli, U.S. federal and state securities laws. None of the outstanding Ordinary Shares were issued in violation of any preemptive rights, rights of first refusal, or other similar rights to subscribe for or purchase securities of BioLine. There are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal, or other rights to purchase, or equity or debt securities convertible into, exchangeable or exercisable for, any share capital of BioLine other than those described in the Form 20-F or any Form 6-K filed or furnished subsequent thereto.

(c) No Actions. There is no legal or governmental action, suit or proceeding pending or, to the knowledge of BioLine, threatened against or affecting BioLine or any of its directors and officers in their capacities as such, which has as the subject thereof any officer or director of, or property owned or leased by, BioLine that would reasonably be expected to result in a material adverse change to BioLine's business, financial position, or results of operations taken as a whole (a **"Material Adverse Change"**) or adversely affect the consummation of the transactions contemplated hereby.

(d) Financial Statements. The financial statements and the related notes thereto of BioLine and its consolidated subsidiaries included in the most recent Form 20-F comply as to form in all material respects with the applicable requirements of Regulation S-X under the Securities Act and present fairly in all material respects the financial position, results of operations and cash flows of BioLine as of the dates indicated and for the periods specified; such financial statements have been prepared in conformity with the International Financial Reporting Standards ("**IFRS**") applied on a consistent basis throughout the periods covered thereby.

(e) SEC Filings. BioLine is subject to and in compliance in all material respects with its United States and Israeli reporting requirements and has filed all reports required to be filed by it on a timely basis. As of their respective dates, all SEC reports filed by BioLine complied in all material respects with Laws and the rules and regulations of the SEC.

(f) NASDAQ. BioLine is in compliance with applicable Nasdaq continued listing requirements, and to BioLine's knowledge there are no proceedings pending or threatened against BioLine to revoke or suspend such listing. BioLine has not received any notice of delisting from Nasdaq and has no knowledge of any facts or circumstances which would reasonably be expected to lead to delisting or suspension.

(g) Agreements. Except as disclosed in its SEC filings, there are no agreements, understandings, instruments, contracts or proposed transactions to which BioLine is a party or by which it is bound that involve (i) the license of any patent, copyright, trademark, trade secret or other proprietary right to or from BioLine, (ii) the grant of rights to manufacture, produce, assemble, license, market, or sell products to any other person that limit BioLine's exclusive right to develop, manufacture, assemble, distribute, market or sell its products, or (iii) indemnification by BioLine with respect to infringements of proprietary rights.

(h) Intellectual Property. BioLine owns or possesses or can acquire on commercially reasonable terms sufficient legal rights to all BioLine intellectual property necessary to conduct its business as described in its SEC filings without any known conflict with, or infringement of, the rights of others. To BioLine's knowledge, no product or service developed, marketed or sold (or proposed to be developed, marketed or sold) by BioLine violates or will violate any license or infringes or will infringe any intellectual property rights of any other party. Except as disclosed in its SEC filings, there are no outstanding options, licenses, agreements, claims, encumbrances or shared ownership interests of any kind relating to BioLine's intellectual property, nor is BioLine bound by or a party to any options, licenses or agreements of any kind with respect to the patents, trademarks, service marks, trade names, copyrights, trade secrets, licenses, information, proprietary rights and processes of any other person. BioLine has not received any communications alleging that BioLine has violated, or by conducting its business, would violate any of the patents, trademarks, service marks, tradenames, copyrights, trade secrets, mask works or other proprietary rights or processes of any other person. Each employee and consultant engaged in the development of intellectual property rights has assigned to BioLine all intellectual property rights he or she owns that are related to BioLine's business as now conducted and as presently proposed to be conducted.

(i) Employees. To BioLine's knowledge, none of its Key Employees is obligated under any contract (including licenses, covenants or commitments of any nature) or other agreement, or subject to any judgment, decree or order of any court or administrative agency, that would materially interfere with such Key Employee's ability to promote the interest of BioLine or that would conflict with the BioLine's business. To BioLine's knowledge, no employee intends to terminate employment with BioLine or is otherwise likely to become unavailable, nor does BioLine have a present intention to terminate the employment of any of the foregoing. There is no labor dispute involving BioLine pending, or to BioLine's knowledge, threatened.

(j) Compliance with Other Instruments. Except as disclosed in SEC filings, BioLine is not in violation or default (i) of any provisions of its certificate of incorporation or bylaws, (ii) of any instrument, judgment, order, writ or decree, (iii) under any note, indenture or mortgage, or (iv) under any lease, agreement, or contract to which it is a party, or (v) of any material provision of federal or state Law applicable to BioLine except in each case for such violations which would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change. The execution, delivery and performance of this Agreement will not result in any such violation or be in conflict with or constitute, with or without the passage of time and giving of notice, either (i) a default under any such provision, instrument, judgment, order, writ, decree, contract or agreement; or (ii) an event which results in the creation of any lien, charge or encumbrance upon any assets of BioLine or the suspension, revocation, forfeiture, or nonrenewal of any material permit or license applicable to BioLine, except for any such default or event which would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change.

(k) Litigation. Except as disclosed in SEC filings, there is no action, suit or proceeding, or governmental inquiry or investigation, pending or, to the knowledge of BioLine, threatened against BioLine or any officer, director or employee of BioLine, and, to BioLine's knowledge, there is no basis for any such action, suit, proceeding, or governmental inquiry or investigation. Neither BioLine nor, to BioLine's knowledge, any of its officers, directors or employees is a party or is named as subject to the provisions of any order, writ, injunction, judgment or decree of any court or governmental authority that would reasonably be expected to result in a Material Adverse Change.

(l) Certain Transactions. Except as disclosed in SEC filings, BioLine is not indebted, directly or indirectly, to any of its directors, officers or employees or to their respective spouses or children or to any Affiliate of any of the foregoing, other than for customary employee benefits made generally available to all employees. To BioLine's knowledge, none of BioLine's directors, officers or Key Employees, or any members of their immediate families, or any Affiliate of the foregoing are, directly or indirectly, indebted to BioLine or, to BioLine's knowledge, have any direct or indirect ownership interest in any firm or corporation with which BioLine is affiliated or with which BioLine has a business relationship, or any firm or corporation which competes with BioLine except that directors, officers, Key Employees or stockholders of BioLine may own stock in (but not exceeding two percent (2%) of the outstanding capital stock of) publicly traded companies that may compete with BioLine.

(m) Officers. To BioLine's knowledge, no officer or person nominated to become an officer of BioLine (i) has been convicted in a criminal proceeding or is a named subject of a pending criminal proceeding (excluding minor traffic violations) or (ii) is, or has been, subject to any judgment or order of, or the subject of, any pending civil or administrative action by the SEC or any self-regulatory organization.

(n) Property. BioLine has good and marketable title (in the case of real property) to, or has valid rights to lease or otherwise use, all items of real and personal property and assets that are material to its business, free and clear of all liens, encumbrances, claims and defects and imperfections of title except those that (i) do not materially interfere with the use made and proposed to be made of such property by BioLine or (ii) would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change.

(o) Insurance. BioLine has in full force and effect fire and casualty insurance policies with extended coverage, which it reasonably believes to be sufficient in amount (subject to reasonable deductions) to allow it to replace any of its properties that might be damaged or destroyed.

(p) Permits. BioLine has all franchises, permits, licenses and any similar authority necessary for the conduct of its business except where the lack of such franchises, permits, licenses and any similar authority would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change. BioLine is not in default under any of such franchises, permits, licenses or other similar authority where such default would reasonably be expected to result in a Material Adverse Change.

(q) Environmental and Safety Laws. To BioLine's knowledge and except as disclosed in SEC filings, (a) it is and has been in material compliance with all applicable environmental laws; and (b) there has been no release or to BioLine's knowledge threatened release of any pollutant, contaminant or toxic or hazardous material, substance or waste or petroleum or any fraction thereof, on, upon, into or from any site currently or heretofore owned, leased or otherwise used by BioLine except for any such matter, as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

(r) Disclosure. The representations and warranties of BioLine contained in this Agreement are true and correct as of the date hereof.

2.2 **Stand-Still Agreement.** The Parties agree to be bound by the following "stand-still" provisions (the "**Stand-Still Agreement**"). During the Term, NVS agrees that it will not, and will cause each of its Affiliates or agents or other persons acting on its behalf not to:

2.2.1 without the prior written agreement of BioLine, acquire, offer to acquire or agree to acquire, alone or in concert with any other individual or entity, by purchase, tender offer, exchange offer, agreement, merger, business combination or any other manner, beneficial ownership of any securities of BioLine, if, after completion of such acquisition or proposed acquisition, the aggregate beneficial ownership of NVS and its Affiliates shall be more than [*]% of the outstanding Ordinary Shares of BioLine (calculated based on the issued and outstanding share capital of BioLine as of the completion of such acquisition); *provided, however*, that such limitation shall not apply to shares acquired directly pursuant to stock dividends or similar distributions of Ordinary Shares made on a pro rata basis to all holders of Ordinary Shares or ADSs;

2.2.2 submit any stockholder proposal or any notice of nomination of director candidates or notice of any other business for consideration, or nominate any director candidate for election to the Board or withhold authority for or oppose any director candidates nominated by the board of directors of BioLine;

2.2.3 call, seek to call, or to request the calling of, a special meeting of the stockholders of BioLine, or seek to make, or make, a stockholder proposal at any meeting of the stockholders of BioLine, alone or in concert with others, seek to control or influence the governance, affairs, business, management or policies of BioLine; or

2.2.4 enter into any agreements, arrangements, commitments, plans or understandings (whether written or oral) with, or advise, finance, assist or knowingly encourage, any other person that engages, or offers or proposes to engage, in any of the foregoing.

2.3 **Trading Restrictions**. NVS agrees that, without the prior written consent of BioLine:

2.3.1 All ADSs issued to NVS in consideration for the investment made pursuant to Section 2.1 shall be subject to a lockup restriction until the *earlier* of: (a) [*] months following such issuance and (b) the payment by NVS of an Option Fee as set out in Section 6.4 below (such date, a "**Partial Release Date**"). Following a Partial Release Date, NVS shall be entitled to sell the *greater* of: (x) [*]% of the ADSs held by NVS prior to the issuance of new ADSs as a result of payment of an Option Fee; and (y) the total number of ADSs issued to NVS in connection with the payment of the aforesaid Option Fee, in both cases subject to the restrictions set out in Sections 2.3.2 through 2.3.5. All remaining ADSs shall remain subject to the lockup for the full Term of this Agreement.

2.3.2 During the Term, NVS shall not sell more than [*]% of its holdings in BioLine during any rolling 6-month calendar period, based on the holdings existing at the beginning of such 6-month period.

2.3.3 On no single day during the Term of this Agreement will NVS sell more than [*]% of the daily share trading volume of BioLine's ADSs on Nasdaq.

2.3.4 For a period of one year following the termination of this Agreement, on no single day will NVS sell more than [*]% of the Nasdaq daily share trading volume of BioLine's ADSs; *provided, however*, that upon termination of this Agreement under Section 12.2 by NVS for breach by BioLine and/or a Change of Control of BioLine, NVS will be released from such restrictions set forth above.

2.3.5 For clarification, where ADSs are subject to a lock up restriction or a restriction on "sale" as stated in Subsections 2.3.1 through 2.3.4, then NVS shall not (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any ADSs or Ordinary Shares or any securities convertible into or exercisable or exchangeable for ADSs or Ordinary Shares, (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the ADSs or Ordinary Shares or such other securities of the Company, or (3) make any demand for or exercise any right with respect to the registration of any ADSs or Ordinary Shares or any security convertible into or exercisable or exchangeable for Ordinary Shares without the prior written consent of BioLine, in each case other than (a) transactions relating to ADSs acquired in open market transactions (not in violation of the Stand-Still Agreement) other than pursuant to this Agreement; or (b) transfers of ADSs to entities which are Affiliates of NVS.

2.4 **Information Disclosure.** BioLine will update NVS, as may be reasonable and appropriate in the circumstances in light of the Collaboration, with respect to the following material corporate developments or decisions of the Board of Directors of BioLine (aside from matters related to partnering or potential partnering with Third Parties, which BioLine will not be required to disclose to NVS): (a) ongoing financial condition of BioLine on a quarterly basis (such as general budget, cash and cash forecasts); (b) material financing activities; (c) material decisions regarding projects (such as closing projects and increasing investment significantly in projects); (d) in-licensing of projects to BioLine (other than through the Collaboration); and (e) major human resource issues. The foregoing updates will be provided to NVS on the condition that any material non-public information provided by BioLine to NVS hereunder will result in a "black-out period" (the scope of which will be defined by BioLine's General Counsel in his or her sole discretion) during which period NVS will be restricted from trading in BioLine shares.

2.5 **No Representation on Board.** For clarity, NVS will not be entitled to appoint a director on, or observer to, BioLine's board of directors.

## ARTICLE 3
## JOINT STEERING COMMITTEE

3.1 **Joint Steering Committee**.

3.1.1 **Formation and Purpose.** Within 30 days of the Effective Date, the Parties will establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**") to oversee, implement and coordinate the Collaboration established pursuant to this Agreement. The JSC shall, *inter alia*, evaluate projects presented by BioLine and decide whether to proceed with further development thereof and on what terms, and shall generally be a forum for consultation and information exchange.

3.1.2 **Members.** Each of BioLine and NVS shall appoint representatives to the JSC, each of whom will have sufficient seniority and expertise within the applicable party to make decisions arising within the scope of the JSC's responsibilities.

(a) NVS Representatives. The initial NVS representatives shall be: [*].

(b) BioLine Representatives. The initial BioLine representatives shall be:[*].

(c) Replacements. Each Party may replace its JSC representatives at any time upon written notice to the other Party.

(d) Attendance by Non-Members. Each Party may also invite non-members to participate in the discussions and meetings of the JSC on an ad hoc basis where appropriate (e.g., representatives from regulatory, IP, commercial, franchise/business units, as well as corporate executives), subject to such individuals being subject to reasonable and customary binders of confidentiality). For clarity, non-member shall have no voting authority at the JSC.

3.1.3 **Chairperson.** The JSC shall have a chairperson, who shall serve for a term of one year, and who shall be selected alternately, on an annual basis, by BioLine or NVS. The initial chairperson shall be selected by NVS. The role of the chairperson shall be to convene and preside at meetings of the JSC and to ensure the preparation of minutes, but the chairperson shall otherwise have no additional powers or rights beyond those held by the other JSC representatives.

3.1.4 **Meetings.** The JSC shall meet at least once every 2 months during the Term to evaluate and discuss new opportunities, review any Flagged Projects, and address the progress and implementation of the Collaboration, as well as various matters addressed herein as applicable. The Parties may mutually agree in writing to a different frequency for such meetings; provided that there should be a face-to-face in-person meeting at least three times per year at a location and time agreed by the Parties (the "**In-person Meeting**"). No later than 10 days prior to any scheduled meeting of the JSC, the chairperson of the JSC shall prepare and circulate an agenda for such meeting and, as soon as practicable, materials for the meeting; *provided, however,* that either Party may propose additional topics to be included on such agenda prior to such meeting. The JSC may meet in person, by video conference or by teleconference (except for the In-person Meetings which shall be in-person). Meetings of the JSC shall be effective only if at least one representative of each Party is present or participating in such meeting. The chairperson of the JSC will be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect, without limitation, material decisions made at such meetings. The JSC chairperson shall send draft meeting minutes to each member of the JSC for review within 15 days after each JSC meeting. The members of the JSC shall then have 15 days to provide comments. The JSC chairperson shall incorporate timely received comments and distribute revised minutes to all members of the JSC for their final review and approval by the later of 45 days after the relevant meeting or the next regularly scheduled meeting of the JSC.

3.1.5 **Decision-Making**. Unless otherwise set forth in this Agreement or as may be mutually agreed by the Parties, the JSC will take action by unanimous consent, with each Party's representatives' (collectively) having a single vote on the JSC, irrespective of the number of representatives actually in attendance at a meeting (i.e., a total of two votes).

3.1.6 **Joint Discussion Teams.** Once a Project is brought into the Collaboration such that the JSC decides to pursue its further development in accordance with one of the mechanisms set out in this Agreement, the JSC will establish a Joint Discussion Team ("**JDT**") with representatives from the Parties (who may, but need not, be members of the JSC) to provide ongoing practical input into and oversee the initial development of the applicable Project. There will be a JDT for each Project. The JDT will meet at least quarterly and in addition ad hoc on an "as needed" basis. The JDT will report regularly to the JSC. The JDT is intended to serve in an advisory capacity only, and will not have decision-making authority unless otherwise agreed in writing by the representatives of the Parties on the JSC.

3.1.7 **Costs.** The Parties agree that the costs incurred by each Party in connection with its travel to and participation in the JSC and the JDT shall be borne solely by such Party.

3.1.8 **Discontinuation of JSC.** The JSC shall continue to exist throughout the Term unless the Parties mutually agree to disband the JSC.

## ARTICLE 4
## SCREENING AND PROJECT SELECTION

4.1 [*]

4.2 [*]

## ARTICLE 5
## PRE-IND PROJECTS

5.1 [*]

5.2 **[*]**

5.3 [*]

## ARTICLE 6
## IND PROJECTS

6.1 [*]

6.2 [*]

6.3 **[*]**

6.4 **Payment of Option Fee.** Within 60 days following (i) the Selected Project Selection Date, and (ii) receipt by NVS of an invoice in the form attached as **Exhibit 6.4** attached hereto (subject to BioLine holding the license to the relevant project from the relevant IP owner at such time), NVS shall pay BioLine a non-refundable $5 million option fee (the "**Option Fee**"). Notwithstanding anything to the contrary herein, upon payment by NVS of the Option Fee and continuing through the end of the ROFN Period, the arrangements and restrictions set out in Section 6.8 shall apply with respect to the applicable Selected Project.

6.5 **Budget and Funding for Selected Projects**. The budget for each Selected Project would be funded as follows:

6.5.1 50% of the balance of the agreed development budget (after taking into account the Option Fee) (the "**Development Budget Balance**") will be provided by NVS in the form of an equity investment in the ADSs of BioLine. The equity investment will be made no later than 30 days following the Selected Project Selection Date at a price per ADS reflecting a 5% premium over the VWAP, as reported on the Nasdaq, for the 10-day period ending on the day prior to the Project Selection Date. The terms and provisions of Section 2.1 and 2.3 above shall apply, *mutatis mutandis*, to the aforesaid investment. Notwithstanding the foregoing, BioLine will have the option to request that such funding be made in the form of debt, including convertible debt on terms that are to be agreed at the time, or in any other form as will be agreed by the Parties.

6.5.2 BioLine will be responsible for funding the remaining 50% of the Development Budget Balance for the Selected Project.

6.5.3 The budget will include all expenses related to the continued development activities for the Selected Project, including expenses for dedicated employees and consultants, as well as IP-related expenses, but will not include specific non-project-related expenses such as overhead costs incurred by either of the Parties. The budget will also include a reserve equal to at least 25% of the total of all other items in the budget, for cost-overruns, or as otherwise mutually agreed by the Parties.

6.6 **Cost Overruns for Selected Projects.** The following arrangements shall apply to cost overruns that may arise during the course of performing the development activities for a Selected Project:

6.6.1 If the costs exceed the agreed budget by *up to* [*]%, the Parties will fund such excess on an equal basis; *provided*, *however*, that where the costs *exceed* the agreed budget by [*]% or more, the Parties will have the option to choose whether they want to continue with the agreed development plan (as included in the Core Terms) or modify it. If both Parties agree to modify the development plan and agree on the allocation of costs with respect thereto (whether on an equal basis or otherwise), then the development plan and budget will be amended accordingly and the Selected Project will continue in accordance therewith.

6.6.2 If there is no agreement on modifying the development plan and the related allocation of costs, the Parties may either negotiate a new arrangement with respect to the Selected Project, including a new development plan and related budget, or the Party supporting the increase in the budget may elect to (i) assume the additional costs in excess of what the Party not supporting the increase is willing to fund - in which event the Selected Project shall continue, or (ii) stop its investment in the project - in which event the Selected Project shall cease to be included in the Collaboration, and BioLine shall be free to proceed with the development and commercialization thereof without any further obligation to NVS (subject, however, to BioLine's obligation to pay NVS the Option Fee Repayment Amount pursuant and subject to the arrangements in Section 6.9.5 below).

6.6.3 Notwithstanding anything to the contrary herein, neither Party will be required, without its prior agreement, to accept a budget for a Selected Project which exceeds the agreed budget by more than [*]%.

6.7 **Development Activities for Selected Project.** BioLine will retain full control over the development process of Selected Projects until the execution of a Sublicense Agreement with respect thereto; *provided, however*, BioLine and NVS shall continue to consult on the progress of the implementation of the development plan for the Selected Project via the JDT.

6.8 **Right of First Negotiation.** At least six months prior to the expected availability of the draft clinical study report in respect of the Clinical Proof of Concept study defined in the Core Terms (the "**CSR**") BioLine shall notify NVS in writing as to the expected date of sending the draft CSR with respect to a Selected Project. Upon receipt of such notice, NVS shall be entitled to access all due diligence materials for the Selected Project. For each Selected Project, NVS shall have a right of first negotiation (meaning, for the purpose of clarity, that BioLine will not actively solicit research, collaboration, co-development, commercialization, licensing or other similar opportunities with Third Parties) ("**ROFN**") for a period of time commencing on the Selected Project Selection Date (in accordance with Section 6.3) and continuing until the *later* to occur of (i) the expiration of 4 months following the presentation to NVS of the draft CSR with respect to such Selected Project, and (ii) the expiration of 30 days following the presentation to NVS of the final CSR with respect to such Selected Project (the "**ROFN Period**"). NVS shall have the right, at any time during the ROFN Period, to commence a period of exclusive negotiations to obtain, to the maximum extent possible, an exclusive, sublicenseable, worldwide sublicense to develop, manufacture, exploit, sell and otherwise commercialize products based on, arising from and/or related to the particular Selected Project, by providing a good faith non-binding term sheet to BioLine, in which case the Parties will in good faith negotiate the terms of a definitive Sublicense Agreement. If no definitive Sublicense Agreement has been entered into prior to the end of the ROFN Period (or any longer period that may be agreed in writing between the Parties), then BioLine shall be entitled, without notice to NVS, to pursue Third Party Opportunities with respect to such Selected Project; [*]

6.9 [*]

## ARTICLE 7
### EXCLUSIVE ARRANGEMENTS

7.1 **Non-Circumvention.** Subject to the terms and conditions set out in this Article 7, except as otherwise set out in this Agreement, the arrangements between BioLine and NVS set out in this Agreement shall be mutually exclusive and neither Party will take any action to circumvent the other with respect to the matters set out in this Agreement. The foregoing shall apply to NVS from and after the Effective Date and shall continue for a period of six months following the end of the Term.

7.2 **BioLine Commitment.** From and after the Effective Date and continuing until the end of the Term, except as otherwise provided in the Agreement, BioLine shall not, directly or indirectly, enter into any discussions or negotiations with a Third Party with a view to out-licensing or otherwise partnering any projects, technology or intellectual property rights sourced from any Israeli sources, or consummate any such transactions in a manner that is not consistent with the terms of this Agreement.

7.3 **Exclusion of Existing Projects.** For the avoidance of doubt, the arrangements set out in this Agreement specifically do not apply to projects that have been in-licensed by BioLine as of the Effective Date, as set out in **Exhibit 7.3** attached hereto.

## ARTICLE 8
## INTELLECTUAL PROPERTY

The Parties acknowledge and agree that, on a Project-by-Project basis and prior to entering into a Sublicense Agreement with respect to a specific Project, as between BioLine and NVS, all data, results, reports, developments, inventions and know-how, and all intellectual property rights therein and thereto, generated or discovered in the course of performing research and development activities in the context of any Project, including in the course of pre-clinical and clinical studies, excluding Pre-existing NVS IP ("**Project IP**"), shall be the exclusive property of BioLine, unless otherwise agreed in the Core Terms Memorandum. Subject to the terms of this Agreement, it is further agreed that (i) BioLine may take actions to protect Project IP (including by way of filing and prosecuting patent applications) and exploit Project IP, in its sole discretion, until such time as the Parties enter into a Sublicense Agreement with respect to the Project in question (as which time such matters will be subject to the arrangements agreed in the Sublicense Agreement); and (ii) rights to the Project IP will be licensed to NVS in the context of the Sublicense Agreement, it being clarified that the scope of such rights will be subject to agreement between the Parties in the context of the negotiations for the definitive Sublicense Agreement.

## ARTICLE 9
## REPRESENTATIONS AND WARRANTIES

9.1 **Mutual Representations and Warranties**. Each Party hereby represents and warrants to the other Party that, as of the Effective Date:

9.1.1 **Corporate Existence and Power**. It is a company or corporation duly organized, validly existing, and in good standing (where such concept is recognized) under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement.

9.1.2 **Authority and Binding Agreement**. It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject to and limited by: (i) applicable bankruptcy, insolvency, reorganization, moratorium, and other laws generally applicable to creditors' rights; and (ii) judicial discretion in the availability of equitable relief.

9.1.3 **No Conflict**. The execution and delivery of this Agreement, and the performance by such Party of its obligations under this Agreement, including the grant of rights to the other Party pursuant to this Agreement, does not and will not: (i) conflict with, nor result in any violation of or default under any instrument, judgment, order, writ, decree, contract or provision to which such Party is otherwise bound; (ii) give rise to any lien, charge or encumbrance upon any assets of such Party or the suspension, revocation, impairment, forfeiture or non-renewal of any material permit, license, authorization or approval that applies to such Party, its business or operations or any of its assets or properties; or (iii) conflict with any rights granted by such Party to any Third Party or breach any obligation that such Party has to any Third Party.

9.1.4 **Required Consents.** It has obtained, or is not required to obtain, the consent, approval, order, or authorization of any Third Party, or has completed, or is not required to complete, any registration, qualification, designation, declaration or filing with, any Governmental Authority, in connection with the execution and delivery of this Agreement and the performance by such Party of its obligations under this Agreement, including any grant of rights to the other Party pursuant to this Agreement.

9.2 **Disclaimer**. NVS acknowledges and understands that (i) the projects that are or will be the subject of the Collaboration are at early-stages of development and are or may be the subject of ongoing pre-clinical or clinical research and development, and (ii) BioLine does not and cannot assure that any projects that become subject of the Collaboration, including those included in the Collaboration Quota, will result in products that will be approved by any Regulatory Authority or that will be marketable or commercially successful.

9.3 **Further Assurances and Indemnification.**

9.3.1 Each Party will cooperate and do such reasonable acts and things in good faith as may be necessary to effectuate the intents and purposes of this Agreement.

9.3.2 BioLine will indemnify and hold NVS and its Affiliates, directors and officers (each, a "NVS Party") harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any such NVS Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by BioLine in this Agreement or (b) any action instituted against the NVS Parties in any capacity, or any of them or their respective Affiliates, by any stockholder of BioLine, with respect to any of the transactions contemplated by this Agreement (unless such action is based upon a breach of NVS' representations or warranties under this Agreement or any violations by the NVS Parties of state or federal securities laws or any conduct by the NVS Parties which constitutes fraud, gross negligence, or willful misconduct).

9.3.3 NVS will indemnify and hold BioLine and its Affiliates, directors and officers (each, a "BioLine Party") harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any such BioLine Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by NVS in this Agreement or (b) any action instituted against the BioLine Parties in any capacity, or any of them or their respective Affiliates, by any stockholder of NVS, with respect to any of the transactions contemplated by this Agreement (unless such action is based upon a breach of BioLine's representations or warranties under this Agreement or any violations by the BioLine Parties of state or federal securities laws or any conduct by the BioLine Parties which constitutes fraud, gross negligence, or willful misconduct).

9.4 **No Other Representations or Warranties**. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 9, SECTION 2.1.3 AND SECTION 2.1.4, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY.

## ARTICLE 10
## LIABILITY

To the maximum extent of applicable law, and except for gross negligence, willful misconduct or fraudulent activity, neither Party shall be liable to the other Party for any special, incidental, punitive, indirect, or consequential damages or loss of profits arising from or relating to any breach of this Agreement, regardless of any notice of the possibility of such damages. Notwithstanding the foregoing, nothing in this section is intended to or shall limit or restrict damages available for a party's breach of the exclusivity arrangements in Article 7 or the confidentiality obligations in Article 11.

## ARTICLE 11
## CONFIDENTIALITY

11.1 **Confidentiality Obligations**. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for a period of seven years thereafter, it shall keep confidential and shall not disclose and shall not use for any purpose other than as expressly provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information of the other Party. To avoid doubt, the foregoing non-use restriction shall include, with respect to NVS, the use by NVS or any Affiliate of NVS of any Confidential Information provided by BioLine to contact, discuss or negotiate with any owners or licensors of information and/or intellectual property rights that are included in a Project; *provided, however*, that such limitation shall terminate upon the in-licensing by BioLine of the subject matter of the Project from the applicable owner or licensor. The foregoing confidentiality and non-use obligations shall not apply to any portion of the Confidential Information that the receiving Party can demonstrate by competent written proof: (i) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party; (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party; (iii) 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; (iv) is subsequently disclosed to the receiving Party by a Third Party who has a legal right to make such disclosure; or (v) is subsequently independently discovered or developed by the receiving Party without the aid, application, or use of the disclosing Party's Confidential Information, as evidenced by a contemporaneous writing.

11.2 **Authorized Disclosure**. Notwithstanding the obligations set forth in Section 11.1, a Party may disclose the other Party's Confidential Information, the terms of this Agreement (which terms shall be the Confidential Information of both Parties) and the existence of this Agreement to the extent:

11.2.1 such disclosure is reasonably necessary: (i) to such Party's directors, attorneys, independent accountants or financial advisors (collectively, "**Advisors**") for the sole purpose of enabling such Advisors to provide advice to the receiving Party, provided that in each such case on the condition that such Advisors are bound by confidentiality and non-use obligations consistent with those contained in this Agreement; or (ii) to actual or potential investors or acquirers solely for the purpose of evaluating an actual or potential investment or acquisition; provided that in each such case on the condition that such actual or potential investors or acquirers are bound by confidentiality and non-use obligations consistent with those contained in the Agreement;

11.2.2 such disclosure is required by securities laws or judicial or administrative process, provided that in such event such Party shall promptly inform the other Party of such required disclosure and provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Article 11, and the Party disclosing Confidential Information pursuant to law or court order shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order, to ensure the continued confidential treatment of such Confidential Information; or

11.2.3 such disclosure is reasonably necessary to its actual and potential collaborators (including CROs, CMOs, hospitals, doctors, consultants and subcontractors) for the purpose of the carrying out the Collaboration, on the condition that such entities and/or individuals are bound by confidentiality and non-use obligations consistent with those contained in the Agreement.

11.3 **Publicity; Use of Names.** Subject to the foregoing and the terms below, no disclosure of the terms of this Agreement may be made by either Party or its Affiliates, and neither Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or other public disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Law.

11.3.1 A Party may disclose this Agreement and its terms in securities filings with the SEC or other regulatory agency (or equivalent foreign agency, including the Israel Securities Authority and the Tel Aviv Stock Exchange) to the extent required by Law after complying with the procedure set forth in this Section 11.4. In such event, the Party seeking such disclosure will prepare a draft confidential treatment request and a proposed redacted version of this Agreement to request confidential treatment for this Agreement, and the other Party agrees to promptly (and in any event, no more than 7 days after receipt of such confidential treatment request and proposed redactions (or such lesser period of time as required by Law)) provide its input in a reasonable manner in order to allow the Party seeking disclosure to file its request within the time lines proscribed by applicable SEC regulations or equivalent foreign agency regulations. The Party seeking such disclosure shall exercise reasonable commercial efforts to obtain confidential treatment of the Agreement and its terms (as applicable) from the SEC or equivalent foreign agency as represented by the redacted version reviewed by the other Party.

11.3.2 Further, each Party acknowledges that the other Party may be legally required to make public disclosures (including in filings with the SEC or other agency) of the execution and delivery of this Agreement as well as certain material developments or material information generated under or pursuant to this Agreement and agrees that each Party may make such disclosures as required by Law, *provided* that the Party seeking such disclosure first provides the other Party a copy of the proposed disclosure.

11.3.3 During the Term, each Party shall have the right to issue a press release or make a public announcement concerning the material terms of this Agreement or the development of a project undertaken as part of the Collaboration. If a Party desires to issue such a press release or make such a public announcement, it shall provide the other Party with reasonable advance notice of the content thereof. The other Party shall have the right to review and comment on such proposed press release or announcement and the Party proposing such press release or public announcement shall take into consideration and incorporate when appropriate the comment from the other Party; *provided, however*, that in the event that a Party does not respond within 3 business days of the date on which the announcement was provided to such Party, the Party desiring to issue the release or make the announcement may proceed to do so.

11.3.4 The Parties agree that after a public disclosure pursuant to Sections 11.4.1, 11.4.2 or 11.4.3 has been reviewed and approved by the other Party (or be deemed to have been approved), the disclosing Party may make subsequent public disclosures or issue a press release disclosing the same content as was contained in such public disclosure without having to obtain the other Party's prior consent and approval.

11.4 **Equitable Relief.** Each Party acknowledges that a breach of this Article 11 may not reasonably or adequately be compensated in damages in an action at law and that such a breach shall cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party may be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to seek preliminary and permanent injunctive and other equitable relief from any court of competent jurisdiction to prevent or curtail any breach of the obligations relating to Confidential Information set forth herein by the other Party.

## ARTICLE 12
## TERM AND TERMINATION

12.1 **Term**. The term ("**Term**") of this Agreement shall commence on the Effective Date and, unless earlier terminated pursuant to this Article 12, will continue in effect until the first to occur of (i) payment by NVS of the Option Fee in respect of three Projects or (ii) the later of (A) three years from the Effective Date or (B) the presentation by BioLine to NVS at the Joint Steering Committee of [*]

12.2 **Termination for Breach**.

12.2.1 **Notice.** If either Party believes that the other Party is in material breach of this Agreement, then the Party holding such belief (the "**Non-Breaching Party**") may deliver written notice of such breach to the other Party (the "**Notified Party**"). The Notified Party shall have 30 days after receipt of such notice to cure such breach.

12.2.2 **Failure to Cure.** If the Notified Party fails to cure a material breach of this Agreement as provided for in Section 12.2.1, then the Non-Breaching Party may terminate this Agreement immediately upon written notice to the Notified Party.

12.2.3 **Disputes.** If a Party gives notice of termination under this Section 12.2 and the other Party disputes whether such termination is proper under this Section 12.2, then the issue of whether this Agreement may properly be terminated (i.e., whether a material breach occurred or whether a material breach was cured) shall be resolved in accordance with Article 13. If as a result of such dispute resolution process it is determined that the notice of termination was proper, then such termination shall be deemed to have been effective 30 days following the date of the notice of breach. If, as a result of such dispute resolution process, it is determined that the notice of termination was improper, then no termination shall have occurred and this Agreement shall remain in effect.

12.3 **Effect of Termination of the Agreement**. Expiration or termination of this Agreement shall not relieve the Parties of any liability which accrued hereunder prior to the effective date of such expiration or termination or to which a Party may be contractually committed as of such effective date nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any material breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation.

12.4 **Survival**. The following provisions shall survive any expiration or termination of this Agreement for the period of time specified: the provisions of Article 1, to the extent definitions are embodied in the following listed Articles and Sections of this Agreement; Articles 7, 8, 10, 11, 13 and 14; and Sections 6.9.5, and this Section 12.4, to the extent applicable. In addition, those provisions of Articles 3, 4, 5 and 6 that are applicable to the selection, decision-making, oversight, development and budgeting process regarding Projects that, as of the date of expiration or termination, remain part of the Collaboration pursuant to the arrangements set out in the Agreement, as well as Sections 2.2 (**Stand-Still Agreement**) and 2.3 (Trading Restrictions), will survive any expiration or termination of this Agreement until such time as the last of such Projects is either in-licensed by NVS pursuant to a Sublicense Agreement or until such time as the JSC decides not to proceed with the further development and funding of such Project (or fails to make a decision with respect thereto within the designated time period). Other provisions either required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement, or which by their express terms, survive such expiration or termination of this Agreement.

## ARTICLE 13
### DISPUTE RESOLUTION

13.1 **Disputes**. The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 13 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement.

13.2 **Internal Resolution.** With respect to all disputes arising between the Parties under this Agreement, including any alleged breach under this Agreement or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within 30 days after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Executives of the Parties for attempted resolution by good faith negotiations within 30 days after such notice is received.

13.3 **Binding Arbitration.** If the Executives are not able to resolve such disputed matter within 30 days and either of the Parties wishes to pursue the matter, each such dispute, controversy or claim shall be referred to and finally determined by arbitration by the International Chamber of Commerce in accordance with its arbitration rules then in effect. The place of arbitration shall be New York, New York. The language to be used in the arbitral proceedings shall be English. The dispute, controversy or claim shall be decided in accordance with the law of the State of New York, and U.S. federal law applicable therein. Judgment on the arbitration award may be entered in any court having jurisdiction thereof. The Parties agree that:

13.3.1 Either Party may apply to the arbitrator(s) for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damage. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration regardless of the outcome of such arbitration.

13.3.2 A Party shall be entitled to deduct or otherwise offset any damage finally awarded under a proceeding initiated under Section 13.3 against payments due under this Agreement, subject to any other decision of the arbitrators.

13.3.3 Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of arbitration without the prior written consent of both Parties. In no event shall arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable statute of limitations under the laws of the State of New York.

13.3.4 Notwithstanding the foregoing, neither Party shall be prevented from seeking injunctive relief from a court of competent jurisdiction including but not limited to the situation contemplated in Section 11.5 (to prevent or curtail any breach of the obligations relating to Confidential Information as set forth in Article 11).

## ARTICLE 14
## MISCELLANEOUS

14.1 **Entire Agreement; Amendment**. This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

14.2 **Payments and Taxes**. All payments made pursuant to this Agreement shall be made by wire transfer to an account designated by BioLine in writing to NVS and shall be made in Dollars. The Parties shall use all reasonable and legal efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by NVS to BioLine under this Agreement.

14.3 **Force Majeure**. Each Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the reasonable control of the nonperforming Party, including an act of God or terrorism, involuntary compliance with any regulation, law or order of any government, war, civil commotion, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than 90 days, then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

14.4 **Notices**. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this section, and shall be deemed to have been sufficiently given for all purposes when received, if in writing and personally delivered, one day following facsimile or email transmission (receipt verified) or 2 days following overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below.

| | | |
|---|---|---|
| If to BioLine | BioLineRx Ltd.<br>19 Hartum Street<br>PO Box 45158<br>Jerusalem, 91450<br>Israel | |
| | Attention:<br>With a copy to:<br>Fax: +972-2-548-9101<br>Email: | Chief Executive Officer<br>Chief Operating Officer<br><br>kinnerets@biolinerx.com<br>phils@biolinerx.com |

With copies to (which shall not constitute notice):

| | |
|---|---|
| Yigal Arnon & Co., Law Offices<br>22 Rivlin Street<br>Jerusalem, 9424018<br>Israel | |
| Attention: | Barry Levenfeld, Adv.<br>Daniel Green, Adv.<br>+972-2-623-9236<br>barry@arnon.co.il<br>danielg@arnon.co.il |

| | | |
|---|---|---|
| If to NVS: | Novartis Pharma AG<br>P.O. Box<br>CH - 4002 Basel<br>Switzerland | |
| | Attention:<br>Fax:<br>Email: | Head, Business Development and Licensing<br>+41-61-324-2511<br>Corinne.savill@novartis.com |

With copies to (which shall not constitute notice):

| | |
|---|---|
| Novartis Pharma AG<br>P.O. Box<br>CH - 4002 Basel<br>Switzerland | |
| Attention:<br>Fax:<br>Email: | Head, Legal Department<br>+41-61-324-7399<br>sean.reilly@novartis.com |

14.5 **No Strict Construction; Headings**. This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

14.6 **Assignment**. Neither party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other; *provided*, *however*, that either Party may assign or transfer this Agreement or any rights or obligations hereunder to an Affiliate of such Party and, in such event, shall provide written notice thereof to the other Party. Any permitted assignee or transferee of rights or obligations hereunder shall expressly assume in writing the performance of such rights or obligations. Any permitted assignment or transfer shall be binding on the successors of the assigning or transferring party. Any assignment or attempted assignment in violation of the terms of this section shall be void and of no legal effect.

14.7 **Performance by Affiliates**. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates, and when any such Affiliate is discharging such obligations or exercising such right, the terms and conditions of this Agreement applicable to such Party also shall be applicable to such Affiliate; *provided*, *however*, that prior to NVS engaging any of its Affiliates to so discharge NVS's obligations and/or exercise any of NVS's rights as aforesaid, NVS shall obtain BioLine's prior written consent to such engagement. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations and/or exercise of such Party's rights under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations and/or exercise of such Party's rights under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

14.8 **Further Cooperation by the Parties.** The Parties shall cooperate in good faith to effectively and efficiently implement the objectives of this Agreement.

14.9 **Severability**. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

14.10 **No Waiver**. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

14.11 **Independent Contractors**. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

14.12 **Expenses.** All fees, costs and expenses of either Party incurred in connection with this Agreement and the transactions contemplated hereby, including fees and expenses of financial advisors, financial sponsors, legal counsel and other advisors, shall be paid by the Party incurring such expenses.

14.13 **No Third Party Beneficiaries**. Except for rights and obligations specifically referred to herein that apply to Affiliates, sublicenses or licensees of the Parties, nothing in this Agreement is intended to confer on any Person other than BioLine or NVS any rights or obligations under this Agreement, and there are no intended Third Party beneficiaries to this Agreement.

14.14 **English Language**. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. To the extent this Agreement requires a Party to provide to the other Party Information, correspondence, notice or other documentation, such Party shall provide such Information, correspondence, notice or other documentation in the English language.

14.15 **Governing Law**. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of New York, and US federal law applicable therein, without giving effect to any choice of law principles that would require the application of the laws of a different state. The applicability of the United Nations Convention on Contracts for the International Sale of Goods of 1980 is hereby expressly excluded.

14.16 **Construction.** Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (a) "include," "includes" and "including" are not limiting and shall be deemed to be followed by "without limitation"; (b) definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms; (c) references to an agreement, statute or instrument mean such agreement, statute or instrument as from time to time amended, modified or supplemented; (d) references to a Person are also to its permitted successors and assigns; (e) the plain meaning of the description for a defined term, and other headings to this Agreement are for convenience only, and shall have no force or effect in construing or interpreting any of the provisions of this Agreement or any other legal effect; (f) references to "Parties", "Article", "Section", "Exhibit" or "Schedule" refer to the Parties to, an Article or Section of, or any Exhibit or Schedule to, this Agreement, unless otherwise indicated; (g) the word "will" shall be construed to have the same meaning and effect as the word "shall" and vice versa; and (h) the word "or" has, except where otherwise indicated or where the context otherwise requires, the inclusive meaning represented by the phrase "and/or".

14.17 **Counterparts**. This Agreement may be executed in one or more counterparts by original or facsimile signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**[Remainder of page left intentionally blank. Signature page follows immediately.]**

**[Signature page to Investment and Collaboration Agreement]**

**In Witness Whereof,** the Parties have executed this Investment and Collaboration Agreement in duplicate originals by their duly authorized officers as of the Execution Date.

| **Novartis Pharma AG** | | **BioLineRx, Ltd.** | |
|---|---|---|---|
| By: | /s/ Marc Ceulemans | By: | /s/ Kinneret Livnat Savitsky |
| Name: | March Ceulemans | Name: | Kinneret Livnat Savitsky |
| Title: | Head Strategic Venture Capital Fund and Pharma Equities | Title: | CEO |
| By: | /s/ Matt Owens | By: | /s/ Philip Serlin |
| Name: | Matt Owens | Name: | Philip Serlin |
| Title: | Head Legal GBS & Strategy | Title: | Chief Financial and Operating Officer |

**Exhibit 2.1**
**ADS Price Adjustment Schedule**

**BIOLINERX LTD.**
**CALCULATION OF SHARE PRICE TO NVS**
**DEC-2014**

| | | |
|---|---|---|
| Total investment amount | $ | 10,000,000 |
| Maximum premium | $ | 3,000,000 |
| Actual value of ADSs | $ | 7,000,000 |
| Number of ADSs of BioLineRx outstanding pre-transaction | | 34,115,051 |

| Closing Price per ADS | Number of ADSs to Issue to Novartis | Price per ADS to NVS | % holdings of Novartis after investment | *Test of aggregate premium* |
|---|---|---|---|---|
| $ 0.80 | 8,750,000 | $ 1.14 | 20.4% | *$ 3,000,000* |
| $ 0.81 | 8,641,975 | $ 1.16 | 20.2% | *$ 3,000,000* |
| $ 0.82 | 8,536,585 | $ 1.17 | 20.0% | *$ 3,000,000* |
| $ 0.83 | 8,433,735 | $ 1.19 | 19.8% | *$ 3,000,000* |
| $ 0.84 | 8,333,333 | $ 1.20 | 19.6% | *$ 3,000,000* |
| $ 0.85 | 8,235,294 | $ 1.21 | 19.4% | *$ 3,000,000* |
| $ 0.86 | 8,139,535 | $ 1.23 | 19.3% | *$ 3,000,000* |
| $ 0.87 | 8,045,977 | $ 1.24 | 19.1% | *$ 3,000,000* |
| $ 0.88 | 7,954,545 | $ 1.26 | 18.9% | *$ 3,000,000* |
| $ 0.89 | 7,865,169 | $ 1.27 | 18.7% | *$ 3,000,000* |
| $ 0.90 | 7,777,778 | $ 1.29 | 18.6% | *$ 3,000,000* |
| $ 0.91 | 7,692,308 | $ 1.30 | 18.4% | *$ 3,000,000* |
| $ 0.92 | 7,608,696 | $ 1.31 | 18.2% | *$ 3,000,000* |
| $ 0.93 | 7,526,882 | $ 1.33 | 18.1% | *$ 3,000,000* |
| $ 0.94 | 7,446,809 | $ 1.34 | 17.9% | *$ 3,000,000* |
| $ 0.95 | 7,368,421 | $ 1.36 | 17.8% | *$ 3,000,000* |
| $ 0.96 | 7,291,667 | $ 1.37 | 17.6% | *$ 3,000,000* |
| $ 0.97 | 7,216,495 | $ 1.39 | 17.5% | *$ 3,000,000* |
| $ 0.98 | 7,142,857 | $ 1.40 | 17.3% | *$ 3,000,000* |
| $ 0.99 | 7,070,707 | $ 1.41 | 17.2% | *$ 3,000,000* |
| $ 1.00 | 7,000,000 | $ 1.43 | 17.0% | *$ 3,000,000* |
| $ 1.01 | 6,930,693 | $ 1.44 | 16.9% | *$ 3,000,000* |
| $ 1.02 | 6,862,745 | $ 1.46 | 16.7% | *$ 3,000,000* |
| $ 1.03 | 6,796,117 | $ 1.47 | 16.6% | *$ 3,000,000* |
| $ 1.04 | 6,730,769 | $ 1.49 | 16.5% | *$ 3,000,000* |
| $ 1.05 | 6,666,667 | $ 1.50 | 16.3% | *$ 3,000,000* |
| $ 1.06 | 6,603,774 | $ 1.51 | 16.2% | *$ 3,000,000* |
| $ 1.07 | 6,542,056 | $ 1.53 | 16.1% | *$ 3,000,000* |
| $ 1.08 | 6,481,481 | $ 1.54 | 16.0% | *$ 3,000,000* |
| $ 1.09 | 6,422,018 | $ 1.56 | 15.8% | *$ 3,000,000* |
| $ 1.10 | 6,363,636 | $ 1.57 | 15.7% | *$ 3,000,000* |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| $ | 1.11 | 6,306,306 | $ | 1.59 | 15.6% | $ | *3,000,000* |
| $ | 1.12 | 6,250,000 | $ | 1.60 | 15.5% | $ | *3,000,000* |
| $ | 1.13 | 6,194,690 | $ | 1.61 | 15.4% | $ | *3,000,000* |
| $ | 1.14 | 6,140,351 | $ | 1.63 | 15.3% | $ | *3,000,000* |
| $ | 1.15 | 6,086,957 | $ | 1.64 | 15.1% | $ | *3,000,000* |
| $ | 1.16 | 6,034,483 | $ | 1.66 | 15.0% | $ | *3,000,000* |
| $ | 1.17 | 5,982,906 | $ | 1.67 | 14.9% | $ | *3,000,000* |
| $ | 1.18 | 5,932,203 | $ | 1.69 | 14.8% | $ | *3,000,000* |
| $ | 1.19 | 5,882,353 | $ | 1.70 | 14.7% | $ | *3,000,000* |
| $ | 1.20 | 5,833,333 | $ | 1.71 | 14.6% | $ | *3,000,000* |
| $ | 1.21 | 5,785,124 | $ | 1.73 | 14.5% | $ | *3,000,000* |
| $ | 1.22 | 5,737,705 | $ | 1.74 | 14.4% | $ | *3,000,000* |
| $ | 1.23 | 5,691,057 | $ | 1.76 | 14.3% | $ | *3,000,000* |
| $ | 1.24 | 5,645,161 | $ | 1.77 | 14.2% | $ | *3,000,000* |
| $ | 1.25 | 5,600,000 | $ | 1.79 | 14.1% | $ | *3,000,000* |
| $ | 1.26 | 5,555,556 | $ | 1.80 | 14.0% | $ | *3,000,000* |
| $ | 1.27 | 5,511,811 | $ | 1.81 | 13.9% | $ | *3,000,000* |
| $ | 1.28 | 5,468,750 | $ | 1.83 | 13.8% | $ | *3,000,000* |
| $ | 1.29 | 5,426,357 | $ | 1.84 | 13.7% | $ | *3,000,000* |
| $ | 1.30 | 5,384,615 | $ | 1.86 | 13.6% | $ | *3,000,000* |
| $ | 1.31 | 5,343,511 | $ | 1.87 | 13.5% | $ | *3,000,000* |
| $ | 1.32 | 5,303,030 | $ | 1.89 | 13.5% | $ | *3,000,000* |
| $ | 1.33 | 5,263,158 | $ | 1.90 | 13.4% | $ | *3,000,000* |
| $ | 1.34 | 5,223,881 | $ | 1.91 | 13.3% | $ | *3,000,000* |
| $ | 1.35 | 5,185,185 | $ | 1.93 | 13.2% | $ | *3,000,000* |
| $ | 1.36 | 5,147,059 | $ | 1.94 | 13.1% | $ | *3,000,000* |
| $ | 1.37 | 5,109,489 | $ | 1.96 | 13.0% | $ | *3,000,000* |
| $ | 1.38 | 5,072,464 | $ | 1.97 | 12.9% | $ | *3,000,000* |
| $ | 1.39 | 5,035,971 | $ | 1.99 | 12.9% | $ | *3,000,000* |
| $ | 1.40 | 5,000,000 | $ | 2.00 | 12.8% | $ | *3,000,000* |

**Exhibit 4.1**

[*]

BioLineRx - Novartis Pharma AG Collaboration Agreement

**Exhibit 6.4**
**Form of Invoice**

**Sender's Logo**

INVOICE

**INVOICE DATE:**

Street

**__ _____ 201_**

Town, Country

Phone and Fax Nr.

**INVOICE No.: XXXX**

**Bill To:**
Novartis Pharma AG
Lichtstrasse 35
CH-4056
Basel, Switzerland

**For:**
[X]

| **DESCRIPTION** *[Please specify the event for which the invoice is due]* | **AMOUNT (USD)** |
|---|---|
| | US$ 000'000.00 |
| Novartis Contract Code | |
| **Please remit by wire transfer within 60 days to:** | |
| Receiving Bank - | |
| Swift Code - | |
| ABA Number - | |
| Credit Account - | |
| Beneficiary - | |
| **TOTAL** | 000'000,00 |

If you have any questions concerning this invoice, contact
or e-mail to
VAT -Reg. No. Xxxxxxxxxx (if applicable)

**Exhibit 7.3**
**Excluded Projects**

BL-8040
BL-7010
BL-1040
BL-5010
BL-7040
BL-9010
BL-9020
BL-8020
BL-8030
BL-1110

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

# LICENSE AGREEMENT

This license agreement ("**Agreement**") is entered into as of December 22nd, 2014 ("**Effective Date**") by and between **BIOLINERX LTD.**, having its principal place of business at 19 Hartum Street, Jerusalem 9777518, Israel ("**Licensor**"), and [*], on behalf of itself and its Affiliates, having its principal place of business at [*] (all such entities to be referred to collectively as "**Licensee**"). Licensor and Licensee may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

## Recitals

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

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

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

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

## 1. Definitions

1.1 "**Affiliate**" means, with respect to a Party, any person, corporation, partnership or other entity that directly or indirectly controls, is controlled by, or is under common control with such Party. As used in this definition, the term "control" (and, with correlative meaning, the terms "controlled by" and "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity (or such lesser maximum ownership interest percentage permitted by applicable law and considered a control percentage in a particular jurisdiction), or by contract or otherwise.

1.2 "**Change of Control**" means, in respect of a Party, the consummation of a single transaction, or of a transaction that is part of a series of transactions, (a) in which a Third Party acquires, merges or consolidates with such Party, or possesses (directly or indirectly) the power to direct or cause the direction of management or policies of such Party through ownership of a majority of securities, partnership, or other ownership rights or agreements; or (b) in which such Party transfers or sells all or substantially all of its assets or business to which this Agreement relates; provided, however, that a transaction in which the stockholders of such Party immediately prior to the transaction own, directly or indirectly, fifty percent (50%) or more of the voting power of the surviving corporation following the transaction shall not be considered a Change of Control.

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

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

a. was already known to the Receiving Party, other than any portion of such information that was under an obligation of confidentiality at the time of its disclosure;

b. Became generally available to the public or otherwise becomes part of the public domain after disclosure of such information to the Receiving Party, other than by breach of this Agreement by the Receiving Party or by anyone to whom the Receiving Party disclosed such information;

c. was subsequently lawfully, and without any restriction on disclosure, disclosed to the Receiving Party by a Third Party; or

d. was independently developed or discovered by employees of the Receiving Party who had no access to the Confidential Information of the Disclosing Party and did not make use of the Confidential Information of the Disclosing Party, as demonstrated by competent, contemporaneous written records.

1.4 "**Control**" or "**Controlled by**" means, in the context of a license to or ownership of intellectual property, the ability on the part of a Party to grant access to or a license or sublicense of such intellectual property as provided for herein without violating the terms of any agreement or other arrangement between such Party and any Third Party existing at the time such Party would be required hereunder to grant such access or license or sublicense.

1.5 "**Field of Use**" means all over-the-counter ("**OTC**") therapeutic applications in any diseases in humans and animals.

1.6 "**First Sale**" means the first commercial sale of a Licensed Product unit by Licensee or one of its Sublicensees.

1.6 "**Inventions**" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by Licensee or its Sublicensees, or any of their respective personnel, in the course of use, practice and/or exploitation of the license rights granted to Licensee under this Agreement.

1.7 "**Licensed Patents**" means the issued patents ("**Issued Patents**") and pending patent applications ("**Pending Patent Applications**") in the Territory (a) Controlled by Licensor; (b) that are filed prior to the Effective Date; and (c) that are necessary or useful for Licensee's research, development, manufacturing, or commercialization activities relating to Licensed Products in the Field of Use. The Licensed Patents existing in the Territory as of the Effective Date are set forth in **Schedule A**, attached hereto and incorporated herein by reference. The term "Licensed Patents" will include any and all related domestic and foreign counterparts, divisions, continuations, continuations-in-part, reissues, reexaminations, substitutes and extensions thereof in the Territory that are Controlled by Licensor and rely on the priority date of an Issued Patent or a Pending Patent Application.

1.8 "**Licensed Product**" means a BL-5010 applicator or formulation or their combination (a) wherein the use or practice of such product would, but for the license granted herein, infringe a Valid Claim within the Licensed Patents, or (b) that uses, comprises, contains or incorporates Licensed Technology.

1.9 "**Licensed Technology**" means data, results, technology, and information of any type whatsoever, in any tangible or intangible form, that is disclosed by Licensor and is necessary or useful for research, development, regulatory or clinical activities, manufacture, commercialization or other use or exploitation of Licensed Product in the Field of Use in accordance with the terms of this Agreement, including (but not limited to) know-how, trade secrets, practices, techniques, methods, devices, instruments, designs, systems, materials, strategies and expertise, test data and other technical data. The term "Licensed Technology" expressly excludes Licensed Patents.

1.10 "**New IP**" means any and all new intellectual property rights (a) arising in the course of use, practice and/or exploitation of the license rights granted to Licensee under this Agreement (including but not limited to information, know-how, data, designs, methods, processes, techniques, materials, formulae, trade secrets, trademarks, copyrights, patents and patent applications and other proprietary information), (b) identified, developed, generated or obtained by Licensee or its Sublicensees, and (c) related to Licensed Patents, Licensed Technology or Licensed Products. For the avoidance of doubt, it is hereby clarified that "New IP" does not include Trademarks as defined in Section 1.14 and that the Trademarks and trade dress of Licensee, related copyrightable material, domain names, used on and/or in connection with any of the Licensed Products whether used on Products, packaging, labeling, advertising, sales promotion materials, or otherwise are and shall remain the ownership of Licensee.

1.11 "**Sublicense**" means any right granted, license given, or agreement entered into, by Licensee to or with any other person or entity, under or with respect to or permitting any use or exploitation of any Licensed Patent or any of the Licensed Technology (or any part thereof) or otherwise permitting the development, manufacture, marketing, distribution and/or sale of Licensed Products.

1.12 "**Sublicensee**" means a person or entity granted a Sublicense in accordance with Section 2.2. For the avoidance of doubt, an Affiliate of Licensee is not considered to be a Sublicensee.

1.13 "**Territory**" means the countries listed in **Schedule B**, attached hereto and incorporated herein by reference.

1.14 "**Trademark**" means any trademark or brand created by Licensee and used in connection with the Licensed Product.

1.15 "**Third Party**" shall mean any person or entity other than the Parties or their Affiliates.

1.16 "**Upstream License Agreement**" shall mean that certain License Agreement dated November 25, 2007 between the Upstream Licensor and BioLine, including its amendments/addendums thereto (if any), as it may be amended from time to time.

1.17 "**Upstream Licensor**" shall mean Innovative Pharmaceutical Concepts (IPC) Inc., having a place of business at Geneva Place, 2nd Floor, Waterfront Drive, PO Box 3339, Road Town, Tortola, British Virgin Islands.

1.18 "**Valid Claim**" means (a) a claim of an Issued Patent that is not expired, which has not been held unpatentable, invalid or unenforceable by a court or other government agency of competent jurisdiction and has not been disclaimed or admitted to be invalid or unenforceable through reissue, re-examination or otherwise, or (b) a claim of a Pending Patent Application that has not been abandoned, finally rejected, or expired.

**2. Grant**

2.1 During the Term, and subject to the terms of this Agreement, Licensor hereby grants to Licensee an exclusive license, with the right to Sublicense (subject to the conditions in Section 2.2), under the Licensed Patents and Licensed Technology to make, use, sell, offer to sell, import and otherwise exploit Licensed Products within the Field of Use in the Territory.

2.2 Sublicenses.

a. Subject to the terms and conditions of this Section 2.2, Licensee shall be entitled to grant Sublicenses to third parties under the license granted to Licensee pursuant to Section 2.1. All such Sublicenses shall be made for consideration and in arm's length transactions.

b. Sublicenses to Sublicensees shall only be granted pursuant to written agreements. Licensee shall provide Licensor with a copy of each Sublicense agreement within twenty (20) days of receipt of an executed agreement from the Sublicensee. Each such Sublicense agreement shall contain, *inter alia*, provisions to the following effect:

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

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

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

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

d. Any permitted Sublicense granted by Licensee (or granted by a Sublicensee in accordance with this Section 2.2) will:

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

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

(iii) contain a prohibition against Sublicensee commercializing [*] that could be competitive with Licensed Products; and

(iv) terminate on termination of this Agreement.

2.3 Notwithstanding anything to the contrary in this Agreement, if a Sublicense granted by Licensee is terminated due to termination of this Agreement and a Sublicensee of Licensee is in compliance in all material respects with the terms of its Sublicense from Licensee in effect on the date of termination of this Agreement, Licensor will negotiate in good faith a grant directly to the Sublicensee of a substantially similar Sublicense under the Licensed Patents and Licensed Technology as compared to the Sublicense agreement executed by Licensee and such Sublicensee.

2.4 Licensor reserves all rights not expressly licensed or granted to Licensee hereunder, and nothing in this Agreement entitles Licensee to use any intellectual property of Licensor other than the Licensed Patents and Licensed Technology to exploit Licensed Products (for clarity, Licensed Products include filled BL-5010 applicators; BL-5010 formulations alone (without BL-5010 applicators); and the combination of BL-5010 applicators and BL-5010 formulations, (but expressly exclude unfilled BL-5010 applicators) in the Field of Use in the Territory. Without Licensor's written approval, Licensee is not permitted to use or reference the name or trade names of Licensor in connection with Licensee's promotion, practice or use of the Licensed Products, Licensed Patents or Licensed Technology.

2.5 During the first two months following the Effective Date, Licensor shall transfer to Licensee the information comprising Licensed Technology at no charge to Licensee. Thereafter, Licensor will provide technical support to Licensee in connection with the Licensed Patents and/or Licensed Technology, including but not limited to assistance in clinical development and regulatory matters, under terms and conditions to be separately negotiated by the Parties in writing.

2.6 A copy of the Upstream License Agreement (with financial terms redacted) has been provided to Licensee prior to the Effective Date. In the event that the Upstream License Agreement is terminated, then pursuant to Section 2.2.2.2 of the Upstream License Agreement, Licensee (as a sublicensee of the Upstream Licensor) has the right to request from the Upstream Licensor a new license agreement between Licensee and the Upstream Licensor. In such case, Licensor shall, at Licensee's request, provide all reasonable assistance to Licensee in Licensee's efforts to enter into a license agreement with the Upstream Licensor on substantially the same terms as those contained in this Agreement, including through enforcement of the provisions of Section 2.2.2.2 of the Upstream License Agreement.

**2A. Joint Steering Committee**

2A.1 Within 30 days after the Effective Date, the Parties will establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**") to oversee and coordinate the Parties' activities under this Agreement with respect to development, pre-commercialization, commercialization and manufacture activities with respect to the Licensed Products in the Field of Use in the Territory. The JSC shall also be a forum for the exchange of information regarding the Parties' performance of their respective obligations under the applicable development and commercialization plans. The JSC shall facilitate, coordinate, support and oversee the Parties' cooperative efforts in order to achieve the mutually desired objective of speed, efficiency and coordination regarding the Parties' research, development, manufacturing and commercialization activities hereunder. Each Party's JSC members shall disclose to the other Party's JSC members all significant issues and decisions related to the research, development, manufacturing and commercialization of the Licensed Product in or for the Territory. To avoid doubt, the Parties acknowledge that the JSC is intended to be an advisory body only.

2A.2 Without limiting the foregoing, Licensee's JSC members shall (i) provide Licensor's JSC members with periodic reports concerning all material activities undertaken in respect of Licensee's exercise of the manufacturing rights granted to Licensee under this Agreement, (ii) at Licensor's request, from time to time, provide Licensor's JSC members with further information relating to Licensee's activities in exercise of the manufacturing rights granted to Licensee under this Agreement and (iii) provide Licensor's JSC members with periodic reports concerning all material activities undertaken in respect of Licensee's development, pre-commercialization and commercialization activities of Licensed Product. During the period between the Effective Date and the date of the First Sale, Licensee's JSC members shall provide the reports specified in (i) and (iii) above not less than once every three months; thereafter, the reports shall be provided not less than once every six months.

2A.3 Each Party shall initially appoint two representatives to the JSC, each of whom will have sufficient seniority and expertise within the applicable Party to make decisions arising with the scope of the JSC's responsibilities. The JSC may change its size from time to time by mutual consent of the Parties. Each Party may replace its JSC representatives at any time upon written notice to the other Party. The JSC may invite non-members to participate in the discussions and meetings of the JSC where appropriate (and subject to such individuals being subject to mutually acceptable binders of confidentiality), provided that such participants shall have no voting authority at the JSC. The JSC shall have a chairperson who shall be selected by Licensor. The role of the chairperson shall be to convene and preside at meetings of the JSC and to ensure the preparation of minutes, but the chairperson shall otherwise have no additional powers or rights beyond those held by the other JSC representatives.

2A.4 The JSC shall meet at least quarterly during the Term unless the Parties mutually agree in writing to a different frequency for such meetings; provided that during the period between the Effective Date and the date of the First Sale, there should be face-to-face in-person meetings at least twice per year at a location and time agreed by the Parties and thereafter, there should be such a meeting at least once per year. No later than 15 days prior to any regularly scheduled meeting of the JSC, the chairperson of the JSC shall prepare and circulate an agenda for such meeting and, as soon as practicable, materials for the meeting; provided, however, that either Party may propose additional topics to be included on such agenda prior to such meeting. The JSC may meet in person, by videoconference or by teleconference. Each Party will bear the expense of its respective JSC members' participation in JSC meetings. Meetings of the JSC shall be effective only if at least one representative of each Party is present or participating in such meeting. The chairperson of the JSC will be responsible for preparing reasonably detailed written minutes in English of all JSC meetings that reflect, without limitation, material decisions made at such meetings. The JSC chairperson shall send draft meeting minutes to each member of the JSC for review within 15 days after each JSC meeting. The members of the Committee shall have 15 days to provide comments. The JSC chairperson shall incorporate timely received comments and distribute revised minutes to all members of the JSC for their final review and approval within the later of 45 days after the relevant meeting or the next regularly scheduled meeting of the JSC.

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

3.1 a. With respect to the Licensed Products referred to in Section 7.2, in consideration for the exclusive license granted to Licensee under Section 2.1, for each Licensed Product unit sold by Licensee and its Sublicensees in a given calendar quarter, Licensee will pay Licensor an amount equal to [*]

b. With respect to the Licensed Products referred to in Section 7.2, in consideration for the exclusive license granted to Licensee under Section 2.1, for each Licensed Product unit sold by Licensee and its Sublicensees in a given calendar quarter, Licensee will pay Licensor an amount equal to [*].

c. For the purpose of this Agreement:

(i) "Licensed Product unit sold" means each Licensed Product that is invoiced by Licensee and its Sublicensees for a value higher than zero and that has not been returned to and credited by Licensee and/or its Sublicensees.

(ii) [*]

(iii) [*]

3.2 [*]

3.3 [*]

3.4 Within twenty-five (25) days of the end of each calendar quarter, Licensee shall deliver to Licensor a report summarizing the previous calendar quarter's Licensed Product units sold together with a calculation of the payments due pursuant to Section 3.1 (the "**Report**"). Upon the basis of the Report, Licensor shall issue an invoice to Licensee for the payments due for the previous calendar quarter. Such invoice will be in EUR and will be paid by Licensee no later than the end of the calendar month following the month in which such invoice is issued. [*] Licensor reserves the right to inspect Licensee's written records supporting such Reports or payments delivered as part of an examination performed in accordance with Section 4.1 below.

3.5 [*]

3.6 Licensee will pay to Licensor interest on late payments computed at the rate of one percent (1%) per month, or the maximum interest rate permitted by applicable law, whichever is less, on each overdue, unpaid amount, in each calendar month that such payment is overdue.

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

The Parties shall use all reasonable and legal efforts to reduce or eliminate Tax withholding or similar obligations in respect of all payments made by Licensee to Licensor under this Agreement. To the extent Licensee is required to deduct and withhold taxes on any payment to Licensor, Licensee shall pay the amounts of such Taxes to the proper Governmental Authority in a timely manner and promptly transmit to Licensor an official Tax certificate or other documentation of the payment of any such withholding Taxes, including copies of receipts or other evidence reasonably required and sufficient to enable Licensor to document such tax withholdings adequately for purposes of claiming foreign tax credits and similar benefits. Licensor shall provide Licensee any Tax forms that may be reasonably necessary in order for Licensee to not withhold tax or to withhold Tax at a reduced rate under an applicable bilateral income Tax treaty. Licensor shall use reasonable efforts to provide any such tax forms to Licensee at least thirty (30) days prior to the due date for any payment for which Licensor desires that Licensee apply a reduced withholding rate. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable law, of withholding Taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding Tax or value added Tax. Licensee shall require its Sublicensees to cooperate with Licensee in a manner consistent with this Section 3.7.

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

**4. Records**

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

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

**5. Patents and Trademarks.**

5.1 Prosecution and Enforcement of Licensed Patents; Inventions and New IP.

a. As between the Parties, Licensor will have the sole right, at its sole expense, to prepare, file, prosecute and maintain all Pending Patent Applications and Issued Patents within the Licensed Patents. For preparation, filing, prosecution and maintenance costs incurred for Pending Patent Applications and Issued Patents in the countries of the Territory listed in Schedule D from and after the Effective Date ("**Territory Patent Costs**"), Licensee will reimburse such Territory Patent Costs within forty-five (45) days after receipt of invoice from Licensor, it being understood that the total Territory Patent Costs (not including the renewal fees) to be reimbursed by the Licensee during the Term shall be limited to a maximum of EUR [*] and any Territory Patent Costs (other than renewal fees) exceeding the EUR [*] shall be for the account of Licensor. For the avoidance of doubt, the maximum payment set forth above does not apply to renewal fees, if any, and the responsibility of Licensee for renewal fees shall continue until earlier of the expiration of the patent or the termination or expiration of this Agreement. [*]

b. During the Term, Licensor will have the sole right, at its sole expense, to determine the appropriate course of action against any third parties infringing any Licensed Patents in the Field of Use in the Territory. All of the proceeds of any such enforcement action will be retained by Licensor. At Licensor's request and expense, Licensee shall reasonably cooperate with Licensor during the Term in connection with any enforcement action brought under this Section 5.1(b), and in particular, agrees to be joined as a party plaintiff, at Licensor's expense, if any such joinder is needed for Licensor to bring or continue an infringement action hereunder.

c. Licensor shall own all Inventions, and Licensee will cooperate, and cause its Sublicensees to cooperate, to ensure that all Inventions are assigned to Licensor. Any and all other new intellectual property rights (a) arising in the course of use, practice and/or exploitation of the license rights granted to Licensee under this Agreement (including but not limited to information, know-how, data, designs, methods, processes, techniques, materials, formulae, trade secrets, patents and patent applications and other proprietary information), (b) identified, developed, generated or obtained by Licensee or its Sublicensees, and (c) related to Licensed Patents, Licensed Technology or Licensed Products (collectively, (a-c) are referred to as "**New IP**") shall be owned by and assigned to Licensor. All Inventions and all New IP will be included automatically within Licensed Patents or Licensed Technology (as applicable) and included in the license granted to Licensee under Section 2.1.

5.2 Upon execution of this Agreement, Licensee will reimburse Licensor for past intellectual property costs associated with the Licensed Product incurred to date in the amount of [*].

5.3 a. All Trademarks will be owned and maintained by Licensee, at its own expense. Licensee has the right to decide which Trademarks and artwork will be used for the Licensed Products.

b. Licensor acknowledges Licensee's rights to the artworks of the Licensed Products and the Trademarks affixed to the Licensed Products and all (other) intellectual property rights (including but not limited to copyrights and design rights) regarding the sale, marketing and distribution of the Licensed Products in the Territory. Licensor acknowledges that none of Licensee's rights in the artworks of the Licensed Products and the Trademarks affixed to the Licensed Products belong to Licensor. Licensee retains the right to use the Trademarks and the artwork during the term of this Agreement and after termination of this Agreement for whatever product it chooses, it being understood that Licensee's right to use the Trademarks and the artwork in connection with Licensor's applicator shall end upon the exhaustion of the remaining inventory as provided in Section 13.1.

c. During and after termination of the Agreement, Licensor shall not use any trademark, trade name and/or artworks similar to the Licensee's artworks of the Licensed Products and the Trademarks affixed to the Licensed Products in respect of any product and shall not register or procure the registration of any trademark similar to the Trademarks for any class of goods in any country of the world.

d. Licensee shall be entitled to conduct all proceedings relating to its intellectual property and shall at its sole discretion decide what action, if any, to take in respect of any infringement, enforcement or alleged infringement of such intellectual property or any other claim or counter-claim brought or threatened in respect of the use, prosecution or registration of the Licensee's intellectual property. Any such proceedings shall be conducted at Licensee's expense and for its own benefit.

e. Licensee is entitled to use its own name, the logo as described in Schedule E (the "**Omega Pharma Logo**"), variants of the Omega Pharma Logo or any other logo with a reasonable size on the Products. All such logos shall at all times remain the sole property of Omega Pharma NV, during and after expiry of this Agreement. Licensee shall be entitled to conduct all proceedings relating to the abovementioned logos and shall at its sole discretion decide what action, if any, to take in respect of any infringement, enforcement or alleged infringement of the abovementioned logos or any other claim or counter-claim brought or threatened in respect of the use, prosecution or registration of the abovementioned logos. Any such proceedings shall be conducted at Licensee's expense and for its own benefit.

f. On the termination of this Agreement for any reason, Licensor shall, to the extent applicable, immediately cease to use in any way any logo of Licensee.

**6. Manufacturing**

6.1 a. Licensee will make all necessary efforts to launch a Licensed Product commercially in the Territory in 2016, including an obligation of Licensee to have secured sufficient Licensed Product supply to support such commercial launch. [*]

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

c. [*]

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

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

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

7.2 a. During the Term, Licensee will use its diligent and commercially reasonable best efforts to develop and obtain regulatory approval for at least one Licensed Product, for at least two OTC indications [*], in the Field of Use in the Territory. If Licensee wishes to change either of such indications, it must obtain Licensor's prior written approval to do so. [*]

b. In the event that any delays, which are not attributable to Licensee, prohibit Licensee to obtain the regulatory approval within the timing specified above, the Parties agree to negotiate an extension of the timing in good faith, provided that there may be only one such extension of not more than two calendar quarters.

c. If Licensee fails to obtain any of the regulatory approvals within the timing specified above and such failure is attributable to Licensee, Licensor shall have the right to terminate this Agreement. Licensee shall cause its agreement with any Third Party for the manufacture of Licensed Product to provide that in such event, Licensor will have the right to request from such Third Party a new agreement for manufacturing services on terms at least as favorable as those set forth in Licensee's agreement for comparable volumes. The Parties agree that the remedies provided for in this Section shall be the only remedies for failure to obtain any of the regulatory approvals within the timing specified above. Licensor agrees that it cannot and shall not claim compensation of whatever kind if Licensee has not obtained any of the regulatory approvals during the timing specified above.

7.3 During the Term, Licensee will use its diligent and commercially reasonable best efforts to commercialize at least one Licensed Product, for the same two OTC indications described in Section 7.2, in the Field of Use in the Territory. [*] Upon regulatory approval for each Licensed Product, Licensee will use its diligent and commercially reasonable best efforts, and will cause its Sublicensees to use their diligent and commercially reasonable best efforts, to promote, market and sell such Licensed Product throughout the Territory. [*]

7.4 Licensee shall prepare marketing plans for the Territory (the "**Licensee Marketing Plans**"), which shall include plans related to the pre-launch, launch, promotion and commercialization activities pertaining to each Licensed Product in the Territory. Licensee shall share with Licensor the Licensee pre-marketing and Marketing Plans on a regular basis. During the period between the Effective Date and the date of the First Sale, Licensee shall provide such Plans not less than once every six months; thereafter, the reports shall be provided not less than once per year. In addition, Licensee shall keep Licensor informed, upon reasonable request by Licensor, with respect to commercialization of the Licensed Products in the Territory. Licensee shall have full control and authority over of the day-to-day commercialization of the Licensed Products in the Territory and implementation of the corresponding Marketing Plans, at Licensee's sole expense.

7.5 For purposes of harmonization and coordination of global commercialization of the Licensed Products, each Party shall keep the other Party informed regarding the preparation of promotional materials, samples, advertising and materials for training sales representatives with respect to commercialization of the Licensed Products. Upon reasonable request of a Party, the other Party shall provide copies of such Product-related written materials. Licensee shall have sole responsibility for the Licensed Product marketing materials used in the Territory. Each Party shall preserve the confidentiality of information and materials exchanged.

7.5 The copyright in any advertising material (including commercials) and literature acquired or designed by or coming into the possession of Licensee and designed, written or produced specifically for the purpose of the promotion of sales of the Licensed Products shall be the sole and exclusive property of Licensee, unless specifically paid for by Licensor and agreed between the Parties that the material is the property of Licensor.

**8. Data Access and Sharing**

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

8.2 During the Term, Licensee will have access to any additional clinical and research and development data generated by Licensor following the Effective Date and pertinent to development and/or commercialization of Licensed Products.

**9. Confidential Information**

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

9.2 Notwithstanding the foregoing Section 9.1, a Receiving Party may disclose Confidential Information of the Disclosing Party:

a. to the extent and to the persons and entities as required by an applicable law, rule, regulation, legal process, court order or the rules (i) of the any securities exchange on which any security issued by either Party is traded or (ii) of a regulatory authority; or

b. in the case of Licensor, as necessary to file, prosecute or defend Licensed Patents; or

c. to prosecute or defend litigation or otherwise establish rights or enforce obligations under this Agreement, but only to the extent that any disclosure is necessary.

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

9.3 A Receiving Party may disclose Confidential Information received under this Agreement to existing or potential investors, acquirers, merger partners, collaborators, consultants, contractors, distributors or licensees, or to professional advisors (e.g., attorneys, accountants and investment bankers) involved in such activities, for the limited purpose of evaluating such investment, transaction, or license and under appropriate conditions of confidentiality, only to the extent necessary and with the agreement by these permitted individuals to maintain such Confidential Information in strict confidence.

9.4 The Parties have mutually agreed upon the text of a press release announcing the execution of this Agreement. Such press release is attached to this Agreement as Schedule F. Except for such mutually agreed initial press release, neither Party shall (a) originate any publicity, news release or other public announcement, written or oral, whether to the public press, stockholders or otherwise, relating to this Agreement, any amendment hereto or performance hereunder, or (b) use the name of the other Party in any publicity, news release or other public announcement, except (i) with the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed, or (ii) as required by applicable law (including securities laws and regulations), in which case the Party wishing to issue the public disclosure (the "**Initiating Party**") shall submit to the other Party (for review and any proposed modifications, as well as the Parties' coordination, prior to such disclosure or use) each such required disclosure, and shall comply with the terms of this Article 9. In this respect, the other Party will use its good faith and Commercially Reasonable Efforts to provide to the Initiating Party its comments on the proposed public disclosure within forty-eight (48) hours of receipt, and the Initiating Party will reasonably consider the other Party's comments thereon if such comments are received within such forty-eight (48) hour period. Either Party may disclose the existence of this Agreement; however, the terms and conditions of this Agreement shall be deemed to be the Confidential Information of each Party.

**10. Representations and Warranties; Indemnification**

10.1 Each Party hereby represents and warrants to the other Party that, as of the Effective Date:

a. it is duly organized and validly existing under the laws of its state of incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

b. it is has taken all corporate action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;

c. this Agreement is legally binding upon it and enforceable in accordance with its terms; and

d. its execution, delivery and performance of this Agreement does not conflict with, constitute a breach of, or in any material way violate any arrangement, understanding or agreement to which it is a party or by which it is bound.

10.2 Licensor hereby represents and warrants that: (a) as of the Effective Date, (i) the Upstream License Agreement is in full force and effect; (ii) Licensor has been granted all the licenses and rights under the Upstream License Agreement which are necessary for granting the licenses and right to Licensee hereunder; (iii) Licensor is not in breach with respect to material obligations under the Upstream License Agreement; and (iv) execution and performance of this Agreement shall not constitute breach of any provisions of the Upstream License Agreement; and (b) during the Term, (i) Licensor shall fulfill its obligations under the Upstream License Agreement; (ii) if Licensor seeks any modification, amendment or revision to the Upstream License Agreement, Licensor shall obtain prior written consent of Licensee to the extent such modification, amendment or revision will affect Licensee's license and rights hereunder; and (iii) Licensor shall not terminate the Upstream License Agreement in whole or with respect to the Territory, without prior written consent of Licensee.

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

10.3 a. Licensee will indemnify, hold harmless, and defend Licensor and its directors, officers, employees, agents, and independent contractors (collectively, the **"Licensor Indemnitees"**) from any and all liability, loss, damage, cost, and expense, including reasonable attorneys' fees and costs (collectively, **"Losses"**) that a Licensor Indemnitee becomes legally obligated to pay because of any Third Party claim or suit to the extent that such claim or suit arises from (a) the use, practice and/or exploitation of the Patents, Licensed Technology or Trademarks by Licensee or its Sublicensees, or by their respective directors, officers, employees, agents, independent contractors, or Sublicensees, (b) the manufacture, use, offer for sale, sale or importation of Licensed Products by or on behalf of Licensee or its Sublicensees, or otherwise in the conduct of Licensee's business, (c) Licensee's breach of its obligations or its representations and warranties under this Agreement, or (d) the negligence, recklessness, or willful misconduct of Licensee or any of its directors, officers, employees, agents, independent contractors and Sublicensees; except in each case to the extent that such Third Party claim or suit results from the negligence, recklessness, or willful misconduct of Licensor or any of its directors, officers, employees, agents or Licensor's breach of its obligations or its representations and warranties under this Agreement.

b. Licensor will indemnify, hold harmless, and defend Licensee and its Sublicensees and their directors, officers, employees, agents, and independent contractors (collectively, the **"Licensee Indemnitees"**) from any and all liability, loss, damage, cost, and expense, including reasonable attorneys' fees and costs (collectively, **"Losses"**) that a Licensee Indemnitee becomes legally obligated to pay because of any Third Party claim or suit to the extent that such claim or suit arises from (a) Licensor's breach of its obligations or its representations and warranties under this Agreement or (b) the negligence, recklessness, or willful misconduct of Licensor or any of its directors, officers, employees, agents and independent contractors; except in each case to the extent that such Third Party claim or suit results from the negligence, recklessness, or willful misconduct of a Licensee Indemnitee or Licensee's breach of its obligations or its representations and warranties under this Agreement.

10.4 a. Licensee's agreement to indemnify, hold harmless and defend the Licensor Indemnitees is conditioned upon Licensor: (a) providing written notice to Licensee of any claim, demand, or action arising out of the indemnified activities within thirty (30) days after Licensor has knowledge of such claim, demand, or action; (b) permitting Licensee to assume full responsibility and authority to investigate, prepare for, and defend against any such claim or demand; and (c) assisting Licensee, at Licensee's reasonable expense, in the investigation of, preparation for, and defense of any such claim or demand.

b. Licensor's agreement to indemnify, hold harmless and defend the Licensee Indemnitees is conditioned upon Licensee: (a) providing written notice to Licensor of any claim, demand, or action arising out of the indemnified activities within thirty (30) days after Licensee has knowledge of such claim, demand, or action; (b) permitting Licensor to assume full responsibility and authority to investigate, prepare for, and defend against any such claim or demand; and (c) assisting Licensor, at Licensor's reasonable expense, in the investigation of, preparation for, and defense of any such claim or demand.

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

**11. Term**

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

**12. Termination**

12.1 Following the fifth anniversary of the First Sale, either party shall be entitled to terminate this Agreement by written notice at least eighteen (18) months prior to the proposed date of termination.

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

12.3 If Licensee files a petition in bankruptcy or is adjudicated as bankrupt or if a petition in bankruptcy is filed against Licensee or if it becomes insolvent, or makes an assignment for the benefit of its creditors or an arrangement pursuant to any bankruptcy law, and such proceeding is not dismissed within 60 days, or if Licensee discontinues all of its business or if a receiver is appointed for it or its business, this Agreement will terminate immediately upon written notice by Licensor.

12.4 This Agreement may be terminated with immediate effect by either Party upon written notice to the other Party if there is a Change of Control of the other Party. If a Change of Control occurs on a Party, such Party shall provide written notice to the other Party of the Change of Control event no later than three (3) business days after the occurrence of such Change of Control event.

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

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

**13. Effect of Termination or Expiration**

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

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

**14. Notices**

14.1 All notices, requests, consents and other communications given or made by a Party under this Agreement shall be in writing and shall be deemed given (a) five (5) days after mailing when mailed (by registered or certified mail, postage paid, only), (b) on the date sent when made by facsimile transmission with confirmation of receipt (with hard copy to follow by registered or certified mail, postage paid, only), or (c) on the date received when delivered in person or by reputable overnight courier; provided that notices and communications with respect to administrative matters under this Agreement (but not legal matters or matters pertaining to rights or obligations under this Agreement), may be provided by e-mail and will be deemed given when sent. All notices shall be provided to the address set forth below or such other place as such Party may from time to time designate in writing:

If to Licensor: BioLineRx, Ltd.

19 Hartum Street
Jerusalem 9777518, Israel
Attention: Chief Financial and Operating Officer
Facsimile: +972-2-548-9101
E-Mail: phils@biolinerx.com

If to Licensor: [*]

Attention:
Facsimile:
E-Mail:

With a copy to:
Omega Pharma NV
Venecoweg 26
9810 Nazareth
Belgium
Attention: Legal Department
Facsimile: +32 9 381 02 68
E-Mail: anja.vanwinsberghe@omega-pharma.com

a. All such notices, requests, and other communications are deemed received on the date of receipt by the recipient thereof if received prior to 5:00 p.m. in the place of receipt and such day is a business day in the place of receipt. Otherwise, any such notice, request, or communication is deemed not to have been received until the next succeeding business day in the place of receipt.

b. The provisions above governing the date on which a notice is deemed to have been received by a recipient Party means and refers to the date on which a recipient Party, and not its counsel or other recipient to which a copy of the notice may be sent, is deemed to have received the notice.

c. If a notice is tendered pursuant to the provisions of this Agreement and is refused by the intended recipient, the notice will nonetheless be deemed to have been given and is effective as of the date provided in this Agreement.

**15. Assignment**

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

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

**16. Dispute Resolution**

16.1 The Parties shall attempt in good faith to resolve any and all disputes that arise between them promptly, voluntarily and amicably. Any dispute arising between the Parties relating to, arising out of, or in any way connected with this Agreement, or any term or condition hereof, or the performance by either Party of its obligations hereunder (a "**Dispute**"), whether before or after expiration or termination of this Agreement, which is not settled by the Parties within thirty (30) days after written notice of such Dispute is first given by one Party to the other Party in writing, will be referred to a senior executive designated by Licensor and a senior executive designated by Licensee who are authorized to settle such Dispute on behalf of their respective companies ("**Senior Executives**"). The Senior Executives will meet (or confer by telephone or video conference) within thirty (30) days after the end of the initial 30-day period referred to above, at a time and place mutually acceptable to both Senior Executives. If the Dispute has not been resolved by the Senior Executives within thirty (30) days after the end of the initial 30-day period referred to above (or such longer time period as may be mutually agreed upon by the Senior Executives), the Dispute will be resolved in accordance with the remainder of this Article 16.

16.2 If a Dispute is not resolved in accordance with Section 16.1, the Parties hereby agree to resolve such Dispute by final and binding arbitration administered under the then-current Rules of Arbitration of the International Chamber of Commerce ("**ICC**").

a. Commencement of Arbitration Proceeding; Arbitrator. Following failure of the Senior Executives to resolve a Dispute under Section 16.1, either Party may commence such arbitration proceeding in accordance with this Section 16.2 and the ICC rules, and shall simultaneously notify the other Party in writing of such commencement. The arbitration shall be conducted by one (1) neutral arbitrator, to be mutually selected by the Parties within thirty (30) days of the commencement of the proceeding; provided that if the Parties are unable to mutually select such arbitrator within such 30-day period, then the Parties shall either mutually agree to extend such period or one neutral arbitrator will be selected by Licensor within such thirty (30) day period, one neutral arbitrator will be selected by Licensee within such thirty (30) day period, and such two selected arbitrators shall, within thirty (30) days after the first two arbitrators have been selected, appoint the single neutral arbitrator who shall preside over the arbitration proceeding.

b. Arbitration Proceeding and Venue. The arbitration and all related hearings, proceedings and written submissions will be in the English language. The arbitration proceeding shall be held in London, England (unless the Parties mutually agree in writing on a different venue). Each Party shall bear its own expenses (including the fees and expenses of its attorneys, consultants and witnesses) in connection with the arbitration proceeding, and each Party shall, on an ongoing basis, pay one-half (½) the fees and expenses of the ICC and the arbitrator(s).

c. Decision; Enforcement. The decision of the arbitrator shall be the sole and exclusive remedy of the Parties, shall be final and shall be fully and irrevocably accepted by the Parties. The arbitrator shall announce his/her decision and award, and the reasons therefor, in writing. The prevailing Party may enforce such decision against the other Party in any court having jurisdiction. In any arbitration proceeding hereunder, the arbitrator will not have the right to modify the terms and conditions of this Agreement. The Parties will exert reasonable efforts to have the decision and award rendered within six (6) months after a Party commences the arbitration proceeding.

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

**17. Miscellaneous**

17.1 Entire Agreement. This Agreement, including the attached schedules, constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all previous oral and written agreements, proposals, negotiations, representations, commitments and other communications between the Parties with respect to its subject matter, except the Confidentiality Agreement between the Parties, dated January 14, 2014, which shall continue in full force and effect with respect to disclosures of Confidential Information made prior to the Effective Date of this Agreement. In the event of any conflict or inconsistency between any provision of any schedule hereto and any provision of this Agreement, the provisions of this Agreement shall prevail.

17.2 Force Majeure. Neither Party shall be held liable or responsible to the other Party, nor be deemed to have defaulted under or breached this Agreement, for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including but not limited to fire, floods, earthquake, embargoes, war, acts of war (whether war is declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party; provided, however, that the Party so affected shall use commercially reasonable efforts to avoid or remove such causes of nonperformance, and shall continue to perform hereunder with reasonable dispatch whenever such causes are removed. Either Party shall provide the other Party with prompt written notice of any delay or failure to perform that occurs by reason of force majeure. The Parties shall mutually seek a resolution of the delay or the failure to perform as noted above.

17.3 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 laws of England and Wales, without reference to conflicts of laws principles.

17.4 Waiver. The waiver by either Party hereto of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

17.5 Severability. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of this Agreement in any other jurisdiction.

17.6 Amendment. This Agreement may be amended, or any term hereof may be modified, only by a written instrument duly executed by an authorized representative of each of the Parties.

17.7 Official Language. The language of this Agreement and of any documents, papers or proceedings required by or under this Agreement, including any such documents, papers or proceedings that arise under Article 16, shall be English. Any Party requesting or requiring translations of such documents, papers or proceedings shall bear all costs and expenses of such translations.

17.8 Independent Contractors. It is expressly agreed that Licensor and Licensee shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Licensor nor Licensee shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so.

17.9 Fees and Expenses. Each Party will pay its respective transaction expenses incident to the execution of this Agreement.

17.10 Headings. Headings used in this Agreement are for reference purposes only and will not be deemed a part of this Agreement or used in the interpretations of the substantive provisions of it.

17.11 Counterparts. This Agreement may be executed in one or more counterparts by original, facsimile or electronic (for example, PDF) signature, each of which is deemed an original and all of which together constitute one and the same instrument.

17.12 Surviving Provisions. All provisions of this Agreement which by their nature survive the expiration or termination of this Agreement will survive expiration or termination including, but not limited to, Articles 1, 4, 5, 9, 10, 13, 16 and 17; and Sections 2.3, 2.4, 6.2, and 8.1.

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

| **BioLineRx Ltd.** | **[*]** |
|---|---|
| /s/ Kinneret Savitsky /s/ Philip Serlin<br>Signature | /s/ Freya Loncin<br>Signature |
| Kinneret Savitsky, Ph.D.<br>CEO<br>Philip Serlin<br>Chief Financial and Operating Officer | Aubisque BVBA (represented by Freya Loncin, permanent representative)<br><br>Director |
| 22 December 2014<br>Date | 22 December 2014<br>Date |

**Schedule A**
**Licensed Patents**

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

**Schedule B**
**Territory**

[*]

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

[*]

**Schedule D**
**List of countries where patents will be registered and verified (Section 5.1.a)**

[*]

**Schedule E**
**OMEGA PHARMA LOGO**

**For Immediate Release**

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

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

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

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

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

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

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

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

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

**About BL-5010**
BL-5010 is a novel product for the non-surgical removal of benign skin lesions. It offers an alternative to painful, invasive and expensive removal treatments including cryotherapy, laser treatment and surgery. Because the treatment is non-invasive, it poses minimal infection risk and eliminates the need for anesthesia or bandaging. The product has completed a phase 1/2 pilot clinical study for the removal of seborrheic keratosis, which showed excellent efficacy and cosmetic results, and has received confirmation in Europe for the regulatory pathway classification as a medical device Class 2a.

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

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

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

For more information on BioLineRx, please visit 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.

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

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**Schedule G**
**SPECIFICATIONS AND CHARACTERISTICS**

[*]

**Exhibit 12.1**

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 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: March 23, 2015

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

**Exhibit 12.2**

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 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: March 23, 2015

/s/ Philip Serlin
Philip Serlin
Chief Financial and Operating Officer

**Exhibit 13.1**

CERTIFICATION OF CHIEF EXECUTIVE OFFICER UNDER SECTION 906 OF THE SARBANES-OXLEY ACT

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of BioLineRx Ltd. (the "Company") hereby certifies to such officer's knowledge that:

(i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2014 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 23, 2015

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

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Exhibit 13.2**

CERTIFICATION OF CHIEF FINANCIAL OFFICER UNDER SECTION 906 OF THE SARBANES-OXLEY ACT

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of BioLineRx Ltd. (the "Company") hereby certifies to such officer's knowledge that:

(i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2014 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 23, 2015

/s/ Philip Serlin
Philip Serlin
Chief Financial and Operating Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Exhibit 15.5**

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-176419, 333-183976 and 333-201326) and on Form F-3 (Nos. 333-179792 and 333-182997) of BIOLINERX LTD. (the "Company"), of our report dated March 23, 2015, relating to the financial statements of the Company, which appears in this Form 20-F.

Tel-Aviv, Israel
March 23, 2015

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited