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

FORM 20-F

(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, 2015**

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 _____

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

Israel
(Jurisdiction of incorporation or organization)

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

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2 HaMa'ayan Street
Modi'in 7177871, Israel
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

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

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

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

None
(Title of Class)

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

None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report. 54,818,057

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 x Non-accelerated filer o

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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INTRODUCTION

Certain Definitions

In this annual report, unless the context otherwise requires:

- references to "BioLineRx," the "Company," "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 0.10 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.

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

The selected consolidated statements of operations data for the years ended December 31, 2015, 2014, and 2013, and the selected consolidated balance sheet data as of December 31, 2015 and 2014, 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, 2012 and 2011, and the selected consolidated balance sheet data as of December 31, 2013, 2012 and 2011, 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 dollars. The amounts in the tables below for the years 2011 through 2014 were previously reported in NIS. Due to the change in our functional and reporting currency from the NIS to the dollar, effective January 1, 2015, the amounts for 2011 through 2014 have been restated in dollars using the methodology set forth in Note 2c to our consolidated financial statements for the year ended December 31, 2015.

	Year Ended December 31,				
Consolidated Statements of Operations Data:[1] [2]	**2011**	**2012**	**2013**	**2014**	**2015**
	(in thousands of U.S. dollars, except share and per share data)				
Research and development expenses, net	(11,912)	(16,677)	(12,208)	(11,866)	(11,489)
Sales and marketing expenses	(925)	(837)	(1,136)	(1,589)	(1,003)
General and administrative expenses	(3,556)	(3,638)	(3,664)	(3,800)	(3,704)
Operating loss	(16,393)	(21,152)	(17,008)	(17,255)	(16,196)
Non-operating income, net	–	1,026	1,161	3,061	1,445
Financial income	3,558	2,287	720	3,566	457
Financial expenses	(1,191)	(1,942)	(1,897)	(448)	(106)
Net loss	(14,026)	(19,781)	(17,024)	(11,076)	(14,400)
Other comprehensive income (loss):					
Currency translation differences	(1,830)	(7)	1,097	(2,834)	–
Comprehensive loss	(15,856)	(19,788)	(15,927)	(13,910)	(14,400)
Net loss per ordinary share	(1.13)	(1.17)	(0.76)	(0.34)	(0.28)
Number of ordinary shares used in computing loss per ordinary share	12,358,703	16,940,473	22,488,516	32,433,883	51,406,434

	As of December 31,				
Consolidated Balance Sheet Data:	**2011**	**2012**	**2013**	**2014**	**2015**
	(in thousands of U.S. dollars)				
Cash and cash equivalents	8,652	18,307	8,899	5,790	5, 544
Short-term bank deposits	17,216	3,070	9,319	28,890	42,119
Property, plant and equipment, net	1,102	850	712	721	2,909
Total assets	29,223	24,325	20,014	36,211	51,302
Total liabilities	6,779	9,343	8,292	4,406	3,692
Total shareholders' equity	22,444	14,982	11,722	31,805	47,610

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

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

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

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

Risks Related to Our Financial Condition and Capital Requirements

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

We are a clinical stage biopharmaceutical development company that was incorporated in 2003. Since our incorporation, we have been focused on research and development. 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 $14.4 million in 2015, $11.1 million in 2014 and $17.0 million in 2013. As of December 31, 2015, we had an accumulated deficit of approximately $159.4 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, 2015, we held cash and short-term investments of approximately $47.7 million. We believe that our existing cash and investment balances and other sources of liquidity, not including potential milestone and royalty payments under our existing and future out-licensing and other collaboration agreements, 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 Economy and Industry, 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, as well as grants from government agencies and foundations. If we are unable to obtain future financing through the methods we describe above or through other means, we may be unable to complete our business objectives and may be unable to continue operations, which would have a material adverse effect on our business and financial condition.

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 three main clinical-stage therapeutic candidates in development: BL-8040 for the treatment of multiple cancer and hematological indications; BL-7010 for the treatment of celiac disease and gluten sensitivity; and BL-5010 for the treatment of benign skin lesions. 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-8040 and BL-7010, 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. In addition, due to the fact that some of our clinical trials are investigator-initiated studies (i.e., we are not the study sponsor), we may have less control over these studies. We estimate that clinical trials of our most advanced therapeutic candidates will continue for several years, but they may take significantly longer to complete. Failure can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future therapeutic candidates, including but not limited to:

- delays in securing clinical investigators or trial sites for the clinical trials;
- delays in obtaining institutional review board and other regulatory approvals to commence a clinical trial;

- slower than anticipated patient recruitment and enrollment;
- negative or inconclusive results from clinical trials;
- unforeseen safety issues;
- uncertain dosing issues;
- an inability to monitor patients adequately during or after treatment; and
- problems with investigator or patient compliance with the trial protocols.

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

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

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

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

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

We generally rely on third parties to conduct our pre-clinical 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 or add more sites to the studies. Although we believe that there are a number of other third-party contractors that we could engage to continue these activities, replacement of these third parties will result in delays and/or additional costs. As a result, our efforts to obtain regulatory approvals for, and to commercialize, our therapeutic candidates may be delayed. The third-party contractors may also have relationships with other commercial entities, some of whom may compete with us. If the third-party contractors assist our competitors, our competitive position may be harmed.

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

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

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

- we have limited control over the amount and timing of resources that our licensees devote to our therapeutic candidates;
- our licensees may experience financial difficulties;
- our licensees may fail to secure adequate commercial supplies of our therapeutic candidates upon marketing approval, if at all;
- our future revenues depend heavily on the efforts of our licensees;
- business combinations or significant changes in a licensee’s business strategy may adversely affect the licensee’s willingness or ability to complete its obligations under any arrangement with us;
- a licensee could move forward with a competing therapeutic candidate developed either independently or in collaboration with others, including our competitors; and
- out-licensing arrangements are often terminated or allowed to expire, which would delay the development and may increase the development costs of our therapeutic candidates.

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

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

We employ a number of methods to identify therapeutic candidates that we believe are likely to achieve commercial success. In addition to our internal research and business developments efforts, we employ a rigorous screening system we developed. In certain instances, our Scientific Advisory Board and disease-specific third-party advisors evaluate therapeutic candidates, as we deem necessary. In addition, therapeutic candidates expected to be developed under our collaboration with Novartis are also evaluated within the framework of the Joint Steering Committee established with Novartis for this purpose. 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 and life-sciences-focused investment funds have set up operations in Israel, both with and without Israeli government funding, in order to identify and in-license new technologies. The presence of these global companies with significantly greater resources than we have may increase the competition with respect to the in-licensing of promising therapeutic candidates. We may not be able to acquire licenses on commercially reasonable terms, or at all. Failure to license or otherwise acquire necessary technologies could materially and adversely affect our business, financial condition and results of operations.

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

We depend on in-licensing agreements with third parties to maintain the intellectual property rights to our therapeutic candidates. Regarding the main therapeutic candidates in clinical trials, we have in-licensed rights 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; and from Innovative Pharmaceutical Concepts, Inc., or IPC, with respect to our BL-5010 therapeutic candidate. See "Item 4. Information on the Company — Business Overview — In-Licensing Agreements." Our in-license agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these agreements. The royalty rates and revenue sharing payments vary from case to case but generally range from 20% 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 40% of the consideration we receive from sublicensing and 10% of net sales, subject to certain limitations, should we independently sell products. These in-license agreements last either throughout the life of the patents that are the subject of the agreements, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

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

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 many other companies which currently market and/or are in the process of developing products that address AML, celiac disease and gluten sensitivity, and skin lesions.

An important element of our strategy for identifying future products is maintaining relationships with universities, medical institutions and biotechnology companies in order to in-license potential therapeutic candidates, and we compete with respect to this in-licensing with a number of global pharmaceutical companies, 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 certified 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;
- significant changes in pricing due to pressure from public opinion, NGOs or governmental authorities
- lack of cost-effectiveness; or
- timing of market introduction of competitive products.

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

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

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

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

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 an annual coverage amount of $20.0 million per occurrence and product liability and clinical trials coverage with an annual coverage amount of $20.0 million each claim and in the aggregate. The maximum indemnity for a single occurrence, claim or circumstances under this insurance is $20.0 million. However, our insurance may not provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage or obtain additional or sufficient insurance at a reasonable cost to protect against losses that could have a material adverse effect on us. If a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as damages awards beyond the coverage of our insurance policies resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any claims, we might be required to direct significant financial and managerial resources to such defense, and adverse publicity is likely to result.

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

A significant invasion, interruption, destruction or breakdown of our information technology systems and/or infrastructure by persons with authorized or unauthorized access could negatively impact our business and operations. We could also experience business interruption, information theft and/or reputational damage from cyber attacks, which may compromise our systems and lead to data leakage either internally or at our third party providers. Our systems have been, and are expected to continue to be, the target of malware and other cyber attacks. Although we have invested in measures to reduce these risks, we cannot assure you that these measures will be successful in preventing compromise and/or disruption of our information technology systems and related data.

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

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

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

Risks Related to Intellectual Property

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

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

We currently have in-licensing agreements relating to our lead therapeutic candidates under clinical development. 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.

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-8040 in-licensing agreement upon 90 days' prior written notice to Biokine. We may terminate the BL-7010 in-licensing agreement or the BL-5010 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, 2015 we owned or exclusively licensed for uses within our field of business 19 patent families that, collectively, contain 34 issued patents, three allowed patent applications and over 57 pending patent applications relating to our main 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 contain, and any contract that we enter into with licensees in the future will likely contain, indemnity provisions that obligate us to indemnify the licensee against any losses arising from infringement of third party intellectual property rights. In addition, our in-license agreements contain provisions that obligate us to indemnify the licensors against any damages arising from the development, manufacture and use of products developed on the basis of the in-licensed intellectual property.

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

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

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

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

Risks Related to our Ordinary Shares and ADSs

We may be a passive foreign investment company, or PFIC, for U.S. federal income tax purposes in 2016 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 2016, 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 2016, 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 4.2 million ADSs at a weighted average exercise price of $3.71 per ADS. In addition, as of March 1, 2016 we have stock options granted to directors, employees and consultants for the purchase of 4.8 million ordinary shares with a weighted average exercise price of $2.00 per ordinary share.

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 sold 1,292,601 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;
- our success in effecting out-licensing arrangements with third-parties;
- our collaboration with Novartis and the extent that upfront licensing fees and program development costs would be covered by the option fees and equity investments paid by Novartis under this collaboration;
- 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 autumn of 2012, Israel was engaged in armed conflicts with Hamas, a militia group and political party operating in the Gaza Strip; during the summer of 2014, another escalation in violence among Israel, Hamas and other groups took place; and since October 2015, Israel has been facing another escalation in violence with the Palestinian population. These conflicts involved missile strikes against civilian targets in various parts of Israel, as well as civil insurrection of Palestinians in the West Bank, on the border with the Gaza Strip and in Israeli cities, and negatively affected business conditions in Israel. In addition, Israel faces threats from more distant neighbors, in particular Iran. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah (a Lebanese Islamist Shiite militia group and political party), and various rebel militia groups in Syria. Recent political uprisings and social unrest in various countries in the Middle East and North Africa are affecting the political stability of those countries. The year 2014 saw the rise of an Islamic fundamentalist group known as ISIS. Following swift operations, ISIS gained control of large areas in the Middle East, including in Iraq and Syria, which have contributed to the turmoil experienced in these areas. As a result, the United States armed forces have engaged in limited operations against ISIS and recently, Russia's armed forces have also engaged in limited operations to defeat ISIS and other rebel groups operating in Syria. 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 some of our employees have been called up from time to time 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.

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

Effective January 1, 2015, our reporting and functional currency is the dollar. However, we pay a significant portion of our expenses in NIS, and we expect this to continue. If the dollar weakens against the NIS in the future, there may be a negative impact on our results of operations. The revenues from our current out-licensing and co-development arrangements are payable in dollars and euros. Although we expect our revenues from future licensing arrangements to be denominated primarily in dollars, we are exposed to the currency fluctuation risks relating to the recording of our revenues in currencies other than dollars. For example, if the euro strengthens against the dollar, our reported revenues in dollars may be lower than anticipated. From time to time, we engage in currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of the currencies mentioned above in relation to the dollar. These measures, however, may not adequately protect us from material adverse effects.

We have received Israeli government grants and loans for 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.

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. 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, as amended, or the Research Law, with respect to these projects. Through December 31, 2015, we have received approximately $19.5 million in funding from the OCS. As of December 31, 2015, we have a contingent obligation to the OCS (other than for BL-8040 – see below) in the total amount of $0.2 million under all of our approved programs. 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 $2.7 million as of December 31, 2015. 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.

The transfer to third parties of know-how or technologies developed under the programs submitted to the OCS and as to which we or our licensors received grants, or manufacturing or rights to manufacture based on and/or incorporating such know-how to third parties, might require the consent of the OCS, and may require certain payments to the OCS. Although such restrictions do not apply to the export from Israel of our products developed with such know-how, they may prevent us from engaging in transactions with our affiliates, customers or other third parties outside Israel, involving product or other asset transfers, which might otherwise be beneficial to us.

In July 2015, the Knesset (the Israeli Parliament) enacted Amendment Number 7 to the Research Law, or the R&D Amendment. The R&D Amendment, effective as of January 1, 2016, amends material provisions of the Research Law (including but not limited to royalty rates and changes to royalty rates upon transfer of manufacturing rights abroad), leaves substantial discretion with the newly established National Authority for Technological Innovation, or the Authority (established to replace the OCS), and includes only guidelines to some of the core issues of the Research Law. Thus the R&D Amendment is currently causing much ambiguity as to its implementation and its effect on companies which developed know-how using funds received from the OCS. While it is possible that some of the core issues regulated by the Research Law following the R&D Amendment, including required approvals prior to the transfer abroad of the manufacturing of any OCS or Authority-supported product or technology, will be similar to the regime prior to the R&D Amendment, there is currently no certainty that procedures and requirements will remain similar to the ones in effect prior to the R&D Amendment. See “Item 4. Information on the Company — Business Overview — Government Regulation and Funding — Israeli Government Programs.”

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

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

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

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

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

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

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

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

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

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

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

We were founded in 2003 by leading institutions in the Israeli life sciences industry, 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, 2013, 2014 and 2015 were $0.1 million, $0.2 million and $2.7 million, respectively. Our current capital expenditures involve acquisitions of laboratory equipment, computers and communications 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 three main clinical-stage therapeutic candidates: BL-8040, a novel peptide for the treatment of multiple cancer and hematological indications; BL-7010, a novel co-polymer for the treatment of celiac disease and gluten sensitivity; and 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. In addition, we have three other therapeutic candidates in various stages of clinical and preclinical 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 focus is principally on the therapeutic areas of oncology and immunology. However, we may also in-license therapeutic compounds outside of these areas in connection with our strategic collaboration with Novartis, as well as to a limited extent for our independent pipeline as the opportunities arise.

Our first 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 multiple cancer and 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 expression often correlates with disease severity. 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) and terminal differentiation. Multiple clinical and pre-clinical studies have shown the safety and efficacy of BL-8040. These studies have shown that BL-8040 inhibits the growth of various tumor types including multiple myeloma, non-Hodgkin's lymphoma, leukemia, non-small cell lung carcinoma, neuroblastoma and melanoma. BL-8040 significantly and preferentially stimulates apoptotic cell death of malignant cells (multiple myeloma, non-Hodgkin's lymphoma and leukemia). 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 acute myeloid leukemia, or AML; and in January 2014, the FDA granted an Orphan Drug Designation to BL-8040 as a treatment for stem cell mobilization. In January 2015, the FDA modified this Orphan Drug Designation for BL-8040 for use either as a single agent or in combination with G-CSF. In addition, findings in the field of immuno-oncology suggest that CXCR4 antagonists may be effective in inducing the migration of anti-tumor T cells into the tumor micro-environment. As such, the combination of BL-8040 with immune checkpoints inhibitors (PD1/PD-L1 monoclonal antibodies) has the potential to expand the benefit of immunotherapy to cancer types currently resistant to immuno-oncology treatments.

In June 2013, we commenced a Phase 2 trial for BL-8040 for the treatment of AML. The study is currently being conducted at five sites in the United States, including MD Anderson Cancer Center in Houston, Memorial Sloan-Kettering Cancer Center in New York, Mayo Clinic in Jacksonville, Johns Hopkins University in Baltimore and Washington University in St. Louis, 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. At the annual ASH conference in December 2015, we presented data from the dose escalation part of the trial. These data showed that BL-8040, as a stand-alone therapy and in combination with high-dose Cytarabine (Ara-C), is safe and well-tolerated at all doses tested up to and including the highest dose level of 1.5 mg/kg, with no major adverse events. The composite complete remission rate, including both complete remission (CR) and complete remission with incomplete blood count recovery (CRi), was 38% in subjects receiving only one cycle of BL-8040 treatment at doses of 1 mg/kg and higher (n=16). Patients included in this part of the study were patients that had undergone a significant number of prior treatment cycles or that were refractory to induction treatment. The data also showed that BL-8040 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, BL-8040 showed a direct and significant apoptotic effect on the immature leukemia progenitor cells in the bone marrow following two days of monotherapy and induced leukemia progenitor cells towards differentiation. Topline results of the entire study are expected in the first quarter of 2016.

Targeting a second AML treatment line, in August 2015 we announced the commencement of a Phase 2b trial as a consolidation treatment for AML patients who have responded to standard induction treatment. The trial is being conducted in collaboration with the German Study Alliance Leukemia Group. It is examining BL-8040 as part of a second stage treatment, termed consolidation therapy, to improve outcomes for AML patients who have achieved remission after the standard initial treatment regimen, known as induction therapy. The consolidation therapy is aimed at eliminating the minimal residual disease left in the bone marrow after induction therapy that can lead to relapse. The study is planned to enroll up to 194 patients at up to 25 sites in Germany. Top-line results of this study are expected in 2018.

In addition, we plan to commence a Phase 2a trial for BL-8040 in the second half of 2016 for the treatment of a third population of AML patients, those with the FLT3-ITD mutation. The 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 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 March 2015, we announced successful top-line results from 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 was conducted at the Hadassah Medical Center in Jerusalem. All safety and efficacy endpoints were met, showing that treatment with BL-8040 as a single agent was safe and well tolerated at all doses and resulted in efficient stem cell mobilization and collection in all study participants. Furthermore, the results support BL-8040 as one-day, single-dose collection regimen, which is a significant improvement in comparison with the current standard of care. In December 2015, we announced the filing of regulatory submissions required to commence a Phase 2 trial at Washington University School of Medicine in St. Louis for use of BL-8040 in stem cell mobilization. The trial is expected to commence shortly after receipt of regulatory approval, anticipated in the first quarter of 2016. We expect to announce partial results of the trial in the fourth quarter of 2016.

In November 2015, we announced the commencement of a Phase 1/2 trial, again in collaboration with the MD Anderson Cancer Center, for a fifth indication of BL-8040 - as a novel 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 methylprednisone). Secondary endpoints include assessment of the clinical efficacy (response rate), time and duration of response to the treatment, and overall survival following treatment.

In January 2016, we announced a collaboration with MSD, known as Merck in the U.S. and Canada, in the field of cancer immunotherapy. We plan to sponsor and conduct a Phase 2 study investigating BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with metastatic pancreatic adenocarcinoma. The study is an open-label, multicenter, single-arm trial designed to evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T cells into the tumor and their reactivity. The study is planned to commence by mid-2016. Upon completion of the study, or at any earlier point, both parties will have the option to expand the collaboration to include a pivotal registration study.

Our second 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 and gluten sensitivity. 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 in the next efficacy study for celiac patients. 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. In January 2016, we received confirmation regarding the classification of BL-7010 as a Class IIb medical device in the European Union. We believe this classification could significantly accelerate the development of BL-7010 in Europe.

Over the last year, we have invested considerable efforts in examining alternative development and commercialization pathways for BL-7010, in addition to the celiac disease pathway, including as a food supplement, in order to potentially address the multi-billion dollar market for gluten sensitivity. We believe the gluten sensitivity market has a significantly shorter time to market than drug or device pathways, especially in the U.S. market, where the device pathway is not available for BL-7010. We are currently conducting a number of activities towards the development of BL-7010 as a food supplement, including the development of a suitable product formulation, preparation of the documents necessary for a "generally recognized as safe," or GRAS, designation submission, and preparations for a relatively small clinical trial to support the marketing efforts we may conduct regarding gluten and/or gluten sensitivity. We expect to complete these activities by mid-2017, in order to support partnering discussions for the food supplement market in the U.S. and other relevant territories at that time. We will also continue to evaluate the pathway for celiac disease in Europe and will make a decision about the timing and scope of the next efficacy study for European registration over the next few months.

Our third clinical-stage therapeutic candidate, BL-5010, is a novel medical device containing a novel, acidic, aqueous solution and applicator for the non-surgical removal of benign skin lesions. It offers an alternative to painful, invasive and expensive removal treatments including cryotherapy, laser treatment and surgery. Since the treatment is non-invasive, it poses minimal infection risk and eliminates the need for anesthesia, antiseptic precautions and bandaging. The pre-filled device controls and standardizes the volume of solution applied to a lesion, ensuring accurate administration directly on the lesion and preventing both accidental exposure of the healthy surrounding tissue and unintentional dripping. It has an ergonomic design, making it easy to handle, and 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 IIa 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, now part of Perrigo Company plc, for the rights to BL-5010 for OTC indications in the territories of Europe, Australia and additional selected countries. We will retain all OTC rights to BL-5010 in the United States and the rest of the world, as well as all non-OTC rights on a global basis. 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. During 2015, Omega Pharma conducted a 30-patient, open-label clinical study in Turkey to evaluate the advantages of BL-5010 in one of the intended OTC indications. Study results indicate that BL-5010 is safe and efficacious. Omega Pharma submitted an application for CE Mark designation for BL-5010 during the third quarter of 2015, and has completed the initial manufacturing process automation to support the product launch. The commercial launch of the first OTC indication for this product is expected during 2016. As a result of this out-licensing arrangement with Omega Pharma, 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, or for OTC indications in territories not out-licensed to Omega Pharma, primarily the U.S.

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.

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. In certain circumstances, our Scientific Advisory Board and disease-specific third-party advisors are active in evaluating certain therapeutic candidates, as deemed necessary. 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 2,300 compounds, presented more than 70 candidates for final internal evaluation, initiated development of 45 therapeutic candidates and terminated 39 development 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 a number of 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 four programs at various stages of development in our pipeline that have already been partnered or under collaboration.
- **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, securing reimbursement codes from insurance companies and HMOs, 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. In certain instances, our Scientific Advisory Board and disease-specific third-party advisors evaluate therapeutic candidates, as deemed necessary. In addition, projects under the Novartis collaboration benefit from additional review and assessment by Novartis.
- **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. A limited number of projects in pre-clinical stages are also eligible for flagging by Novartis, for initial development by BioLineRx. Such projects, once reaching the clinical stage, will be eligible for selection by Novartis under the terms set forth above. The companies intend to develop up to three clinical-stage 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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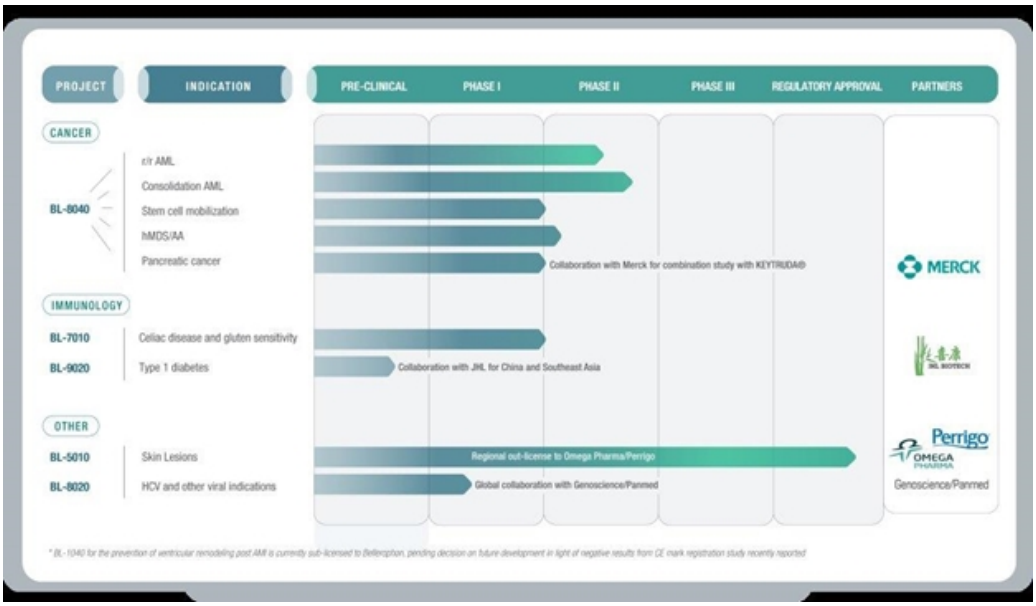
Our Product Pipeline

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



Main Therapeutic Candidates

BL-8040

BL-8040 is a novel, short peptide that functions as a high-affinity antagonist for CXCR4, which we are developing for multiple cancer and 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 disease severity. We in-licensed BL-8040 from Biokine in September 2012.

The following paragraphs are a high-level summary of the therapeutic areas we are currently investigating for BL-8040:

Acute Myeloid Leukemia (AML). AML is a cancer of the blood and bone marrow and is the most common type of acute leukemia in adults. According to the American Cancer Society, approximately 19,000 new cases of AML were diagnosed in the United States in 2014, and the median age of AML patients was 67 years old. The first treatment line for patients with AML includes a combination of chemotherapy drugs and is called induction treatment. The median survival for AML patients receiving induction chemotherapy is less than two years, with shorter survival for patients over the age of 60 or for those with certain gene or chromosome aberrations. Due to relapsed or refractory disease (where the disease is not responsive to standard treatments), the overall five-year survival rate for AML is between 10 and 40 percent.

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

Hypoplastic myelodysplastic syndrome (hMDS) and aplastic anemia (AA). hMDS and AA are hematological conditions caused by progressive bone marrow failure, and characterized by ineffective production of all blood cells, leading to severe anemia and cytopenias (low blood counts). These conditions result from disorders of the hematopoietic stem cells in the bone marrow, where hematopoiesis is disrupted and the number and quality of blood-forming cells decline irreversibly, further impairing blood production. 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 may include immunosuppressive therapy, chemotherapy or hematopoietic stem cell transplant.

Pancreatic cancer. There are a number of types of pancreatic cancer. Based on available worldwide numbers, in 2014, pancreatic cancers of all types were the seventh most common cause of cancer-related deaths. According to the American Cancer Society, in 2015, nearly 50,000 were diagnosed with pancreatic cancer and an estimated 40,000 will die from the disease. The most common type of pancreatic cancer is pancreatic adenocarcinoma, which accounts for about 85 percent of cases. These adenocarcinomas start within the part of the pancreas that makes digestive enzymes. There are usually no symptoms in the early stages of the disease and symptoms that are specific enough to suggest the onset of pancreatic cancer typically do not develop until the disease has reached an advanced stage. The five-year survival rate of pancreatic adenocarcinoma is around 7 percent.

Regulatory Approvals. In September 2013, the FDA granted an Orphan Drug Designation to BL-8040 as a therapeutic for the treatment of AML. In January 2014, the FDA granted an Orphan Drug Designation to BL-8040 for use, in combination with G-CSF, in mobilizing human stem cells from the bone marrow to the peripheral blood for collection for autologous or allogeneic (donor-based) transplantation. In January 2015, the FDA modified this Orphan Drug Designation for BL-8040 for use either as a single agent or in combination with G-CSF. 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 therapies. In addition, BL-8040 directly induces apoptosis of cancer cells. BL-8040 was efficient, both alone and in combination with chemotherapy, in reducing malignant bone marrow cells and stimulating their cell death.

In August 2013, we announced that BL-8040 has been shown in 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). This data was also presented at the 2014 Annual Meeting of the Society of Hematologic Oncology, or SOHO Conference.

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. All patients receiving transplants (n=17) exhibited rapid engraftment, with median time to neutrophil and platelet recovery of 12 and 14 days, respectively, at the highest dose given (0.9 mg/kg).

In June 2013, we commenced a Phase 2 trial for BL-8040 for the treatment of patients with relapsed or refractory AML, or r/r AML. The study is being conducted at five sites in the United States, including MD Anderson Cancer Center in Houston, Memorial Sloan-Kettering Cancer Center in New York, Mayo Clinic in Jacksonville, Johns Hopkins University in Baltimore and Washington University in St. Louis, 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 r/r AML. 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 comprised of two parts – the dose escalation phase and the current expansion phase at the highest tolerated dose found during the escalation phase. During the dose escalation phase, trial participants were recruited in cohorts of three patients at a time, and the dose was increased for each subsequent cohort depending on the safety and tolerability results of the previous cohort, which was determined by an independent data monitoring committee, or DMC. Twenty-two patients with r/r AML were enrolled in the dose escalation stage of the study (16 of whom received a dose of 1 mg/kg and higher). Each patient received a once daily dose of BL-8040 monotherapy (from 0.5 to 2.0 mg/kg) on days 1-2 followed by the same dose of BL-8040 plus Ara-C on days 3-7. Extensive pharmacodynamic parameters, such as mobilization of leukemic cells and induction of apoptosis, were assessed after monotherapy with BL-8040 using peripheral blood sampling and bone marrow aspirates at baseline and on day 3 prior to Ara-C administration. Clinical response to treatment was evaluated by bone marrow biopsy on day 30.

At the annual ASH conference in December 2015, we presented data from the dose escalation part of the trial. Results showed that BL-8040, as a single agent and in combination with Cytarabine (Ara-C), was safe and well tolerated at all doses tested up to and including the highest dose level of 1.5 mg/kg, with no major adverse events. The composite complete remission rate, including both complete remission (CR) and complete remission with incomplete blood count recovery (CRi), was 38% in subjects receiving only one cycle of BL-8040 treatment at doses of 1 mg/kg and higher (n=16). Patients included in this part of the study were patients that had undergone a significant number of prior treatment cycles or that were refractory to induction treatment. Treatment with BL-8040 had a triple effect on the leukemic cells. First, following only two days of monotherapy, BL-8040 triggered an average 40-fold mobilization of immature AML progenitor cells from the bone marrow to the peripheral blood, thereby sensitizing these cells to the Ara-C chemotherapy and improving its efficacy. Second, BL-8040 showed a direct and significant apoptotic effect on the immature leukemia progenitor cells in the bone marrow following the two days of monotherapy. Last, BL-8040 induced leukemia progenitor cells towards differentiation, as evidenced by a 58% median decrease in the number of bone marrow leukemia progenitor cells, along with a three-fold increase in differentiated granulocytes, in the bone marrow biopsy conducted on day 3 of the treatment cycle prior to the Ara-C treatment, as compared to the biopsy performed at baseline.

Topline results of the full study are expected in the first quarter of 2016.

In order to test a second AML treatment line, we commenced a Phase 2b trial in Germany as a consolidation treatment for AML patients who have responded to standard induction treatment. It will examine BL-8040 as part of a second stage treatment, termed consolidation therapy, to improve outcomes for the approximately 70% of AML patients who have achieved remission after the standard initial treatment regimen, known as induction therapy. The consolidation therapy is aimed at eliminating the minimal residual disease left in the bone marrow after induction therapy that can lead to relapse in 40-60% of the patients within 12-18 months after entering remission.

The Phase 2b trial, which is being conducted in collaboration with the University of Halle as sponsor and with the participation of two large leukemia study groups in Germany, is a double-blind, placebo-controlled, randomized, multi-center study aimed at assessing the efficacy of BL-8040 in addition to standard consolidation therapy in AML patients. The primary endpoint of the study is to compare the relapse free survival (RFS) time in AML subjects in their first remission during a minimum follow-up time of 18 months after randomization. In addition, pharmacodynamic measurements will be conducted in order to assess the minimal residual disease, and biomarker analyses will be performed to identify predictors of BL-8040 response. The study will enroll up to 194 patients at up to 25 sites in Germany. AML patients between 18 and 75 years of age with documented first remission will be randomized in a 1:1 ratio to receive high dose Cytarabine, either with BL-8040 or with a matching placebo, as consolidation therapy. Top-line results of this study are expected in 2018.

We plan to commence a Phase 2a trial for BL-8040 for the treatment of a third population of AML patients, those with the FLT3-ITD mutation, in the second half of 2016. AML patients with the FLT3-ITD mutation exhibit poor response and high relapse rates when treated with chemotherapy, and exhibit 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 a FLT3 inhibitor. We plan to enroll approximately 30-40 patients at two or three sites. Patients testing positive for the FLT3-ITD mutation will receive several treatment cycles of BL-8040 in combination with a FLT3 inhibitor. The safety of the combination treatment, as well as the response rates to the treatment and the duration of the responses will be evaluated.

In March 2015, we announced successful top-line results from 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 was conducted at the Hadassah Medical Center in Jerusalem. It was performed on healthy volunteers and consisted of two parts. The first part of the study was a randomized, double-blind, placebo-controlled, dose-escalation study in three cohorts of eight participants each, with each participant receiving two consecutive injections of BL-8040. Results show that BL-8040 is safe and well tolerated up to a dose of 1 mg/kg, and that dramatic mobilization of hematopoietic stem and progenitor cells, or HSPCs, was observed across all doses tested. The robust mobilization supports the further use of a single injection of BL-8040 for HSPC collection.

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

In December 2015, we announced the filing of regulatory submissions required to commence a Phase 2 trial for use of BL-8040 in stem cell mobilization. The submission was made following a meeting with the FDA in October 2015 to discuss the BL-8040 stem cell mobilization development program. The open-label trial will be conducted as an investigator-initiated study in collaboration with the Division of Oncology and Hematology of Washington University School of Medicine, and will enroll up to 24 donor/recipient pairs. On the donor side, the primary endpoint of the study is the ability of a single injection of BL-8040 to mobilize sufficient amounts of cells for transplantation following up to two leukapheresis collections. On the recipient side, the study aims to evaluate the functionality and engraftment following transplantation of the BL-8040 collected graft. The trial is expected to commence shortly after receipt of regulatory approval, anticipated in the first quarter of 2016.

A fifth clinical development program for BL-8040 is the assessment of the drug for the treatment of hypoplastic myelodysplastic syndrome, or hMDS, and aplastic anemia, or AA. One type of 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.

In November 2015, we announced the commencement of a Phase 1/2 trial, in collaboration with the MD Anderson Cancer Center, for BL-8040, in combination with standard of care immunosuppressive therapy, as a treatment for hMDS and AA. The open-label trial will examine BL-8040's ability to improve bone marrow cellularity and peripheral blood counts in up to 25 patients suffering from these bone marrow failure conditions. The study's primary endpoint is to evaluate the safety and tolerability of treatment with BL-8040 on top of the standard immunosuppressive regimen of Anti-Thymocyte Globulin (hATG), Cyclosporine and Methylprednisolone (steroids) in hMDS and AA patients. Secondary endpoints include assessment of the clinical efficacy (response rate), time and duration of response to the treatment, and overall survival following treatment. Safety and efficacy will be assessed at defined time points throughout the study. Duration of response and overall survival will also be assessed as part of the study's long term follow up protocol.

In January 2016, we announced a collaboration with MSD, known as Merck in the U.S. and Canada, in the field of cancer immunotherapy. We plan to sponsor and conduct a Phase 2 study investigating BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with metastatic pancreatic adenocarcinoma. Findings in the field of immuno-oncology suggest that CXCR4 antagonists such as BL-8040 may be effective in inducing the migration of anti-tumor T cells into the tumor micro-environment. KEYTRUDA® is a humanized monoclonal antibody that works by increasing the ability of the body's immune system to help detect and fight tumor cells. KEYTRUDA® blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T- lymphocytes, which may affect both tumor cells and healthy cells. The study is an open-label, multicenter, single-arm trial designed to evaluate the clinical response, safety and tolerability of the combination of BL-8040 and KEYTRUDA® as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T cells into the tumor and their reactivity. The study is planned to commence by mid-2016. Upon completion of the study, or at any earlier point, both parties will have the option to expand the collaboration to include a pivotal registration study.

BL-7010

BL-7010 is a novel, non-absorbable, orally available, high-molecular-weight co-polymer intended for the treatment of celiac disease and gluten sensitivity. 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.

Non-Celiac Gluten Sensitivity (NCGS). NCGS is defined as a clinical condition induced by ingestion of gluten and leading to intestinal and/or extra-intestinal symptoms in subjects in which celiac disease and wheat allergy have been ruled out. The overall prevalence of NCGS in the general population is considered to be higher than celiac disease. However the exact number is still unknown and the estimates vary widely, mainly due to the absence of biomarkers and the fact that many patients are self-diagnosed. As is the case with celiac disease, a gluten-free diet is currently the only therapy available for persons with NCGS. The total market for gluten-free products has grown to about 40 million consumers, of whom only up to four million suffer from celiac disease. This reinforces the large potentially available market size for products addressing NCGS.

Preclinical Results. BL-7010 was evaluated in preclinical safety and efficacy studies. As we received conditional approval for device designation in Europe, the safety data available included 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, selected drugs or additional selected proteins.

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 as the optimal repeated dose in the next efficacy study for celiac patients.

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. In January 2016, we received confirmation regarding the classification of BL-7010 as a Class IIb medical device in the European Union. We believe this classification could significantly accelerate the development of BL-7010 in Europe.

Over the last year, we have invested considerable efforts in examining alternative development and commercialization pathways for BL-7010, in addition to the celiac disease pathway, including as a food supplement, in order to potentially address the multi-billion dollar market for gluten sensitivity. We believe the gluten sensitivity market has a significantly shorter time to market than drug or device pathways, especially in the U.S. market, where the device pathway is not available for BL-7010. We are currently conducting a number of activities towards the development of BL-7010 as a food supplement, including the development of a suitable product formulation, preparation of the documents necessary for a GRAS designation submission, and preparations for a relatively small clinical trial to support the marketing efforts we may conduct regarding gluten and/or gluten sensitivity. We expect to complete these activities by mid-2017 in order to support partnering discussions for the food supplement market in the U.S. and other relevant territories at that time. We will also continue to evaluate the pathway for celiac disease in Europe and will make a decision about the timing and scope of the next efficacy study for European registration over the next few months.

BL-5010

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

Development and 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-5010 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 OTC rights to BL-5010 in the United States and the rest of the world, as well as the non-OTC rights on a global basis. Under our out-licensing arrangement with 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. During 2015, Omega Pharma conducted a 30-patient, open-label clinical study in Turkey to evaluate the advantages of BL-5010 in one of the intended OTC indications. Study results indicate that BL-5010 is safe and efficacious. Omega Pharma submitted an application for CE Mark designation for BL-5010 during the third quarter of 2015, and has completed the initial manufacturing process automation to support the product launch. The commercial launch of the first OTC indication for this product is expected during 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, or for OTC indications in territories not out-licensed to Omega Pharma, primarily the U.S.

Other Therapeutic Candidates

BL-8020

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.

BL-1040

BL-1040 (now called "Bioabsorbable Cardiac Matrix," or BCM), 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 2009, we entered into an out-licensing arrangement with Bellerophon 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 at the rate of 11-15% 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.

In December 2011, Bellerophon commenced PRESERVATION I, a CE mark registration clinical trial of BL-1040. Enrollment for this trial was completed in December 2014, with 303 AMI patients having been recruited and treated. In July 2015, Bellerophon reported top-line results from PRESERVATION I, showing no statistically significant difference between patients treated with BCM versus placebo for both the primary and the secondary endpoints of the study. We have not yet received any notification from Bellerophon about their plans regarding the future of this program.

We are obligated to pay 28% of all net consideration received under this arrangement to B.G. Negev Technologies, the party from which we in-licensed BL-1040 in 2005. 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.

Therapeutic Candidates in Preclinical Development

As of the date of this annual report, we have one preclinical stage therapeutic candidate. BL-9020 is a novel monoclonal antibody treatment designed to prevent immune-mediated destruction of insulin-producing beta cells in the pancreas. It was developed to treat Type 1 diabetes in early stage patients, during what is known as the "honeymoon period," where the pancreatic beta cells have not been completely destroyed and continue to secrete insulin. BL-9020 targets NKp46, a unique target that is involved in the innate response against the pancreas. Pre-clinical studies in mouse models of Type 1 diabetes suggest that BL-9020 can inhibit beta cell death, thus preventing full maturation of the disease. This effect could significantly delay, and potentially prevent, the need for chronic insulin use by Type 1 diabetes patients, as well as provide a potential benefit in minimizing diabetes-related complications. Based on its mechanism of action, additional therapeutic indications may be relevant to BL-9020 as well, and we are currently evaluating these additional indications. We in-licensed BL-9020 from the Yissum Research Development Company of the Hebrew University of Jerusalem Ltd., B.G. Negev Technologies and Hadasit Medical Research Services and Development Ltd., or Hadasit (the technology transfer company of Hadassah Medical Organization).

Termination of Therapeutic Candidates

As part of our business strategy, we continue to actively source, rigorously evaluate and in-license selected therapeutic candidates. In line with this strategy, during 2015 and the period subsequent thereto through the date of this report, we terminated one clinical and three pre-clinical stage therapeutic candidates.

BL-7040 was an orally available synthetic oligonucleotide which was in clinical development for the treatment of inflammatory bowel disease, or IBD. Over the last two years, we invested significant efforts in attempting to locate a potential co-development, collaboration or licensing partner for this asset, and conducted numerous discussions with both mid-sized and large pharma companies in this direction. Ultimately, due to a combination of factors, we were unsuccessful in our efforts and have notified the licensors of our decision to terminate the project.

BL-8030 was a small molecule which we were developing for the treatment of hepatitis C. The compound was in pre-clinical development in collaboration with Jiangsu Chia-tai Tianqing Pharmaceutical Co., Ltd., or CTTQ, for China and Hong Kong. For addition details regarding CTTQ, see "— Other Out-licensing/Collaboration Agreements." BL-1110 was a small molecule which we were developing for the treatment of neuropathic pain. BL-9010 was a bi-specific antibody intended to treat severe allergies and asthma. These three pre-clinical projects were terminated due to lack of efficacy and other scientific considerations as well as market considerations.

Product Development Approach

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

Our focus is principally on the therapeutic areas of oncology and immunology. However, we may also in-license therapeutic compounds outside of these areas in connection with our strategic collaboration with Novartis, as well as to a limited extent for our independent pipeline as the opportunities arise.

We have established relationships with various universities, academic and research institutions and biotechnology companies that permit us to identify and select compounds at various stages of clinical and pre-clinical development. 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 early development stage therapeutic candidates, over the last few years we have begun evaluating clinical and later-stage pre-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, as necessary, a therapeutic candidate may also be evaluated by our Scientific Advisory Board and by disease-specific advisors for external scientific review. 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 2,300 compounds, presented more than 70 candidates for final internal evaluation, initiated development of 45 therapeutic candidates and terminated 39 feasibility programs.

Once we approve a compound, we in-license the candidate and any related technology and our drug development team and project managers identify, define and oversee the necessary steps to development and commercialization. The design of an appropriate development plan is critical to our approach. We design experiments and studies that challenge the identified weaknesses of a compound, and often verify initial data by testing the compound in additional animal models, as well as in early-stage clinical studies.

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, intellectual property protection and business development. We perform all of our development activities in our certified 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.

Collaboration and Out-Licensing Agreements

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."

Collaboration Agreement with MSD (Merck)

In January 2016, we announced a collaboration with MSD, known as Merck in the U.S. and Canada, to support a Phase 2 study investigating BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with metastatic pancreatic cancer. The Phase 2 study will evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T cells into the tumor and their reactivity. Per the terms of the agreement, we will sponsor and perform the study, which is planned to commence by mid-2016, and a portion of the study costs will be funded by Merck. Upon completion of the study, or at any earlier point, both parties will have the option to expand the collaboration to include a pivotal registration study.

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 all OTC rights to BL-5010 in the United States and the rest of the world, as well as all non-OTC rights on a global basis. 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

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.

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.

In January 2015, we reached an agreement with Bellerophon to amend the BL-1040 license agreement. The amendment 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.

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." 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.

CTTQ

In June 2013, we signed an out-licensing agreement with 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.

In January 2016, we received notice from CTTQ that it was exercising its right to terminate the agreement with us, effective in April 2016. We have also provided notice to the licensors of BL-8030 of the termination of our in-licensing agreement with them, which took effect in early March 2016.

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. In addition, we are required to pay 12% of all net consideration we receive as a result of the out-licensing of BL-9020, including without limitation the net consideration we receive from JHL, to a party that is assisting us in the initial development of BL-9020.

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 20% to 29.5% of the consideration we receive from sublicensing the applicable therapeutic candidate. We are required to pay a substantially lower percentage, generally less than 5%, if we elect to commercialize the subject therapeutic candidate independently. 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-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 currently paying a development fee of $50,000 per month, which is expected to end following completion of the r/r AML study in the first quarter of 2016.

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 10% 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 40% of the amounts we receive as consideration in connection with any sublicensing, development, manufacture, marketing, distribution or sale of the licensed technology.

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 that 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-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.

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.

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 1, 2016, we owned or exclusively licensed for uses within our field of business 18 patent families that collectively contain over 35 issued patents, three allowed patent applications and over 56 pending patent applications relating to the three 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 three main therapeutic candidates are described below and include both issued patents and pending patent applications we exclusively license. We vigorously defend our intellectual property to preserve our rights and gain the benefit of our investment.

- With respect to BL-8040, we have an exclusive license to two patent families that cover the molecule that is the active ingredient of our proprietary drug. Patents and patent applications of these families have been granted or are pending in the 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, which may add an additional term of up to 5 years on the patent. 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 data 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, as well as its use as a food. 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 a novel applicator uniquely configured for applying the BL-5010 composition to targeted skin tissue safely and effectively. Patents applications of this family are pending in the United States, Israel, Europe, Japan, Canada, China, Russia and Australia. Patents to issue will expire in 2034.

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

Trade Secrets

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

Scientific Advisory Board

Until 2015, our Scientific Advisory Board consisted of a number of leading scientists and physicians who played an active role in the evaluation of many of our in-licensing opportunities and the development of our pipeline. In addition, we sought advice from our Scientific Advisory Board on scientific and medical matters generally. As a result of our strategic decision over the last few years to focus on the therapeutic fields of oncology and immunology, in 2015 we decided to disband the previous Scientific Advisory Board and establish two separate new Boards to focus on providing insight and guidance for our activities in the fields of oncology and immunology. In December 2015, we announced the establishment of our oncology Scientific Advisory Board. We are currently in the process of setting up our immunology Scientific Advisory Board and hope to finalize this process by mid-2016.

With respect to each of the two therapeutic fields, the new Scientific Advisory Boards will, as deemed necessary:

- screen certain potential relevant in-licensing and current therapeutic candidates;
- oversee our research and development programs;
- address specific scientific and technical issues relevant to the field; and
- review certain strategic decisions we may consider related to the field.

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

Name	Position/Institutional Affiliation
J. Aaron Ciechanover, M.D., Ph.D.	Professor Ciechanover is a Distinguished University Professor at the Rappaport Faculty of Medicine of the Technion and the co-director of the Technion Integrated Cancer Center. He shared the 2004 Nobel Prize in Chemistry with Professors Avram Hershko and Irwin Rose for the discovery of ubiquitin-mediated protein degradation. Among his many other prizes are 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 and the National Academies of Sciences and of Medicine of the USA (Foreign Associate). Professor Ciechanover was also a member of our original Scientific Advisory Board.
Jorge Eduardo Cortes, M.D.	Dr. Cortes is Professor of Medicine, Deputy Chair, and Chief of the CML and AML Sections of the Department of Leukemia at The University of Texas, MD Anderson Cancer Center (MDACC). Dr. Cortes has authored hundreds of peer-reviewed manuscripts, abstracts, book chapters, and other medical publications. He is an associate editor for the medical journal, *Blood* and serves on the editorial board of other journals such as the *Journal of Clinical Oncology*, the *American Journal of Hematology* and *Clinical Cancer Research*. In addition, Dr. Cortes serves on the Board of the International CML Foundation. Dr. Cortes has received numerous awards including The Service to Mankind Award from the Leukemia and Lymphoma Society and the Faculty Scholar Award from the MDACC for clinical research and for education.
Debasish Roychowdhury, M.D.	Dr. Roychowdhury is a leader in the pharmaceutical industry with a strong background in oncology research and development, and regulatory and commercial operations, having previously served in key senior leadership roles at Sanofi, GlaxoSmithKline and Eli Lilly. Dr. Roychowdhury has a distinguished track record in the field of oncology having been involved in the approval of nine oncology drugs, including Almita, Tykerb and Jevtana. Currently, he is President of Nirvan Consultants, LLC and in this capacity he serves in senior advisory roles for biotechnology companies to help advance their pipeline of therapeutic medicines. Dr. Roychowdhury also serves as a member of the Board of Directors for Lytix Biopharma AS and Radius Health, Inc. In his academic career, Dr. Roychowdhury served as a faculty member at the University of Cincinnati.
Yosef Yarden, Ph.D.	Professor Yarden is The Harold and Zeda Goldenberg Chair of Molecular Cell Biology 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. Among his many awards, he has 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. Professor Yarden is also a member of the European Molecular Biology Organization, the European Cancer Academy and the Asia-Pacific International Molecular Biology Network. Professor Yarden was also a member of our original Scientific Advisory Board.

Manufacturing

Our laboratories, which are located in our headquarters in Modi'in, Israel, are compliant with both current good manufacturing practices, or cGMP, and certified 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 "— Other Out-Licensing Agreements — Bellerophon." 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. There can be no assurance that our therapeutic candidates, if approved, can be manufactured in sufficient commercial quantities, in compliance with regulatory requirements and at an acceptable cost. We and our contract manufacturers are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products or medical devices. We and our contract manufacturers must ensure that all of the processes, methods and equipment are compliant with 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-8040

If approved, BL-8040 will compete with currently approved treatments for AML that include chemotherapy (Doxorubicin, Cytarabine, Vincristine), radiation therapy, stem cell transplantation and the hypomethylating agents Dacogen (decitabine), which has been developed by Eisai and Johnson & Johnson, and Vidaza (azacitidine), which has been developed by Celgene.

There are a number of potentially competitive compounds under development that act as CXCR4 inhibitors, including, among others, Mozobil (plerixafor), which is being marketed by Genzyme and Sanofi as a stem cell mobilizer for autologous stem cell transplantation; LY-2510924, which is being developed by Eli Lilly & Co; BMS-936564 (MDX-1338; ulocuplumab) developed by Bristol-Myers Squibb; F-50067 developed by Pierre Fabre; TG-0054 (burixafor) developed by TaiGen Biotechnology Co; POL-6326 developed by Polyphor Ltd; PTX-9908 developed by MicroConstants China and Pertinax Therapeutics Inc.; and X4P-001 developed by X4 Pharmaceuticals Inc.

Immuno-oncology is an area of great interest in the pharmaceutical market, specifically, immuno-oncology combination therapies. Recently, there has been growing attention to the combination of immuno-oncology agents with chemokines such as CXCR4 antagonist. One such combination therapy that is currently under development is BMS-936564 and Opdivo (ulocuplumab and nivolumab respectively, both of which are being developed by Bristol-Myers Squibb).These combination therapies, among others, could potentially compete with the combination of BL-8040 and Keytruda® (pembrolizumab, developed by Merck & Co.).

In addition there are a number of potentially competitive compounds under development to treat AML including, among others, Qinprezo (vosaroxin), which is being developed by Sunesis Pharmaceuticals (pre-registration in Europe); BI-6727 (volasertib), BIBF-1120 (nintedanib) and BI-836858, which are under development by Boehringer Ingelheim; Sprycel (dasatinib) 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; Odomzo (sonidegib) developed by Novartis; venetoclax developed by AbbVie Inc.; 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; Velcade (bortezomib) developed by Janssen and Takeda; uprosertib developed by Novartis; Revlimid (lenalidomide) developed by Celgene; Tarceva (erlotinib) developed by Roche Astellas and Chugai; Mekinist (trametinib) developed by Novartis; Zolinza (vorinostat) developed by Merck and Co.; SGI-110 developed by Astex Pharmaceuticals; alvocidib developed by Tolero Pharmaceuticals Inc.; pracinostat developed by MEI Pharma; Estybon (rigosertib) developed by Onconova Therapeutics, Baxter International and Symbio; Sapacitabine developed by Cyclacel Pharmaceuticals; RP-323 under development by Rich Pharmaceuticals; AG-221 (enasidenib) developed by Agios Pharmaceuticals Inc. and Celgene Corp; guadecitabine, developed by Astex Pharmaceuticals Inc.; CPX-351 (liposomal Cytarabine + Daunorubicin), developed by Celator Pharmaceuticals Inc.; Some of these treatments are being developed for specific AML patient populations and lines of treatment (e.g., quizartinib developed by Ambit Biosciences as treatment for FLT3-ITD mutated AML patients; Nexavar (sorafenib), developed by Bayer; midostaurin, developed by Novartis; and ASP-2215 (gilteritinib), developed by Astellas Pharma Inc.) 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 and gluten sensitivity that are currently undergoing development. There are several potentially competitive compounds under development for celiac disease such as larazotide acetate (AT-1001, Innovate Biopharmaceuticals Inc.), which inhibits the activity of zonulin; latiglutenase (ALV-003, AbbVie Inc. and Alvine Pharmaceuticals Inc.), which is a combination of gluten targeting proteases; nexvax2 (BTG plc and ImmusanT Inc.), which is a gluten epitope-based injectable vaccine, for the potential treatment of HLA DQ2-associated celiac disease. Currently, 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 (except nexvax2), is envisioned to be prescribed to patients who are on a gluten-free diet but still suffer from disease symptoms. In addition, there are a few marketed OTC products, based on various mixtures of enzymes, that are taken in addition to a gluten-free diet and aim to enhance digestion of residual gluten, e.g., Tolerase®, G GlutenEase™, Enzymedica; Gluten Defense™, Enzymatic Therapy; BioCore DPP-IV® and NEC.

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 Metvixia® (Galderma Pharma) are cream-based treatments for skin lesions which have been approved in many countries.

Insurance

We maintain insurance for our offices and laboratory in Israel. This insurance covers approximately $5.3 million of equipment, consumables and lease improvements against risk of fire, lightning, natural perils and burglary (the latter coverage limited to $250,000), and $1.5 million of consequential damages (covering fixed damages and extra expenses). For our clinical activities, we carry life science liability insurance covering general liability with an annual coverage amount of $20.0 million per occurrence and product liability and clinical trials coverage with an annual coverage amount of $20.0 million each claim and in the aggregate. The maximum indemnity for a single occurrence, claim or circumstances under this insurance is $20.0 million. In addition, we maintain the following insurance: employer's liability with coverage of approximately $10.0 million for each occurrence and in the aggregate; third party liability with coverage of approximately $5.0 million for each occurrence and in the aggregate; all risk coverage of approximately $2.0 million for electronic and mechanical equipment; 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, a 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 what is now known as the International Council on Harmonisation, or ICH (created as the International Conference on Harmonisation in 1990), is gradually narrowing these differences. In many cases, compliance with ICH standards can help avoid duplication of non-clinical and clinical trials and enable companies to use the same basis for submissions to each of the respective regulatory authorities. The adoption of the Common Technical Document format by the ICH has greatly facilitated use of a single regulatory submission for seeking approval in the ICH regions and certain other countries 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 development;
- 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 as well as to establish the exposure levels;
- 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, formulation and stability, as well as animal studies. For studies conducted in the United States, and certain studies carried out outside the United States, we submit the results of the preclinical studies, together with manufacturing information and analytical results, to the FDA as part of an IND, which must become effective before we may commence human clinical trials. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND does not always result in the FDA allowing clinical trials to commence and the FDA may halt a clinical trial if unexpected safety issues surface or the study is not being conducted in compliance with applicable requirements.

The FDA may refuse to accept an IND for review if applicable regulatory requirements are not met. Moreover, the FDA may delay or prevent the start of clinical trials if the manufacturing of the 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. An additional pathway for approval of follow-on biologics is discussed in the section "Generic Competition" below. As interpreted by the FDA, Section 505(b)(2) also permits the FDA to rely for such approvals on literature or on a finding by the FDA of safety and/or efficacy for a previously approved drug product. Under this interpretation, a 505(b)(2) NDA for changes to a previously approved drug product may rely on the FDA's finding of safety and efficacy of the previously approved product coupled with new clinical data and information needed by the FDA to support the change. NDAs submitted under 505(b)(2) are potentially subject to patent and non-patent exclusivity provisions which can block effective approval of the 505(b)(2) application until the applicable exclusivities have expired, which in the case of patents may be several years. The cost of preparing and submitting an NDA may be substantial. Under U.S. federal law, the submission of NDAs, including 505(b)(2) NDAs, is generally subject to substantial application user fees, and the manufacturer and/or sponsor under an NDA approved by the FDA is also subject to annual product and establishment user fees. These fees are typically increased annually. Separate fees are payable for an Abbreviated New Drug Application, or ANDA, and for Biosimilar Biological Product Development, or BPD.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the FDA threshold determination that the NDA is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under U.S. federal law, the FDA has agreed to certain performance goals in the review of NDAs. Most such applications for non-priority drug products are to be reviewed within 10 months. The review process may be significantly extended by FDA requests for additional information or clarification. 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 complete response letter. The complete response letter indicates that the review cycle for an application is complete and that the application is not ready for approval. The complete response letter will describe specific deficiencies and, when possible, will outline recommended actions the applicant might take in order to place the application in condition for approval. Following receipt of a complete response letter, the company may submit additional information and start a new review cycle, withdraw the application or request a hearing. Failure to take any of the above actions may result in the FDA considering the application withdrawn following 1 year from issuance of the complete response letter. In such cases, the FDA will notify the company and the company will have 30 days to respond and request an extension of time in which to resubmit the application. The FDA may grant reasonable requests for extension. If the company does not respond within 30 days of the FDA's notification, the application will be considered withdrawn. Even with submission of additional information for a new review cycle, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The Pediatric Research Equity Act, or PREA, requires NDAs (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). In addition, under the Best Pharmaceuticals for Children Act, or BPCA, the FDA may issue a written request to the company to conduct clinical trials in the pediatric population that are related to the moiety and expand on the claimed indication. The studies are voluntary, but may award the company with 6 months of marketing exclusivity if conducted according to good scientific principles and address the written request. Finally, a sponsor can request that a product that must be studied under PREA to be studied also under the BPCA to allow the sponsor to be eligible for six-months of pediatric exclusivity.

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

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

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

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

FDA Nutritional Segment

In the United States, two regulatory pathways exist for dietary ingredients, one for ingredients marketed in food and the other for dietary ingredients marketed in nutritional supplements. Dietary ingredients that were marketed in nutritional supplements prior to October 1994 are not subject to premarket authorization requirements. All other dietary ingredients must undergo a "premarket notification" process. This process requires the manufacturer to detail the quality and safety of the ingredient and file such information with the FDA at least 85 days prior to placing the ingredient on the market as a dietary supplement.

Food ingredients must be determined to be safe prior to being added to foods. The following categories of food ingredients are considered to be safe by the FDA:

- a food additive that has received pre-market approval from the FDA;
- an ingredient that is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use (referred to as generally recognized as safe, or "GRAS"); or
- an ingredient that was determined to be safe for use in food prior to September 6, 1958 (a list of these substances that are GRAS are published by the FDA in the Federal Register).

For an ingredient to be considered GRAS, the manufacturer of the ingredient must provide information on the quality and safety of the ingredient for its intended use as well as the results of relevant clinical studies. Such information is reviewed by qualified experts who determine whether the ingredient has been adequately shown to be GRAS. Additionally, such information may be voluntarily submitted to the FDA for review. If the FDA is satisfied with the determination of the new ingredient as GRAS, it will issue an Agency Response Letter advising that the agency has no questions regarding the safety conclusions of the ingredient.

Manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. That means that these firms are responsible for evaluating the safety and labeling of their products before marketing to ensure that they meet all the requirements of DSHEA and FDA regulations. The FDA is responsible for taking action against any adulterated or misbranded dietary supplement product after it reaches the market.

European Economic Area

Clinical Trials

The European Medicines Agency relies on the results of clinical trials carried out by pharmaceutical companies to reach its opinions on the authorization of medicines. Although the authorization of clinical trials occurs at Member State level, the Agency plays a key role in ensuring that the standards of good clinical practice (GCP) are applied across the European Economic Area (EEA) in cooperation with the Member States. It also manages a database of clinical trials carried out in the European Union. Clinical trials are currently regulated under Directive 2001/20/EC. However, in April 2014 a new Regulation on clinical trials on medicinal products for human use was adopted. The Regulation entered into force on in June 2014 but will apply no earlier than May 28, 2016. The Regulation will apply to interventional clinical trials on medicines once the Regulation is in operation, and to all trials authorized under the previous legislation (Directive (EC) No. 2001/20/EC) and still ongoing three years(the transition period) after the Regulation has come into operation. The regulation ensures that:

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

Marketing Authorization Procedures

A medicinal product may only be placed on the market in the 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, as amended, or its predecessor, Regulation 2309/93. There are essentially three EU procedures created under prevailing European pharmaceutical legislation that, if successfully completed, allow an applicant to place a medicinal product on the market in the EEA.

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; (c) all medicinal products that are designated as orphan medicinal products pursuant to Regulation 141/2000; and (d) medicines derived from biotechnology processes or advanced therapy medicinal products, such as gene therapy, tissue engineered and somatic cell therapy products. An applicant may also opt for assessment through the centralized procedure if it can show that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization centrally is in the interests of patients at the EU level. For each application submitted to the EMA for scientific assessment, the EMA is required to ensure that the opinion of the Committee for Medicinal Products for Human Use, or CHMP, is given within 210 days after receipt of a valid application or within 150 days by means of an accelerated procedure. If the opinion is positive, the EMA is required to send the opinion to the European Commission, which is responsible for preparing the decision granting a marketing authorization, within 67 days. If the initial opinion of the CHMP is negative, the applicant is afforded an opportunity to seek a re-examination of the opinion. The CHMP is required to re-examine its opinion within 60 days following receipt of the request by the applicant. A refusal of a centralized marketing authorization constitutes a prohibition on placing the given medicinal product on the market in the EU.

Mutual Recognition and Decentralized Procedures.

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

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

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

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

National Procedure

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

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

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

Types of Marketing Authorization Applications:

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

A. Full Applications. A full application is one that is made under any of the EU procedures described above and "stands alone" in the sense that it contains all of the particulars and information required by Article 8(3) of Directive 2001/83/EC, as amended, to allow the competent authority to assess the quality, safety and efficacy of the product and in particular the balance between benefit and risk. Article 8(3)(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.

B. Abridged Applications. Article 10 of Directive 2001/83/EC contains exemptions from the requirement that the applicant provide the results of its own preclinical and clinical research. There are four regulatory routes for an applicant to seek an exemption from providing such results, namely (1) cross-referral to an innovator's results without consent of the innovator (used for generic medicines or similar biological medicinal products), (2) well established use according to published literature, (3) fixed combination products, and (4) informed consent to refer to an existing dossier of research results filed by a previous applicant.

(1) Cross-referral to Innovator's Data

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

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

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

Hybrid Applications (equivalent to the U.S. 505(b)(2) NDA). If the copy product does not meet the definition of a generic medicinal product or if certain types of changes occur in the active substance(s) or in the therapeutic indications, strength, pharmaceutical form or route of administration in relation to the reference medicinal product, Article 10(3) of Directive 2001/83/EC provides that the results of the appropriate preclinical studies or clinical trials must be provided by the applicant.

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

(2) Well-established Medicinal Use

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

(3) Fixed Combination Application

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

(4) Informed Consent

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

C. Mixed Marketing Authorization Applications

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

Law Relating to Pediatric Research

Regulation (EC) 1901/2006 (as amended by Regulation (EC) 1902/2006) was adopted on December 12, 2006. This Regulation governs the development of medicinal products for human use in order to meet the specific therapeutic needs of the pediatric population. It requires any application for marketing authorization made after July 26, 2008 in respect of a product not authorized in the EU on January 26, 2007, the time the Regulation entered into force, to include studies in children conducted in accordance with a pediatric investigation plan agreed to by the relevant European authorities, unless the product is subject to an agreed waiver or deferral or unless the product is excluded from the scope of Regulation 1902/2006 (generics, hybrid medicinal products, biosimilars, homeopathic and traditional (herbal) medicinal products and medicinal products containing one or more active substances of well-established medicinal use. Waivers can be granted in certain circumstances where pediatric studies are not required or desirable. Deferrals can be granted in certain circumstances where the initiation or completion of pediatric studies should be deferred until appropriate studies in adults have been performed. Moreover, this regulation imposes the same obligation from January 26, 2009 on an applicant seeking approval of a new indication, pharmaceutical form or route of administration for a product already authorized and still protected by a supplementary protection certificate granted under Regulation (EEC) 1768/92 codified as Regulation (EC) no. 469/2009 or by a patent that qualifies for the granting of such a supplementary protection certificate. The pediatric Regulation 1901/2006 also provides, subject to certain conditions, a reward for performing such pediatric studies, regardless of whether the pediatric results provided resulted in the grant of a pediatric indication. This reward comes in the form of an extension of six months to the supplementary protection certificate granted in respect of the product, unless the product is subject to orphan drug designation, in which case the 10-year market exclusivity period for such orphan products is extended to 12 years. If any of the non-centralized procedures for marketing authorization have been used, the six month extension of the supplementary protection certificate is only granted if the medicinal product is authorized in all member states. Where the product is no longer covered by a patent or supplementary protection certificate, the applicant may make a separate application for a Pediatric Use Marketing Authorization, or PUMA, which, on approval, will provide eight years' protection for data and 10 years' marketing protection for the pediatric results.

In June 2013, the European Commission published a **report on the first five years of implementation of the 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 provision of a risk management plan and provision of annual periodic safety update reports, carrying out of post-authorization efficacy studies and/or post-authorization safety studies, maintenance of a pharmacovigilance system master file, adverse event reporting, signal detection and management and other pharmacovigilance activities conducted under an established quality system, advertising, packaging and labeling, patient package leaflets, distribution and wholesale dealing. The regulations frequently operate within a criminal law framework, and failure to comply with the requirements may not only affect the authorization, but also can lead to financial and other sanctions levied on the company in question and responsible officers.

Any authorization granted by member state authorities, which within three years of its granting is not followed by the actual placing on the market of the authorized product in the authorizing member state ceases to be valid. When an authorized product previously placed on the market in the authorizing member state is no longer actually present on the market for a period of three consecutive years, the authorization for that product shall cease to be valid. The same two three year periods apply to authorizations granted by the European Commission based on the centralized procedure.

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, as amended by Directive 2007/47/EC, 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. Revisions include extension of the scope for legislation, better supervision of independent assessment bodies, clear rights for manufacturers/distributors and stronger requirements for medical evidence.

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 December 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

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 Research Law. Through December 31, 2015 we have received approximately $19.5 million in aggregate funding from the OCS. As of December 31, 2015, we have a contingent obligation to the OCS (other than for BL-8040 – see below) in the total amount of $0.2 million under all of our approved programs. 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 $2.7 million as of December 31, 2015. 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 as in effect prior to the R&D Amendment and the terms of the grants, royalties on the revenues derived from sales of products developed with the support of the OCS were 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 dollar/shekel exchange rate, plus interest and any additional amounts as described below. However, we could be required to pay an increased total amount of royalties (possibly up to 300% of the grant amounts plus interest) if we receive approval to manufacture or to transfer the rights to manufacture our products developed with OCS grants outside of Israel, depending on the portion of total manufacturing that was performed outside of Israel, as further described below, and we could be required to pay additional amounts in respect of the technology developed under these projects that was otherwise transferred outside of Israel, as further described below. The amounts received bear interest equal to the 12-month London Interbank Offered Rate applicable to dollar deposits that was published on the first business day of each calendar year.

Pursuant to the Research Law as in effect prior to the R&D Amendment, recipients of funding from the OCS were 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 could, in special cases, approve the transfer of manufacture or of manufacturing rights of a product developed in an approved program or which resulted therefrom, outside of Israel. If we were to receive approval to manufacture or to transfer the rights to manufacture our products developed with 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 was performed outside of Israel. In addition, the royalty rate applicable to us could possibly increase. Such increased royalties constituted the total repayment amount required in connection with the transfer of manufacturing rights of OCS funded products outside Israel. The Research Law, as in effect prior to the R&D Amendment, did 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 granted such prior approval.

Under the Research Law, as in effect prior to the R&D Amendment, we were 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. The required approvals may not have been received for any proposed transfer and, if received, we could 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 already paid to the OCS, the amount of time that 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 were to be taken into account in order to calculate the amount of the payment to the OCS. The repayment amount was 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, could require us to notify, or to obtain the approval of, the OCS, and could 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 was performed outside of Israel.

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

In July 2015, the Knesset enacted the R&D Amendment after reaching the conclusion that the pre-R&D Amendment regime was not flexible enough to allow the OCS and the recipients of research and development funding to respond quickly to the challenges of a changing world. Pursuant to the R&D Amendment, the OCS was replaced with the Authority, which is comprised of the Council of the Authority, or Council, a Director General and the Research Committees. The Chief Scientist will become the head of the Authority. According to the R&D Amendment, the Council will have broad discretion regarding material matters, including, among others, with respect to the new funding programs, or Tracks, and requirements with respect to manufacture in Israel and transfer of manufacture abroad (including payment for such transfer). While the pre-R&D Amendment regime provided base-line default terms and conditions with respect to the core issues relevant for OCS grant recipients, as provided above, these default provisions have been largely rescinded by the R&D Amendment. Many of these matters will now be decided separately for each Track by the Council, based on certain guidelines stipulated in the R&D Amendment. Such guidelines provide, for example, that considerable preference should be given to having ownership of Authority-funded know-how and rights vest with the recipient of assistance and/or with an Israeli company, with transfer of know-how and related rights abroad to be permitted only in exceptional circumstances. In addition, the R&D Amendment stipulates that the transfer of manufacturing rights abroad, whether under a license or otherwise, shall only be allowed in special circumstances. Nonetheless, these matters are merely guidelines, and the essential matters will be determined by the Council in its discretion. While the R&D Amendment is designed to provide flexibility in a rapidly-changing business environment, leaving the above essential matters to the Council's discretion currently causes much ambiguity as to the implementation of the R&D Amendment.

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

Israel Ministry of Health

Israel's Ministry of Health, which regulates medical testing, has adopted protocols that correspond, generally, to those of the FDA and the 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 one wholly-owned inactive subsidiary: BioLineRx USA Inc. Until the end of 2014, BioLineRx Ltd. had two other wholly-owned entities: BioLine Innovations Jerusalem Limited Partnership, or BIJ L.P. and BioLine Innovations Jerusalem Ltd., or BIJ Ltd. Both BIJ L.P. and BIJ Ltd. were engaged in the operation of our biotechnology incubator. 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., and liquidated BIJ L.P. and BIJ Ltd. in December 2014 and 2015, respectively.

D. Property, Plant and Equipment

We are headquartered in Modi'in, Israel. Until June 2015, our headquarters were located in Jerusalem. The facility consists of 1,663 square meters (approximately 17,900 square feet) of space and lease payments are approximately $27,000 per month, including maintenance fees and parking. This facility houses both our administrative and research operations and our central laboratory. The central laboratory consists of approximately 380 square meters and includes an analytical chemistry laboratory, a formulation laboratory and a tissue culture laboratory. Our central laboratory is compliant with both cGMP and certified GLP, which allows us to manufacture therapeutic supplies for our current clinical trials. All of our employees are based in this facility.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this annual report. 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."

We are a clinical stage biopharmaceutical development company dedicated to identifying, in-licensing and developing therapeutic candidates that have advantages over currently available therapies or address unmet medical needs. Our current development pipeline consists of three main clinical therapeutic candidates: BL-8040, BL-7010 and BL-5010. In addition, we have three other therapeutic candidates in clinical and 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. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case by case basis, the commercialization of our therapeutic candidates independently. Our focus is principally on the therapeutic areas of oncology and immunology. However, we may also in-license therapeutic compounds outside of these areas in connection with our strategic collaboration with Novartis, as well as to a limited extent for our independent pipeline as the opportunities arise.

Clinical Stage Pipeline

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

- BL-8040 is a novel, short peptide that functions as a high-affinity antagonist for CXCR4, which we intend to develop for multiple cancer and hematological indications.

  Ø In June 2013, we commenced a Phase 2 trial for the treatment of r/r AML, which is currently being conducted at five world-leading cancer research centers in the U.S. and at five premier sites in Israel. In November 2015, we announced positive results from the dose escalation stage of this study, including clinical response data. Top-line results of the study are expected in the first quarter of 2016.

  Ø In March 2015 we reported successful top-line safety and efficacy results from a Phase 1 safety and efficacy trial for the use of BL-8040 as a novel treatment for stem cell mobilization, which was conducted at the Hadassah Medical Center in Jerusalem. More comprehensive data from this study was reported at the European Hematology Association (EHA) Conference in June 2015. In October 2015, we held a "Type B" meeting with the FDA to discuss the next steps in the clinical development plan for stem cell mobilization. In December 2015, we announced the filing of regulatory submissions required to commence a Phase 2 trial at Washington University School of Medicine in St. Louis for use of BL-8040 in stem cell mobilization for allogeneic transplantation. The trial is expected to commence shortly after receipt of regulatory approval, anticipated in the first quarter of 2016.

- Ø In August 2015, we initiated 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. The Phase 2b trial is a double-blind, placebo-controlled, randomized, multi-center study aimed at assessing the efficacy of BL-8040 in addition to standard consolidation therapy in AML patients. Up to 194 patients will be enrolled in the trial. The primary endpoint of the study is to compare the relapse free survival (RFS) time in AML subjects in their first remission during a minimum follow-up time of 18 months after randomization. Top-line results of this study are expected in 2018.

- Ø In November 2015, we commenced a Phase 1/2 trial, in collaboration with the MD Anderson Cancer Center, for BL-8040 as a treatment for hypoplastic myelodysplastic syndrome (hMDS) and aplastic anemia (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 methylprednisone).

- Ø In January 2016, we entered into a collaboration with MSD, known as Merck in the U.S. and Canada, in the field of cancer immunotherapy. We plan to sponsor and conduct a Phase 2 study investigating BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with metastatic pancreatic adenocarcinoma. The study is an open-label, multicenter, single-arm trial designed to evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T cells into the tumor and their reactivity. The study is planned to commence by mid-2016.

- Ø We are also planning to commence a Phase 2a trial for BL-8040 in the second half of 2016, also in collaboration with the MD Anderson Cancer Center, for the treatment of AML patients with the FLT3-ITD mutation.

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

- BL-7010 is a novel, non-absorbable, orally available, high-molecular-weight co-polymer intended for the treatment of celiac disease and gluten sensitivity. In December 2013, we commenced a Phase 1/2 trial for BL-7010 at Tampere Hospital in Finland, a leading site for celiac research. This study was conducted based on an initial medical device submission, under a conditional approval received from the regulatory authorities. 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 in the next efficacy study for celiac patients. In January 2016, we received confirmation regarding the classification of BL-7010 as a Class IIb medical device in the European Union.

  Over the last year, we have invested considerable efforts in examining alternative development and commercialization pathways for BL-7010, in addition to the celiac disease pathway, including as a food supplement, in order to potentially address the multi-billion dollar market for gluten sensitivity. We believe the gluten sensitivity market has a significantly shorter time to market than drug or device pathways, especially in the U.S. market, where the device pathway is not available for BL-7010. We are currently conducting a number of activities towards the development of BL-7010 as a food supplement, including the development of a suitable product formulation, preparation of the documents necessary for a GRAS designation submission, and preparations for a relatively small clinical trial to support the marketing efforts we may conduct regarding gluten and/or gluten sensitivity. We expect to complete these activities by mid-2017 in order to support partnering discussions for the food supplement market in the U.S. and other relevant territories at that time. We will also continue to evaluate the pathway in Europe for celiac disease and will make a decision about the timing and scope of the next efficacy study for European registration over the next few months.

- 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 BSI of the regulatory pathway classification of BL-5010 as a Class IIa medical device. In December 2014, we entered into an exclusive out-licensing arrangement with Omega Pharma (now a subsidiary of Perrigo Company plc) for the rights to BL-5010 for over-the-counter, or OTC, indications in the territory of Europe, Australia and additional selected countries. In September 2015, we reported that Omega Pharma submitted an application for CE marking for BL-5010. During 2015, Omega Pharma conducted a 30-patient, open-label clinical study in Turkey to evaluate the advantages of BL-5010 in one of the intended OTC indications. Study results indicate that BL-5010 is safe and efficacious. Omega Pharma submitted an application for CE Mark designation for BL-5010 during the third quarter of 2015, and has completed the initial manufacturing process automation to support the product launch. The commercial launch of the first OTC indication for this product is expected during 2016.

Principal Partnering and Collaboration Agreements

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 all OTC rights to BL-5010 in the United States and the rest of the world, as well as all non-OTC rights on a global basis. 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, as well as manufacturing data, generated during the performance of the development plan and may use these data in order to develop or license the product in other territories and fields of use where we retain the rights.

In January 2016, we entered into a collaboration with MSD, known as Merck in the U.S. and Canada, in the field of cancer immunotherapy. We plan to sponsor and conduct a Phase 2 study investigating BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with metastatic pancreatic adenocarcinoma. The study is an open-label, multicenter, single-arm trial designed to evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T cells into the tumor and their reactivity. The study is planned to commence by mid-2016. Upon completion of the study, or at any earlier point, both parties will have the option to expand the collaboration to include a pivotal registration study.

Other Partnering and Collaboration Agreements

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, granting CTTQ exclusive rights to develop, manufacture and commercialize BL-8030, an orally available treatment for HCV, in China and Hong Kong. In January 2016, we received notice from CTTQ that it was exercising its right to terminate the agreement with us, effective in April 2016. We have also provided notice to the licensors of BL-8030 of the termination of our in-licensing agreement with them, which took effect in early March 2016.

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.

History of Losses

Since inception in 2003, we have generated significant losses in connection with our research and development. As of December 31, 2015, we had an accumulated deficit of $159.4 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 upfront, milestone, royalty or other payments that we may receive from Omega Pharma, Novartis and other out-licensing or collaboration 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, 2015, we held approximately $47.7 million of cash, cash equivalents and short-term bank deposits.

Revenues

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

We expect our revenues for the next several years to be derived primarily from payments under our current out-licensing agreement with Omega Pharma, our collaboration agreement with Novartis, as well as other potential collaboration arrangements, including future royalties on product sales.

Research and Development

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

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

Project	Status	Expected Near-Term Milestone
BL-8040	1. Phase 2 study for AML; dose expansion stage ongoing	1. Top-line results expected in Q1 2016
	2. Phase 1 study in stem cell mobilization completed; Type B (end of Phase 1 meeting) with FDA conducted; regulatory submissions for Phase 2 study completed	2. Phase 2 trial expected to commence in Q1 2016. Partial results expected by end of 2016
	3. Phase 2b consolidation treatment for AML initiated	3. Completion of enrollment by mid-2017. Top-line results expected in 2018
	4. Phase 1/2 study for hMDS and AA initiated	4. Partial results expected by end of 2016
	5. Phase 2a study in pancreatic cancer, in collaboration with Merck, in final planning stages	5. Commencement of study expected in mid-2016
	6. Phase 2a study for AML patients with FLT3-ITD mutation in final planning stages	6. Commencement of study expected in H2 2016
BL-7010	Completed Phase 1/2 study; classified as Class IIb medical device in the EU	Submission of package for GRAS designation as food supplement in the U.S.; completion of formulation development as food supplement; initiation of clinical study for marketing purposes as food supplement; determination of appropriate timing for continued medical device development in Europe
BL-5010	Out-licensed to Omega Pharma; application for CE mark submitted in Q3 2015	CE mark approval; commercial launch of first OTC indication in Europe during 2016; pursuit of potential out-licensing partner(s) for OTC and non-OTC rights still held by us

In addition to the projects set forth above, we have three additional projects in clinical and pre-clinical stages of development (BL-8020, BL-1040 and BL-9020) that are significantly less material to the Company's ongoing research and development expenditures. 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, 2013, 2014 and 2015, 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
	2013	2014	2015	
	(U.S. $ in thousands)			
BL-8040	3,910	4,698	7,045	16,376
BL-7010	1,905	3,756	1,657	8,152
BL-5010	251	1,282	400	4,069
Other projects	5,097	1,537	1,916	103,332
Total project costs	11,163	11,273	11,018	131,929

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.” We have not received significant funding from the OCS since 2012, and there can be no assurance that we will receive significant funding from the OCS in the future, if at all.

From our inception through December 31, 2015, we have incurred research and development expense of approximately $166.0 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 cost of drug substance/product manufacturing, storage and shipment;
- the number of patients that participate in the clinical trials;
- the duration of patient follow-up;
- whether the patients require hospitalization or can be treated on an out-patient basis;
- the development stage of the therapeutic candidate; and
- the efficacy and safety profile of the therapeutic candidate.

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

Sales and Marketing Expenses

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

General and Administrative Expenses

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

Non-Operating Expense and Income

Non-operating expense and income includes fair-value adjustments of derivative liabilities on account of the warrants issued in 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.

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, 2015. 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 and Presentational Currency

From the Company's inception through December 31, 2014, the Company's functional and presentation currency was the NIS. As a result of a number of factors, including the strategic collaboration agreement with Novartis that will be managed solely in dollars, as well as expectations regarding a significant increase in expenses denominated in dollars relating to advanced clinical trials, effective January 1, 2015, the Company's functional and presentation currency was changed to the dollar. See Note 2c to our consolidated financial statements for the year ended December 31, 2015 included elsewhere in this report.

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, and we may receive such funding in the future. 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.

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

The following standards have been adopted by the Company for the first time for the fiscal year beginning January 1, 2015:

- Annual Improvements to IFRSs – 2010-2012 Cycle; 2011-2013 Cycle
- Defined Benefit Plans: Employee Contributions – Amendments to IAS 19

The adoption of these amendments did not have any impact on the current period or any prior period and is not likely to affect future periods. In addition, the Company also elected to early adopt the following two amendments:

- Annual Improvements to IFRSs – 2012-2014 Cycle
- Disclosure Initiative: Amendments to IAS 1.

As these amendments merely clarify the existing requirements, they do not affect the Company's accounting policies or any of the disclosures.

For information concerning new standards and interpretations not yet adopted, see Note 2t to our consolidated financial statements for the year ended December 31, 2015 included elsewhere in this report.

Results of Operations -- Overview

Revenues

We did not record any revenues for the years ended December 31, 2013, 2014 and 2015.

Cost of revenues

We did not record any cost of revenues for the years ended December 31, 2013, 2014 and 2015.

Research and development expenses

At December 31, 2012, our drug development pipeline consisted of 14 therapeutic candidates. During 2013, we added two new compounds to our pipeline and discontinued the development of six compounds from the pipeline, so that our drug development pipeline as of December 31, 2013 consisted of 10 therapeutic candidates. During 2014, we added a new compound to our pipeline and discontinued the development of one compound from the pipeline, so that our drug development pipeline as of December 31, 2014 consisted of 10 therapeutic candidates. During 2015, we did not add any new compounds to our pipeline and we discontinued the development of one compound from the pipeline, so that our drug development pipeline as of December 31, 2015 consisted of nine therapeutic candidates. Subsequent to December 31, 2015, we terminated three therapeutic candidates in our pipeline, so that our drug development pipeline of the date of this report consists of six therapeutic candidates.

Comparison of the Year Ended December 31, 2015 to the Year Ended December 31, 2014

Research and development expenses

Research and development expenses for the year ended December 31, 2015 were $11.5 million, a decrease of $0.4 million, or 3.4%, compared to $11.9 million for the year ended December 31, 2014. The decrease results primarily from a decrease in spending on BL-7010 and various other projects, partially offset by increased spending on BL-8040.

Sales and marketing expenses

Sales and marketing expenses for the year ended December 31, 2015 were $1.0 million, a decrease of $0.6 million, or 37.5%, compared to $1.6 million for the year ended December 31, 2014. The decrease resulted primarily from professional fees related to business development activities carried out in 2014, including professional services related to the collaboration agreement with Novartis and the out-licensing agreement with Omega Pharma regarding BL-5010.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2015 were $3.7 million, a decrease of $0.1 million, or 2.6%, compared to $3.8 million for the year ended December 31, 2014. The decrease primarily results from a decrease in salary-related payments, partially offset by a small increase in professional fees.

Non-operating income (expense), net

We recognized net non-operating income of $1.4 million for the year ended December 31, 2015, compared to net non-operating income of $3.1 million for the year ended December 31, 2014. 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 (i.e., warrant revaluation date).

Financial income (expense), net

We recognized net financial income of $0.4 million for the year ended December 31, 2015, compared to net financial income of $3.1 million for the year ended December 31, 2014. Net financial income for 2015 primarily relates to investment income earned on our bank deposits, partially offset by banking fees. The 2014 period includes significant exchange rate differences primarily relating to changes in the USD/NIS exchange rate prior to the adoption of the dollar as our functional and reporting currency, effective as of January 1, 2015.

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 $11.9 million, a decrease of $0.3 million, or 2.5%, compared to $12.2 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 $1.6 million, an increase of $0.5 million, or 45.4%, compared to $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 Pharma regarding BL-5010.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2014 were $3.8 million, an increase of $0.1 million, or 2.7%, compared to $3.7 million for the year ended December 31, 2013. The small increase resulted primarily from an increase in salary-related payments.

Non-operating income (expense), net

We recognized net non-operating income of $3.1 million for the year ended December, 2014, compared to net non-operating income of $1.2 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 (i.e., warrant revaluation date).

Financial income (expense), net

We recognized net financial income of $3.1 million for the year ended December 31, 2014, compared to net financial expenses of $1.2 million for the year ended December 31, 2013. Net financial income and expenses in 2013 and 2014 resulted primarily from changes in the average exchange rate of the dollar in relation to the NIS during the respective periods, prior to the adoption of the dollar as our functional and reporting currency as of January 1, 2015, which had a direct effect on our net assets denominated in dollars during those two years.

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
	2014				2015			
	(in thousands of U.S. dollars)							
Consolidated Statements of Operations								
Revenues	–	–	–	–	–	–	–	–
Cost of revenues	–	–	–	–	–	–	–	–
Research and development expenses, net	(2,719)	(2,792)	(2,975)	(3,380)	(3,211)	(2,891)	(2,576)	(2,811)
Sales and marketing expenses	(367)	(285)	(305)	(632)	(260)	(299)	(265)	(179)
General and administrative expenses	(990)	(834)	(791)	(1,185)	(856)	(976)	(762)	(1,110)
Operating loss	(4,076)	(3,911)	(4,071)	(5,197)	(4,327)	(4,166)	(3,603)	(4,100)
Non-operating income expenses), net	1,687	279	1,380	(285)	(40)	(847)	1,983	349
Financial income, net	355	–	1,991	1,288	73	205	85	98
Financial expenses, net	(81)	(435)	–	–	(17)	(2)	(91)	–
Net loss	(2,115)	(4,067)	(700)	(4,194)	(4,311)	(4,810)	(1,626)	(3,653)
Other comprehensive loss – currency translation differences	(136)	(424)	(2,027)	(1,095)	–	–	–	–
Comprehensive loss	(2,251)	(3,643)	(2,727)	(5,289)	(4,311)	(4,810)	(1,626)	(3,653)

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, funding from the OCS, and payments received under our strategic licensing and collaboration arrangements. At December 31, 2015, we held approximately $47.7 million in cash, cash equivalents and short-term bank deposits. 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 sold an aggregate of approximately $2.6 million of our ADSs to LPC, leaving an available balance under the facility of approximately $17.4 million.

Net cash used in operating activities for the year ended December 31, 2015 was $14.2 million, compared to $15.8 million for the year ended December 31, 2014 and $19.5 million for the year ended December 31, 2013. The decrease in net cash used in operating activities in 2015 was primarily the result of a decrease in our operating loss in 2015. The 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, 2015 was $15.6 million, compared to $19.7 million for the year ended December 31, 2014 and $5.3 million for the year ended December 31, 2013. 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, 2015 was $29.5 million, compared to $32.6 million for the year ended December 31, 2014, and $15.1 million for the year ended December 31, 2013. The cash flows in 2015 primarily reflect the underwritten public offering of our ADSs in March 2015. The cash flows in 2014 primarily reflect the underwritten public offering of our ADSs in March 2014, as well as the investment made by Novartis pursuant to our strategic collaboration agreement with them signed in December 2014. The cash flows in 2013 primarily reflect the direct placement to OrbiMed completed in February 2013, as well as funding under the previous share purchase agreement with LPC.

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, 2015:

	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
	(in thousands of U.S. dollars)				
Car leasing obligations	337	199	138	–	–
Premises leasing obligations	1,024	225	449	351	–
Purchase commitments	2,427	1,400	1,022	4	–
Total	3,788	1,824	1,609	355	–

The premises leasing obligations in the foregoing table include our commitments under the lease agreement for our facility in Modi'in. See "Item 4. Information on the Company — Property, Plant and Equipment." The term of the lease began on June 15, 2015 and will end June 30, 2020. During the lease term, we are obligated to pay initial monthly rental payments of approximately $18,500 and initial monthly parking charges of approximately $1,800. We are furthermore obligated to pay building maintenance charges during the lease term not exceeding approximately $6,700 per month.

The foregoing table does not include our in-licensing agreements. Under our in-licensing agreements, we are obligated to make certain payments to our licensors upon the achievement of agreed upon milestones. We are unable at this time to estimate the actual amount or timing of the costs we will incur in the future under these agreements; however, we do not expect any material 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, 2016. Unless otherwise stated, the address for our directors and officers is c/o BioLineRx Ltd., 2 HaMa'ayan Street, Modi'in 7177871, Israel.

Name	Age	Position(s)
Kinneret Savitsky, Ph.D.	49	Chief Executive Officer
Philip Serlin, CPA, MBA	55	Chief Financial and Operating Officer
Arnon Aharon, M.D.	47	Chief Medical Officer
David Malek, MBA	38	Chief Business Officer
Merril Gersten, M.D., Ph.D	64	Chief Scientific Officer
Aharon Schwartz, Ph.D.	73	Chairman of the Board
Michael J. Anghel, Ph.D.	76	Director
Nurit Benjamini, MBA	49	External Director
B.J. Bormann, Ph.D.	57	Director
Raphael Hofstein, Ph.D.	66	Director
Avraham Molcho, M.D.	58	External Director
Sandra Panem, Ph.D.	69	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). 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.

Arnon Aharon, M.D., has served as our Chief Medical Officer since January 2016. From January 2014 through December 2015, Dr. Aharon served as our Vice President of Medical Affairs. 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 Chief Business Officer since January 2016. From October 2011 through December 2015, Mr. Malek served as of Vice President of Business Development. 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.

Merril Gersten, M.D., Ph.D., has signed an agreement to serve as our Chief Scientific Officer beginning in May 2016. Prior to joining the Company, Dr. Gersten was a post-doctoral research fellow at the Department of Bioengineering of the University of California, San Diego, from 2012 to 2016. Dr. Gersten's experience includes serving as Senior Director, Head of Experimental Medicine at Pfizer Global Research and Development in La Jolla, California, Medical Research Director at Agouron Pharmaceuticals, Medical Director at Lidak Pharmaceuticals and as a consultant assisting Dr. Jonas Salk at the Salk Institute for Biological Sciences in La Jolla. Dr. Gersten holds a Ph.D. in Bioinformatics and Systems Biology from the University of California, San Diego, an M.D. from Cornell University Medical College and a B.A. in chemistry from Barnard College, Columbia University.

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 D-Pharm 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. Ms. Benjamini serves on the board of directors, and as chairperson of the audit committee, of Allot Communications Ltd. (Nasdaq:ALLT, TASE:ALLT) and of RedHill Biopharma Ltd. (NASDAQ:RDHL, TASE:RDHL). 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 Supportive Therapeutics, LLC, a Boston based company that is developing two molecules for use in the supportive care of oncology patients. In the past several years Dr. Bormann has held executive positions in several biotechnology companies including NanoMedical Systems (Austen, Texas), Harbour Antibodies (Rotterdam, The Netherlands) and Pivot Pharmaceuticals (PVTF: OTC listed). Prior to these engagements, Dr. Bormann was Senior Vice President responsible for world-wide alliances, licensing and business development at Boehringer Ingelheim Pharmaceuticals, Inc. from 2007 to 2013. From 1996 to 2007, she served in a number of positions at Pfizer, Inc., the last one being Vice President of Pfizer Global Research and Development and world-wide Head of Strategic Alliances. Dr. Bormann serves on the board of directors of various companies, including Supportive Therapeutics, LLC, 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. She is also co-founder and President of NeuroNetworks Fund, a not-for-profit venture capital fund focusing on epilepsy, schizophrenia and autism. From 1994 to 1999, Dr. Panem was President of Vector Fund Management, the then asset management affiliate of Vector Securities International. Prior thereto, Dr. Panem served as Vice President and Portfolio Manager for the Oppenheimer Global BioTech Fund, a mutual fund that invested in public and private biotechnology companies. Previously, she was Vice President at Salomon Brothers Venture Capital, a fund focused on early and later-stage life sciences and technology investments. Dr. Panem was also a Science and Public Policy Fellow in economic studies at the Brookings Institution, and an Assistant Professor of Pathology at the University of Chicago. Dr. Panem currently serves on the boards of directors of Acorda Therapeutics, Inc. (NASDAQ:ACOR), Labcyte, Inc. and GQLife Sciences, 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, 2015. 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 (USD)	Pension, retirement, options and other similar benefits (USD)
All directors and senior management as a group, consisting of 12 persons	1,292,000	784,000

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, 2015.

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	232	41	94	183	19	569
Philip Serlin, Chief Financial and Operating Officer	170	47	75	71	22	385
David Malek, Vice President of Business Development	143	37	14	70	19	283
Leah Klapper, Chief Scientific Officer [until December 31, 2015]	156	22	-	72	93	343
Arnon Aharon, Vice President of Medical Affairs	139	31	31	46	15	263

(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, 2015.

(3) "All Other Compensation" includes automobile-related expenses pursuant to the Company's automobile leasing program, telephone, basic health insurance and holiday presents. In the case of Leah Klapper, it also includes a severance payment.

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

C. Board Practices

Board of Directors

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

Under the Companies Law, we are not required to have a majority of independent directors. We are required to appoint at least two external directors. 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 March 2015. 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 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 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."

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 "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, 2015, we had 48 employees, all of whom are employed in Israel. Of our employees, 21 hold M.D. or Ph.D. degrees.

	December 31,		
	2013	**2014**	**2015**
Management and administration	13	12	12
Research and development	27	31	32
Sales and marketing	3	3	4

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 1, 2016 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)]	20,836	*
Michael J. Anghel[(2)]	20,836	*
Nurit Benjamini[(3)]	18,750	*
B.J. Bormann[(4)]	19,586	*
Raphael Hofstein[(5)]	40,836	*
Avraham Molcho[(6)]	18,750	*
Sandra Panem[(7)]	17,086	
Executive officers		
Kinneret Savitsky[(8)]	257,220	*
Philip Serlin[(9)]	117,920	*
David Malek[(10)]	70,500	*
Arnon Aharon[(11)]	15,000	*
Merril Gersten	–	–
All directors and executive officers as a group (11 persons)[(12)]	617,320	1.1%

* Less than 1.0%.

(1) Includes 20,836 ordinary shares issuable upon exercise of outstanding options within 60 days of March 1, 2016. Does not include 14,164 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2016.

(2) Includes 20,836 ordinary shares issuable upon exercise of outstanding options within 60 days of March 1, 2016. Does not include 14,164 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2016.

(3) Includes 18,750 ordinary shares issuable upon exercise of outstanding options within 60 days of March 1, 2016. Does not include 1,250 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2016.

(4) Includes 19,586 ordinary shares issuable upon exercise of outstanding options within 60 days of March 1, 2016. Does not include 15,414 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2016.

(5) Includes 40,836 ordinary shares issuable upon exercise of outstanding options within 60 days of March 1, 2016. Does not include 14,164 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2016.

(6) Includes 18,750 ordinary shares issuable upon exercise of outstanding options within 60 days of March 1, 2016. Does not include 1,250 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2016.

(7) Includes 17,086 ordinary shares issuable upon exercise of outstanding options within 60 days of March 1, 2016. Does not include 15,414 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2016.

(8) Includes 91,603 issued ordinary shares and 165,617 ordinary shares issuable upon exercise of outstanding options within 60 days of March 1, 2016. Does not include 241,100 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2016.

(9) Includes 117,920 ordinary shares issuable upon exercise of outstanding options within 60 days of March 1, 2016. Does not include 249,800 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2016.

(10) Includes 70,500 ordinary shares issuable upon exercise of outstanding options within 60 days of March 1, 2016. Does not include 238,100 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2016.

(11) Includes 15,000 ordinary shares issuable upon exercise of outstanding options within 60 days of March 1, 2016. Does not include 235,000 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2016.

(12) Includes 617,320 ordinary shares issuable upon exercise of outstanding options within 60 days of March 1, 2016. Does not include 1,039,820 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 1, 2016.

Equity Compensation Plan

2003 Share Incentive Plan

In 2003, we adopted the BioLineRx Ltd. 2003 Share Incentive Plan, or the Plan. The Plan provides for the granting of options, ordinary shares, restricted stock units and performance stock units to our directors, employees, consultants and service providers, and to the directors, employees, consultants and service providers of our subsidiaries and affiliates. The Plan provides for equity grants to be made at the determination of our Board of Directors in accordance with applicable law. As of December 31, 2015, there were 3.3 million ordinary shares issuable upon the exercise of outstanding options under the Plan. As of March 1, 2016, there were 4.8 million ordinary shares issuable upon the exercise of outstanding options under the Plan.

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

In January 2016, our Board of Directors approved amendments to the Plan in order to permit the granting of restricted stock units, or RSUs, and performance stock units, or PSUs, to eligible grantees.

From time to time, our Board of Directors has approved an increase in the number of shares reserved for the purpose of equity grants pursuant to the Plan. As of December 31, 2015, the number of shares so reserved was 5.3 million.

Administration of Our Share Incentive Plan

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

Options granted under the Plan generally vest over four years, and they expire 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. The right to receive ordinary shares pursuant to PSUs granted under the Plan will vest upon the grantee's achievement of certain performance goals to be established by the Board of Directors.

In the event of a merger, consolidation, reorganization or similar transaction or our voluntary liquidation or dissolution, all of our unexercised vested equity grants and any unvested equity grants will be automatically terminated. However, in the event of a change of control, or merger, consolidation, reorganization or similar transaction resulting in the acquisition of at least 50% of our voting power, or the sale or transfer of all or substantially all of our outstanding shares assets, the equity grants then outstanding may be assumed or substituted for an appropriate number of shares of each class of shares or other securities and/or assets of the successor company in such transaction (or a parent or subsidiary or another affiliate of such successor company) as were distributed to our shareholders in respect of the transaction.

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 1, 2016 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 54,818,057ordinary shares outstanding as of March 1, 2016 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 1, 2016, 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]	5,000,000	9.1
Senvest Management, LLC [2]	3,952,950	7.2
Broadfin Healthcare Master Fund, Ltd.[3]	3,500,000	6.4
Pan Atlantic Bank and Trust Limited[4]	3,480,397	6.3

(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 349,650 ordinary shares issuable upon exercise of outstanding warrants within 60 days of March 1, 2016. Based upon information provided by the shareholder in its Schedule 13G filed with the SEC on February 12, 2016. The securities indicated above are held in the accounts of Senvest Master Fund, L.P., Senvest Israel Partners, L.P., and a separately managed account (collectively with the Senvest Funds, the “Investment Vehicles”). Senvest Management, LLC may be deemed to beneficially own the securities held by the Investment Vehicles by virtue of Senvest Management, LLC's position as investment manager of the Investment Vehicles. Richard Mashaal may be deemed to beneficially own the securities held by the Investment Vehicles by virtue of Mr. Mashaal’s status as the managing member of Senvest Management, LLC. None of the foregoing should be construed in and of itself as an admission by either Senvest Management, LLC or Mr. Mashaal as to beneficial ownership of the securities indicated above. The address of the principal business office of Senvest Management, LLC is 540 Madison Avenue, 32nd Floor, New York, New York 10022.

(3) Based upon information provided by the shareholder in its Schedule 13G filed with the SEC on February 12, 2016. 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.

(4) Includes 700,000 ordinary shares issuable upon exercise of outstanding warrants within 60 days of March 1, 2016. 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.

B. Related Party Transactions

Agreements with Directors and Officers

Employment Agreements

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

Indemnification Agreements

Our Articles of Association and 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 dollars.

	U.S.$ Price Per ADS	
	High	**Low**
Annual:		
2015	2.84	1.23
2014	3.07	1.23
2013	4.75	1.58
2012	5.55	2.23
2011 (from July 25, 2011)	5.44	2.75
Quarterly:		
Fourth Quarter 2015	1.62	1.24
Third Quarter 2015	2.65	1.23
Second Quarter 2015	2.66	1.85
First Quarter 2015	2.84	1.71
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
Most Recent Six Months:		
March 2016 (through March 8, 2016)	1.14	1.03
February 2016	1.10	0.90
January 2016	1.30	0.94
December 2015	1.62	1.25
November 2015	1.45	1.24
October 2015	1.55	1.32
September 2015	1.81	1.50

On March 8, 2016, the last reported sales price of our ADSs on the Nasdaq Capital Market was $1.13 per ADS. As of March 8, 2016 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 dollars. Dollar per ordinary share amounts are calculated using the 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:				
2015	10.23	4.94	2.57	1.27
2014	10.49	4.76	3.01	1.24
2013	17.99	5.90	4.89	1.62
2012	21.15	8.92	5.58	2.32
2011	32.40	11.27	9.12	3.03
Quarterly:				
Fourth Quarter 2015	6.16	5.05	1.58	1.30
Third Quarter 2015	10.21	4.94	2.70	1.27
Second Quarter 2015	9.83	7.36	2.61	1.92
First Quarter 2015	10.23	6.70	2.57	1.72
Fourth Quarter 2014	7.11	4.76	1.81	1.24
Third Quarter 2014	7.33	5.69	2.14	1.56
Second Quarter 2014	8.02	6.76	2.31	1.95
First Quarter 2014	10.49	7.70	3.01	2.21
Most Recent Six Months:				
March 2016 (through March 8, 2016)	4.55	4.08	1.16	1.05
February 2015	4.27	3.67	1.09	0.94
January 2015	5.21	3.68	1.34	0.92
December 2015	6.14	5.08	1.58	1.30
November 2015	6.16	5.05	1.58	1.30
October 2015	6.05	5.37	1.56	1.39
September 2015	7.25	5.78	1.85	1.47

On March 8, 2016, the last reported sales price of our ordinary shares on the TASE was NIS 4.55 per share, or $1.16 per share (based on the exchange rate reported by the Bank of Israel for such date). On March 8, 2016, the exchange rate of the NIS to the dollar was $1.00 = NIS 3.911, as reported by the Bank of Israel. As of March 8, 2016, there were two 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. Articles of Association

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

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

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

Our Articles of Association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Companies Law and must be approved by a resolution duly passed by our shareholders at a general or special meeting by voting on such change in the capital. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings and profits and an issuance of shares for less than their nominal value (under certain circumstances), require a resolution of our Board of Directors and court approval. In May 2015, at an Extraordinary General Meeting of our shareholders, they approved a 1-for-10 reverse share split of our ordinary shares and a corresponding amendment to our Articles of Association, and further approved an increase to our share capital from NIS 7,500,000 divided into 75,000,000 ordinary shares of a nominal value of NIS 0.10 each to NIS 15,000,000 divided into 150,000,000 ordinary shares of nominal value NIS 0.10, and a corresponding amendment to our Articles of Association, effective immediately after the reverse share split became effective.

Dividends

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

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

Election of Directors

Our ordinary shares do not have cumulative voting rights in the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors, other than with respect to the special approval requirements for the election of external directors 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 sold 1,292,601 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.

In cases of pre-clinical projects selected by the JSC (a "Flagged Project"), we will develop these Flagged Projects under the guidance of the JSC, and once these projects reach the IND (i.e., clinical) stage, Novartis will have the right to define the project as a Selected Project under all the same terms as described above.

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 on their taxable income. The regular corporate tax rate in Israel for the year 2013 was 25%, for the years 2014 and 2015 it was 26.5% and it is now set to be 25% for the year 2016 and thereafter. Capital gains derived by an Israeli company are now generally subject to tax at the same rate as the corporate tax rate.

In May 2012, the Israeli Tax Authority, or ITA, approved our eligibility for tax benefits as a "Benefited Enterprise" under the Law for the Encouragement of Capital Investments, 5719-1959, as amended, or Investments Law, with respect to a portion of the consideration deriving from certain of our development programs, or Eligible Projects. Subject to compliance with the applicable requirements, the portion of our undistributed income derived from our Benefited Enterprise programs will be entitled to a seven-year period of tax benefits due to the Company's location in Modi'in (a tax exemption for a period of two years, followed by five years at the Benefited Enterprise tax rate of 25%) commencing in the first year in which we generate taxable income after setting off our losses for Israeli tax purposes from prior years in the amount of approximately $152 million. The seven-year period may not extend beyond 12 years from the beginning of the Benefited Enterprise's election year. We received Benefited Enterprise status with respect to the Eligible Projects in 2009 and 2012 tax years, so depending on when the Benefited Enterprise programs begin to generate taxable income, the benefit period could continue through 2023. However, any distribution of income derived from exempt income sourced in our Benefited Enterprise programs will result in such income being subject to a rate of corporate tax no greater than 25%.

We have the option to transition to a "Preferred Enterprise" regime under the Investments Law with respect to the year 2016 (through May 31, 2016), according to which all of our income which is eligible for benefits under the regime would be subject to flat corporate tax rates of 16% in 2016 and thereafter, whether or not distributed. A transition to a Preferred Enterprise regime may not be reversed.

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

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

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

Taxation of Israeli Resident Corporations on Receipt of Dividends. Israeli resident corporations are generally exempt from Israeli corporate tax for dividends paid on our 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). Different tax rates might apply to dividends sourced from profits attributable to a Preferred Enterprise, but this matter is not currently relevant to the Company.

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

A "substantial shareholder" is generally a person who alone, or together with his relative or another person who collaborates with him on a regular basis, holds, directly or indirectly, at least 10% of any of the "means of control" of the corporation. "Means of control" generally include the right to vote, receive profits, nominate a director or an officer, receive assets upon liquidation, or instruct someone who holds any of the aforesaid rights regarding the manner in which he or she is to exercise such right(s), and all regardless of the source of such right.

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

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

Capital Gains Taxes Applicable to Israeli Resident Shareholders. An individual is subject to a tax at a rate of 25% on 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 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 2016, and it is possible that we will be a PFIC in 2016 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 dollar amount calculated by reference to the exchange rate in effect on the date such dividend is received, regardless of whether the payment is in fact converted into dollars. If the dividend is converted to dollars on the date of receipt, a U.S. Investor generally will not recognize a foreign currency gain or loss. However, if the U.S. Investor converts the NIS into dollars on a later date, the U.S. Investor must include, in computing its income, any gain or loss resulting from any exchange rate fluctuations. The gain or loss will be equal to the difference between (i) the dollar value of the amount included in income when the dividend was received and (ii) the amount received on the conversion of the NIS into dollars. Such gain or loss will generally be ordinary income or loss and United States source for U.S. foreign tax credit purposes. U.S. Investors should consult their own tax advisors regarding the tax consequences to them if we pay dividends in NIS or any other non-U.S. currency.

Subject to certain significant conditions and limitations, including potential limitations under the United States-Israel income tax treaty, any Israeli taxes paid on or withheld from distributions from us and not refundable to a U.S. Investor may be credited against the investor's U.S. federal income tax liability or, alternatively, may be deducted from the investor's taxable income. This election is made on a year-by-year basis and applies to all foreign taxes paid by a U.S. Investor or withheld from 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. 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 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, 2014 and 2015. We were not a PFIC in 2009, 2010 and 2013, and we have not yet determined whether we will be a PFIC in 2016. 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 2016 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 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

Effective January 1, 2015, our reporting and functional currency is the dollar. However, we pay a significant portion of our expenses in NIS, and we expect this to continue. If the dollar weakens against the NIS in the future, there may be a negative impact on our results of operations. The revenues from our current out-licensing and co-development arrangements are payable in dollars and euros. Although we expect our revenues from future licensing arrangements to be denominated primarily in dollars, we are exposed to the currency fluctuation risks relating to the recording of our revenues in currencies other than dollars. For example, if the euro strengthens against the dollar, our reported revenues in dollars may be lower than anticipated. To date, fluctuations in the exchange rates have not materially affected our results of operations or financial condition for the periods under review.

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

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Set forth below is a summary of 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 one 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, 2015.

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

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

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

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2015 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, 2 HaMa'ayan Street, Modi'in 7177871, Israel (Telephone no. +972-8-642-9100) (e-mail: info@BioLineRx.com).

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Registered Public Accounting Firm

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

	Year Ended December 31,	
	2014	**2015**
Services Rendered	(*in thousands of U.S. dollars*)	
Audit Fees[1]	110	110
Audit-Related Fees[2]	13	7
Tax Fees[3]	22	26
All Other Fees	–	–
Total	145	143

(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 "Item 6. Directors, Senior Management and Employees — Board Practices — Board of Directors." The nominations for directors, which are presented to our shareholders, are generally made by our directors, but nominations may be made by one or more of our shareholders as provided in our Articles of Association, under the Companies Law or in an agreement between us and our shareholders. Currently, there is no agreement between us and any shareholder regarding the nomination of directors. In accordance with our Articles of Association, under the Companies Law, any one or more shareholders holding, in the aggregate, either (1) 5% of our outstanding shares and 1% of our outstanding voting power or (2) 5% of our outstanding voting power, may nominate one or more persons for election as directors at a general or special meeting by delivering a written notice of such shareholder's intent to make such nomination or nominations to our registered office. Each such notice must set forth all of the details and information as required to be provided in our Articles of Association.

- *Compensation Committee and Compensation of Officers*. Israeli law, and our 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 under Nasdaq's listing standards related to compensation committee independence and responsibilities; nor do they require that the Company adopt and file a compensation committee charter. Instead, our compensation committee has been established and conducts itself in accordance with provisions governing the composition of and the responsibilities of a compensation committee as set forth in the Companies Law, and is 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, as amended May 31, 2015
2.2[2]	Form of Deposit Agreement dated as of July 21, 2011 among the Registrant, The Bank of New York Mellon, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder
2.3[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, between BioLine Innovations Jerusalem L.P. and B.G. Negev Technologies and Applications Ltd.
4.7[1]	Assignment Agreement entered into as of January 1, 2009 entered into between BioLine Innovations Jerusalem L.P. and the Registrant
4.16†[1]	License Agreement entered into as of November 25, 2007 between BioLine Innovations Jerusalem L.P. and Innovative Pharmaceutical Concepts, Inc.
4.17[11]†	Amended and Restated License and Commercialization Agreement among Ikaria Development Subsidiary One LLC, the Registrant and BioLine Innovations Jerusalem L.P. dated August 26, 2009, as amended and supplemented
4.18	BioLineRx Ltd. Amended and Restated 2003 Share Incentive Plan
4.20[1]	Amendment to Employment Agreement with Kinneret Savitsky, Ph.D., dated January 2, 2004.
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 the Registrant and Biokine Therapeutics Ltd.
4.34[10]	Consulting Agreement with Arnon Aharon, M.D., dated January 1, 2014
4.35[10]†	License Agreement entered into as of February 15, 2011 between the Registrant and Valorisation-Recherche, Limited Partnership
4.36[9]	Executive Compensation Plan
4.37[11]	Lease Agreement entered into as of August 7, 2014 between S.M.L. Solomon Industrial Buildings Ltd. and Infrastructure Management and Development Established by C.P.M. Ltd. as Lessor and the Registrant as Lessee, as amended (English summary of the Hebrew original)
4.38[11]†	Investment and Collaboration Agreement entered into as of December 16, 2014 between the Registrant and Novartis Pharma AG

Exhibit Number	Exhibit Description
4.39[11]†	License Agreement entered into as of December 22, 2014 between the Registrant and Wartner Europe BV
4.40†	Clinical Trial Collaboration and Supply Agreement entered into as of January 11, 2016 between Merck Sharp & Dohme B.V. and the Registrant
4.41	Employment Agreement with Merril Gersten, dated March 1, 2016
12.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1	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 the Registrant and the Purchasers named therein, dated February 2012
15.4[7]	Subscription Agreement entered into as of February 6, 2013 between the Registrant and OrbiMed Israel Partners Limited Partnership
15.5	Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Registrant
15.6[6]	Purchase Agreement entered into as of May 28, 2014 between the Registrant and Lincoln Park Capital Fund, LLC
15.7[6]	Registration Rights Agreement entered into as of May 28, 2014 between the Registrant and Lincoln Park Capital Fund, LLC

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

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

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

(3) Incorporated by reference to the Registrant's Form 6-K filed on February 15, 2012.

(4) Incorporated by reference to the Registrant's Registration Statement on Form F-1 (No. 333-179792) filed on February 29, 2012.

(5) Incorporated by reference to the Registrant's Registration Statement on Form F-3 (No. 333-205700) filed on July 16, 2015.

(6) Incorporated by reference to the Registrant's Form 6-K filed on May 30, 2014.

(7) Incorporated by reference to the Registrant's Form 6-K filed on February 6, 2013.

(8) Incorporated by reference to the Registrant's Form 6-K filed on October 16, 2012.

(9) Incorporated by reference to the Registrant's Form 6-K filed on November 13, 2013.

(10) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 17, 2014.

(11) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 23, 2015.

SIGNATURES

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

BIOLINERX LTD.

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

Date: March 10, 2016

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Audited Consolidated Financial Statements at December 31, 2015 and 2014 and for each of the three years in the period ended December 31, 2015

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders of

BIOLINERX LTD.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, changes in shareholders' equity and cash flows present fairly, in all material respects, the financial position of BioLineRx Ltd. and its subsidiaries at December 31, 2015, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, in conformity with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management's Report on Internal Control over Financial Reporting" appearing under Item 15(b). Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

Without qualifying our opinion above, we draw attention to note 2c, as from January 1, 2015, the Company changed its functional and reporting currency from New Israeli Shekels to US dollars.

Tel-Aviv, Israel
March 8, 2016

/s/ Kesselman & Kesselman
Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers
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BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31,		
		2013(*)	2014	2015
		in USD thousands		
Assets				
CURRENT ASSETS				
Cash and cash equivalents	5	8,899	5,790	5,544
Short-term bank deposits	6	9,319	28,890	42,119
Prepaid expenses		258	221	229
Other receivables	15a	360	257	291
Total current assets		18,836	35,158	48,183
NON-CURRENT ASSETS				
Restricted deposits	13b	165	166	-
Long-term prepaid expenses	15b	49	49	58
Property and equipment, net	7	712	721	2,909
Intangible assets, net	8	253	117	152
Total non-current assets		1,179	1,053	3,119
Total assets		20,015	36,211	51,302
Liabilities and equity				
CURRENT LIABILITIES				
Current maturities of long-term bank loan	9	-	-	93
Accounts payable and accruals:				
Trade	15c	2,289	1,654	1,910
Other	15c	764	1,252	1,137
Total current liabilities		3,053	2,906	3,140
NON-CURRENT LIABILITIES				
Long-term bank loan, net of current maturities	9	-	-	344
Warrants	10c	5,240	1,500	208
Total non-current liabilities		5,240	1,500	552
COMMITMENTS AND CONTINGENT LIABILITIES	13			
Total liabilities		8,293	4,406	3,692
EQUITY	10			
Ordinary shares		640	1,055	1,455
Share premium		134,390	167,331	196,201
Other comprehensive income (loss)		1,418	(1,416)	(1,416)
Capital reserve		9,163	9,800	10,735
Accumulated deficit		(133,889)	(144,965)	(159,365)
Total equity		11,722	31,805	47,610
Total liabilities and equity		20,015	36,211	51,302

(*) See note 2c regarding the presentation of 2013 balance sheet information.

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

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Note	Year ended December 31,		
		2013	2014	2015
		in USD thousands		
RESEARCH AND DEVELOPMENT EXPENSES, NET	15d	(12,208)	(11,866)	(11,489)
SALES AND MARKETING EXPENSES	15e	(1,136)	(1,589)	(1,003)
GENERAL AND ADMINISTRATIVE EXPENSES	15f	(3,664)	(3,800)	(3,704)
OPERATING LOSS		(17,008)	(17,255)	(16,196)
NON-OPERATING INCOME, NET	15g	1,161	3,061	1,445
FINANCIAL INCOME	15h	720	3,566	457
FINANCIAL EXPENSES	15i	(1,897)	(448)	(106)
NET LOSS		(17,024)	(11,076)	(14,400)
OTHER COMPREHENSIVE INCOME (LOSS):				
CURRENCY TRANSLATION DIFFERENCES		1,097	(2,834)	-
COMPREHENSIVE LOSS		(15,927)	(13,910)	(14,400)
		in USD		
LOSS PER ORDINARY SHARE – BASIC AND DILUTED	12	(0.76)	(0.34)	(0.28)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	12	22,488,516	32,433,883	51,406,434

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

BioLineRx Ltd.

STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	Share premium	Capital reserve	Other comprehensive income (loss)	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2013	482	121,998	9,046	321	(116,865)	14,982
CHANGES IN 2013:						
Issuance of share capital, net	157	11,596	-	-	-	11,753
Employee stock options exercised	1	396	(394)	-	-	3
Warrants exercised	-	69	-	-		69
Employee stock options forfeited and expired	-	331	(331)	-	-	-
Share-based compensation	-	-	842	-	-	842
Other comprehensive income	-	-	-	1,097	-	1,097
Comprehensive loss for the year	-	-	-	-	(17,024)	(17,024)
BALANCE AT DECEMBER 31, 2013	640	134,390	9,163	1,418	(133,889)	11,722
CHANGES IN 2014:						
Issuance of share capital, net	415	32,523	-		-	32,938
Employee stock options exercised	-	22	(22)		-	-
Employee stock options forfeited and expired	-	396	(396)		-	-
Share-based compensation	-	-	1,055		-	1,055
Other comprehensive loss	-	-	-	(2,834)	-	(2,834)
Comprehensive loss for the year	-	-	-		(11,076)	(11,076)
BALANCE AT DECEMBER 31, 2014	1,055	167,331	9,800	(1,416)	(144,965)	31,805
CHANGES IN 2015:						
Issuance of share capital, net	400	28,653	-	-	-	29,053
Employee stock options exercised	-	-	-	-	-	-
Employee stock options forfeited and expired	-	217	(217)	-	-	-
Share-based compensation	-	-	1,152	-	-	1,152
Comprehensive loss for the year	-	-	-	-	(14,400)	(14,400)
BALANCE AT DECEMBER 31, 2015	1,455	196,201	10,735	(1,416)	(159,365)	47,610

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

BioLineRx Ltd.

CONSOLIDATED CASH FLOW STATEMENTS

	Year ended December 31,		
	2013	2014	2015
	in USD thousands		
CASH FLOWS - OPERATING ACTIVITIES			
Net loss	(17,024)	(11,076)	(14,400)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(2,501)	(4,674)	232
Net cash used in operating activities	(19,525)	(15,750)	(14,168)
CASH FLOWS - INVESTING ACTIVITIES			
Investments in short-term deposits	(35,665)	(57,186)	(63,130)
Maturities of short-term deposits	29,669	37,650	50,083
Maturities of restricted deposits	795	-	166
Purchase of property and equipment	(85)	(187)	(2,683)
Purchase of intangible assets	(32)	(6)	(36)
Net cash used in investing activities	(5,318)	(19,729)	(15,600)
CASH FLOWS - FINANCING ACTIVITIES			
Issuance of share capital and warrants, net of issuance costs	15,108	32,635	29,053
Proceeds of bank loan	-	-	467
Repayments of bank loan	(37)	-	(31)
Proceeds from exercise of employee stock options	3	-	-
Net cash provided by financing activities	15,074	32,635	29,489
DECREASE IN CASH AND CASH EQUIVALENTS	(9,769)	(2,844)	(279)
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	18,307	8,899	5,790
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	361	(265)	33
CASH AND CASH EQUIVALENTS - END OF YEAR	8,899	5,790	5,544

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

BioLineRx Ltd.

CONSOLIDATED CASH FLOW STATEMENTS

	Year ended December 31,		
	2013	2014	2015
	in USD thousands		
APPENDIX			
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization	318	269	441
Write-off of intangible assets	38	105	-
Retirement benefit obligations	2	(42)	-
Long-term prepaid expenses	10	(6)	(9)
Exchange differences on cash and cash equivalents	653	(261)	(33)
Warrant issuance costs	130	-	-
Gain on adjustment of warrants to fair value	(1,432)	(3,454)	(1,292)
Commitment fee paid by issuance of share capital	-	303	-
Share-based compensation	842	1,055	1,152
Interest and exchange differences on short-term deposits	395	(2,787)	(182)
Interest and linkage differences on bank loan	(3)	-	1
Interest and exchange differences on restricted deposits	11	(20)	-
	964	(4,838)	78
Changes in operating asset and liability items:			
Decrease (increase) in trade accounts receivable and other receivables	253	80	(42)
Increase (decrease) in accounts payable and accruals	(3,718)	84	196
	(3,465)	164	154
	(2,501)	(4,674)	232
Supplementary information on investing and financing activities not involving cash flows:			
Credit received in connection with purchase of property and equipment	-	143	87
Supplementary information on interest received in cash	139	97	173

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

NOTE 1 – GENERAL INFORMATION

a. General

BioLineRx Ltd. ("BioLineRx"), headquartered in Modi'in, 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 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. BIJ Ltd. was liquidated in 2015. See Note 13a(1).

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

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. Approval of consolidated financial statements

The consolidated financial statements of the Company for the year ended December 31, 2015 were approved by the Board of Directors on March 8, 2016, 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, 2015 and 2014, and for each of the three years in the period ended December 31, 2015, 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.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

a. Basis of presentation (cont.)

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 reporting currency

Effective January 1, 2015, the Company changed its functional currency to the U.S. dollar ("dollar", "USD" or "$") from the New Israeli Shekel ("NIS"). This change was based on an assessment by Company management that the dollar is the primary currency of the economic environment in which the Company operates. Accordingly, the functional and reporting currency of the Company in these financial statements is the U.S. dollar.

In determining the appropriate functional currency to be used, the Company followed the guidance in International Accounting Standard (IAS) 21, which states that economic factors relating to sales, costs and expenses, financing activities and cash flows, as well as other potential factors, should be considered both individually and collectively. In this regard, a significant element in the Company's decision to effect the functional currency change resulted from the strategic collaboration agreement that it entered into with Novartis in December 2014, which will be managed solely in dollars. In addition, the Company expects a significant increase in expenses denominated in dollars relating to advanced clinical trials. These changes, as well as the fact that the Company's principal source of financing is the U.S. capital market, and all of the Company's budgeting and planning is conducted solely in dollars, led to the decision to make the change in functional currency as of January 1, 2015, as indicated above.

In effecting the change in functional currency to the dollar, as of January 1, 2015, all assets and liabilities of the Company were translated using the current rate method, using the dollar exchange rate as of December 31, 2014, and equity was translated using historical exchange rates at the relevant transaction dates. The resulting amounts translated into dollars for non-monetary items have been treated as their historical cost. Translation differences resulting from the change in functional currency have been reported as a component of shareholders' equity.

In accordance with paragraph 40 of IAS 1, due to the aforementioned change in functional currency, an additional balance sheet as of December 31, 2013 has been presented in the financial statements. IAS 1 does not require such additional information in the detailed financial statement notes.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

c. Functional and reporting currency (cont.)

For presentation purposes, comparative figures in these financial statements have been translated into dollars on the following basis: (i) assets and liabilities have been translated using the exchange rate prevailing at December 31, 2014; (ii) the statement of comprehensive loss has been translated at the average exchange rates for the relevant reporting periods; and (iii) the results of translation differences have been recorded as "currency translation differences" within other comprehensive income (loss).

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 shorter of the lease term or 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 receivables," "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 bank deposits 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 13b.

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 and reverse split of ordinary shares

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.

In June 2015, BioLineRx effected a 1:10 reverse split of its ordinary shares. All share and per share amounts in these financial statements have been retroactively adjusted to reflect the reverse split as if it had been effected prior to the earliest financial statement period included herein. Following the reverse split, one ordinary share traded on the TASE is equivalent to one ADS traded on NASDAQ (prior to the split, the ratio of ordinary shares to ADSs was 10:1). In connection with the reverse split, shareholders also approved an increase in BioLineRx's authorized share capital to 150,000,000 ordinary shares, NIS 0.10 par value each.

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. These payables are classified as current liabilities if payment is due within one year or less. If not, they are presented as non-current liabilities. Trade payables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method.

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, 2015, 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 13a(1), and in the form of grants, as described in Note 13a(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 employment agreements require the Company to pay retirement benefits to employees terminated or leaving their employment in certain other circumstances. Most of the Company's employees are covered by a defined contribution plan under Section 14 of the Israel Severance Pay Law.

With respect to the remaining employees, the Company records a liability on its balance sheet for defined benefit plans that represents the present value of the defined benefit obligation as of each reporting date, net of the fair value of plan assets. The present value of the defined benefit liability is determined by discounting the anticipated future cash outflows, using interest rates that are denominated in the currency in which the benefits will be payable.

The amounts recorded as an employee benefit expense in respect of pension and severance pay obligations for the years 2013, 2014 and 2015 were $484,000, $465,000 and $466,000, 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 2013, 2014 and 2015, 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, 2015:

- Annual Improvements to IFRSs – 2010-2012 Cycle; 2011-2013 Cycle
- Defined Benefit Plans: Employee Contributions – Amendments to IAS 19

The adoption of these amendments did not have any impact on the current period or any prior period and is not likely to affect future periods.

In addition, the Company also elected to early adopt the following two amendments:

- Annual Improvements to IFRSs – 2012-2014 Cycle
- Disclosure Initiative: Amendments to IAS 1.

As these amendments merely clarify the existing requirements, they do not affect the Company's accounting policies or any of the disclosures.

New standards and interpretations not yet adopted

Certain new accounting standards and interpretations have been published that are not mandatory for reporting period prior to January 1, 2016, and have not been early adopted by the Company. The Company's assessment of the impact of these new standards and interpretations is set out below.

IFRS 9, "Financial Instruments", addresses the classification, measurement and derecognition of financial assets and financial liabilities and introduces new rules for hedge accounting, and it must be applied for financial years commencing on or after January 1, 2018. In July 2014, the IASB made further changes to the classification and measurement rules and also introduced a new impairment model. These latest amendments now complete the new financial instruments standard.

Following the changes approved by the IASB in July 2014, the Company no longer expects any impact from the new classification, measurement and derecognition rules on the Company's financial assets and financial liabilities. In addition, while the Company has yet to undertake a detailed assessment of the debt instruments currently classified as available-for-sale financial assets, it would appear that they would satisfy the conditions for classification as at fair value through other comprehensive income (FVOCI) based on their current business model for these assets. Hence there will be no change to the accounting for these assets. There will also be no impact on the Company's accounting for financial liabilities, as the new requirements only affect the accounting for financial liabilities that are designated at fair value through profit or loss and the Company does not have any such liabilities.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

t. Changes in accounting policy and disclosures (cont.)

The new hedging rules align hedge accounting more closely with the Company's risk management practices. As a general rule it will be easier to apply hedge accounting going forward as the standard introduces a more principles-based approach. The new standard also introduces expanded disclosure requirements and changes in presentation. The new impairment model is an expected credit loss (ECL) model which may result in the earlier recognition of credit losses. The Company has not yet assessed how its own hedging arrangements and impairment provisions would be affected by the new rules.

IFRS 15, "Revenue from Contracts with Customers", is a new standard for the recognition of revenue issued by the IASB. This will replace IAS 18 which covers contracts for goods and services and IAS 11 which covers construction contracts. The standard permits a modified retrospective approach for the adoption. Under this approach, entities will recognize transitional adjustments in retained earnings on the date of initial application (January 1, 2017) – i.e., without restating the comparative period; and will only need to apply the new rules to contracts that are not completed as of the date of initial application.

The new standard is based on the principle that revenue is recognized when control of a good or service transfers to a customer – i.e., the notion of control replaces the existing notion of risks and rewards. Management is currently assessing the impact of the new rules and has identified the following areas that are likely to be affected:

- extended warranties, which will need to be accounted for as separate performance obligations, which will delay the recognition of a portion of the revenue
- consignment sales where recognition of revenue will depend on the passing of control rather than the passing of risks and rewards
- the balance sheet presentation of rights of return, which will have to be grossed up in future (separate recognition of the right to recover the goods from the customer and the refund obligation)

In January 2016, the IASB issued IFRS 16, "Leases", which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract and replaces the previous lease standard, IAS 17, "Leases". IFRS 16 eliminates the classification of leases for the lessee as either operating leases or finance leases as required by IAS 17, and instead introduces a single lessee accounting model whereby a lessee is required to recognize assets and liabilities for all leases with a term that is greater than 12 months, unless the underlying asset is of low value, and to recognize amortization of lease assets separately from interest on lease liabilities in the income statement. IFRS 16 is effective from January 1, 2019, with early adoption allowed only if IFRS 15, " Revenue from Contracts with Customers," is also applied.

At this stage, the Company is not able to estimate the impact of the new rules on the Company's financial statements. The Company will make more detailed assessments of the impact over the next twelve months.

There are no other standards that are not yet effective and that would be expected to have a material impact on the Company in the current or future reporting periods and on foreseeable future transactions.

NOTE 3 – FINANCIAL RISK MANAGEMENT

Based on assessments by Company management, the Company's exposure to credit risk as of December 31, 2015 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 non-dollar currencies (primarily the NIS), which exposes the Company to risks resulting from changes in exchange rates.

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

	December 31, 2015				
	Income (loss)		Value on	Income (loss)	
Sensitive instrument	10% increase	5% increase	balance sheet	5% decrease	10% decrease
	in USD thousands				
NIS-linked balances:					
Cash and cash equivalents	(199)	(104)	2,192	244	115
Other receivables	(24)	(13)	266	30	14
Trade payables	34	18	(374)	(42)	(20)
Other payables	103	54	(1,137)	(126)	(60)
Total NIS-linked balances	(86)	(45)	947	106	49
Euro-linked trade payables	(16)	(8)	(169)	19	9
Total	(102)	(53)	778	125	58

* See also Note 13b.

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

	December 31, 2014				
	Income (loss)		Value on	Income (loss)	
Sensitive instrument	10% increase	5% increase	balance sheet	5% decrease	10% decrease
	in USD thousands				
NIS-linked balances:					
Cash and cash equivalents	(215)	(112)	2,360	262	124
Other receivables	(23)	(12)	257	29	14
Trade payables	51	27	(558)	(62)	(29)
Other payables	114	60	(1,252)	(139)	(66)
Total NIS-linked balances	(73)	(37)	807	90	43
Euro-linked trade payables	19	10	(208)	(23)	(11)
Total	(54)	(27)	599	67	32

* See also Note 13b.

NOTE 3 – FINANCIAL RISK MANAGEMENT (cont.)

a. Market risk (cont.)

1) Concentration of currency risk (cont.)

Set forth below is certain data regarding dollar exchange rates and the Israeli CPI:

	Exchange rate of NIS per $1	Exchange rate of Euro per $1	Israeli CPI*
	USD	USD	Points
As of December 31:			
2014	3.889	0.823	132.78
2015	3.902	0.919	131.45
Percentage increase (decrease) in:			
2014	12.0%	13.0%	(0.2)%
2015	0.3%	11.7%	(1.0)%

* 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, 2014			December 31, 2015		
	Dollar	NIS	Other currencies	Dollar	NIS	Other currencies
	USD in thousands					
Assets:						
Current assets:						
Cash and cash equivalents	3,423	2,360	7	3,352	2,192	-
Short term bank deposits	28,890	-	-	42,119	-	-
Other receivables	-	257	-	-	266	25
Non-current assets:						
Restricted deposits	166	-	-	-	-	-
Total assets	32,479	2,617	7	45,471	2,458	25
Liabilities:						
Current liabilities:						
Current maturities of bank loan	-	-	-	93	-	-
Accounts payable and accruals:						
Trade	831	558	265	1,218	374	318
Other	-	1,252	-	-	1,137	-
Non-current liabilities						
Long-term bank loan, net of current maturities	-	-	-	344	-	-
	831	1,810	265	1,655	1,511	318
Net asset value	31,648	807	(258)	43,816	947	(293)

	December 31, 2014			December 31, 2015		
	Dollar	NIS	Other currencies	Dollar	NIS	Other currencies
	USD in thousands					
Assets:						
Current assets:						
Cash and cash equivalents	3,423	2,360	7	3,352	2,192	-
Short term bank deposits	28,890	-	-	42,119	-	-
Other receivables	-	257	-	-	266	25
Non-current assets:						
Restricted deposits	166	-	-	-	-	-
Total assets	32,479	2,617	7	45,471	2,458	25
Liabilities:						
Current liabilities:						
Current maturities of bank loan	-	-	-	93	-	-
Accounts payable and accruals:						
Trade	831	558	265	1,218	374	318
Other	-	1,252	-	-	1,137	-
Non-current liabilities						
Long-term bank loan, net of current maturities	-	-	-	344	-	-
	831	1,810	265	1,655	1,511	318
Net asset value	31,648	807	(258)	43,816	947	(293)

NOTE 3 – FINANCIAL RISK MANAGEMENT (cont.)

a. Market risk (cont.)

2) Fair value of financial instruments

As of December 31, 2015, 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 10c(1), 10c(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, 2014 and 2015 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,	
	2014	2015
	in USD thousands	
Assets:		
Cash and cash equivalents	5,790	5,544
Short-term bank deposits	28,890	42,119
Other receivables	257	291
Restricted deposits	166	-
Total	35,103	47,954

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 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, 2014 and 2015, 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 10c. 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, 2015, the foregoing conditions have not been met and therefore development expenses have not been capitalized for any project.

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

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 13a(1) and 13a(2) with regard to the potential amount repayable to the OCS as of December 31, 2015.

NOTE 5 – CASH AND CASH EQUIVALENTS

	December 31,	
	2014	**2015**
	in USD thousands	
Cash on hand and in bank	2,233	747
Short-term bank deposits	3,557	4,797
	5,790	5,544

The short-term bank deposits included in cash and cash equivalents bear interest at annual rates of between 0.06% and 0.30%. 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 1.41%.

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 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	2012	2013
	In USD thousands				In USD thousands				In USD thousands	
Composition in 2013										
Office furniture and equipment	233	-	-	233	79	13	-	92	155	141
Computers and communications equipment	432	37	(120)	349	327	74	(120)	281	105	68
Laboratory equipment, net*	1,365	40	(842)	563	858	156	(842)	172	507	391
Leasehold improvements	1,099	-	(908)	191	1,050	14	(908)	156	49	35
	3,129	77	(1,870)	1,336	2,314	257	(1,870)	701	816	635
*Item is net of OCS grants received - see 13a(1)	579	-	-	579	549	24	-	573	30	5

	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
	In USD thousands				In USD thousands				In USD thousands	
Composition in 2014										
Office furniture and equipment	233	-	-	233	92	13	-	105	141	128
Computers and communications equipment	349	40	-	389	281	53	-	334	67	55
Laboratory equipment, net*	563	63	-	626	172	156	-	328	392	298
Leasehold improvements	191	213	-	404	156	8	-	164	35	240
	1,336	316	-	1,652	701	230	-	931	635	721
*Item is net of OCS grants received – see 13a(1)	579	-	-	579	573	5	-	578	5	1

NOTE 7 – PROPERTY AND EQUIPMENT (cont.)

	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, 2014	December 31, 2015
	In USD thousands				In USD thousands				In USD thousands	
Composition in 2015										
Office furniture and equipment	233	177	(212)	198	105	120	(212)	13	128	185
Computers and communications equipment	389	78	(21)	446	334	42	(21)	355	55	91
Laboratory equipment, net*	626	568	-	1,194	328	154	-	482	298	712
Leasehold improvements	404	1,791	(170)	2,025	164	110	(170)	104	240	1,921
	1,652	2,614	(403)	3,863	931	426	(403)	954	721	2,909
*Item is net of OCS grants received – see 13a(1)	579	-	-	579	578	1	-	579	1	-

NOTE 8 – INTANGIBLE ASSETS

	Cost				Accumulated depreciation and impairment				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	2011	2013
	In USD thousands				In USD thousands				In USD thousands	
Composition in 2013										
Intellectual property	422	-	(35)	387	193	-	-	193	229	194
Computer software	309	25	(62)	272	265	37	(62)	240	44	32
	731	25	(97)	659	458	37	(62)	433	273	226

	Cost				Accumulated depreciation and impairment				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
	In USD thousands				In USD thousands				In USD thousands	
Composition in 2014										
Intellectual property	387	-	(194)	193	193	-	(97)	96	194	97
Computer software	272	5	-	277	240	17	-	257	32	20
	659	5	(194)	470	433	17	(97)	353	226	117

	Cost				Accumulated depreciation and impairment				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	2014	2015
	In USD thousands				In USD thousands				In USD thousands	
Composition in 2015										
Intellectual property	193	-	-	193	96	-	-	96	97	97
Computer software	277	51	-	328	257	16	-	273	20	55
	470	51	-	521	353	16	-	369	117	152

During 2013, the Company wrote-off intellectual property in the total amount of $35,000 in respect of the termination of BL-5040. During 2014, the Company wrote-off intellectual property in the total amount of $97,000 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 – LONG-TERM BANK LOAN

a. Composition

	December 31,	
	2014	2015
	In USD thousands	
Loan balance	-	437
Less current maturities	-	(93)
	-	344

The loan is denominated in USD and bears interest at an annual rate of 3.75%. The book value of the loan approximates its fair value.

The loan is repayable in 60 monthly installments and is collateralized by certain lab equipment.

b. Future repayments

Future repayments of the long-term bank loan (other than current maturities) in the years subsequent to the balance sheet date are as follows (in USD thousands):

2017	93
2018 thru 2020	251
	344

NOTE 10 – EQUITY

a. Share capital

As of December 31, 2015 and 2014, share capital is composed of ordinary shares, as follows:

	Number of Ordinary Shares	
	December 31,	
	2014*	2015
Authorized share capital	75,000,000	150,000,000
Issued and paid-up share capital	39,115,051	54,818,057

	In USD and NIS	
	December 31,	
	2014	2015
Authorized share capital (in NIS)	7,500,000	15,000,000
Issued and paid-up share capital (in NIS)	3,911,505	5,481,806
Issued and paid-up share capital (in USD)	1,054,851	1,455,159

* Number of ordinary shares for 2014 reflects, on a retroactive basis, the 1:10 reverse split carried out by BioLineRx in June 2015. See Note 2L.

As of December 31, 2015, the market price on NASDAQ of BioLineRx's ADSs was $1.30, and the market price on the Tel Aviv Stock Exchange of BioLineRx's ordinary shares was NIS 5.12.

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, 2015 and 2014, all outstanding share capital consisted of ordinary shares.

NOTE 10 – EQUITY (cont.)

c. Changes in the Company's equity

1) In February 2012, BioLineRx issued in a private placement warrants to purchase up to 2,622,157 ADSs at an exercise price of $3.57 per ADS. 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 of the issuance date, based on their fair value as calculated on the basis of the Black-Scholes model. The changes in fair value for the years ended December 31, 2013, 2014 and 2015, of approximately $100,000, $2,000,000 and $700,000, 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. 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 reflected 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 years ended December 31, 2014 and 2015, amounting to approximately $1,600,000, $1,100,000, and $600,000, respectively, has been recorded as non-operating income on the statement of comprehensive loss.

NOTE 10 – EQUITY (cont.)

c. Changes in the Company's equity (cont.)

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, after deducting fees and expenses.

4) In March 2015, the Company completed an underwritten public offering of 14,375,000 ADSs at a public offering price of $2.00 per ADS. The offering raised a total of $28.8 million, with net proceeds of approximately $26.4 million, after deducting fees and expenses.

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, as well as an initial finder's fee, in cash, to Oberon Securities, LLC Additional commitment and finder's fees associated with the agreement, payable only upon the issuance of shares, were recorded as issuance expenses against share premium on the statement of financial position.

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 10 – 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.

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.

During the year ended December 31, 2015 and on a cumulative basis, BioLineRx sold a total of 1,292,601 ADSs to LPC for aggregate gross proceeds of $2,643,000. In connection with these issuances, a total of 32,315 ADSs was issued to LPC as a commitment fee and a total of $53,000 was paid to Oberon Securities as a finder's fee.

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. 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, 2015, there were 3,560,152 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 10 – 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.

In November 2014 and December 2015, the Company's Board of Directors approved increases of 1.6 million and 5.0 million shares, respectively, to the total pool of authorized ordinary shares reserved for purposes of the Plan and any other present or future share incentive plans of the Company, bringing the pool to an aggregate of 9.6 million shares. As of December 31, 2015, there were 5.3 million remaining authorized but unissued ordinary shares in the pool reserved for future share-based incentive grants.

NOTE 10 – 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,					
	2013		2014		2015	
	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	1,293,602	13.2	1,861,280	12.0	3,187,092	9.1
Granted	755,800	9.7	1,478,200	5.7	500,800	6.8
Forfeited and expired	(162,976)	13.5	(150,985)	13.0	(187,630)	11.1
Exercised	(25,146)	4.0	(1,403)	4.0	-	-
Outstanding at end of year	1,861,280	12.0	3,187,092	9.1	3,500,262	8.7
Exercisable at end of year	273,780	20.4	641,960	15.1	1,169,540	12.6

The total consideration received from the exercise of stock options during 2013, 2014 and 2015 was not material.

The weighted average prices of BioLineRx's shares on the dates of exercise were NIS 0.78 and NIS 0.77 for 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,					
	2013		2014		2015	
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 10.00	250,889	6.12	1,717,686	6.61	2,117,886	5.76
10.01-20.00	1,547,594	5.78	1,406,609	4.84	1,334,866	3.81
20.01-30.00	10,903	2.82	10,903	1.82	10,340	0.88
30.01-40.00	11,125	1.56	11,125	2.36	10,000	1.55
Over 40.00	40,770	2.24	40,770	1.34	27,170	1.00
	1,861,280	5.70	3,187,092	5.73	3,500,262	4.96

NOTE 10 – EQUITY (cont.)

e. Share-based payments (cont.)

2) Employee stock options (cont.)

The fair value of all options granted to employees through December 31, 2015 has been determined using the Black-Scholes option-pricing model. These values are based on the following assumptions as of the applicable grant dates:

	2013	2014	2015
Expected dividend yield	0%	0%	0%
Expected volatility	69%	65%	68%
Risk-free interest rate	2%	2%	2%
Expected life of options (in years)	7	5	5

3) Stock options to consultants

From inception through December 31, 2012, the Company issued to consultants options for the purchase of 76,523 ordinary shares at a weighted average exercise price of NIS 21.54 per share.

In 2015, the Company issued options to consultants for the purchase of 5,000 ordinary shares at a weighted average exercise price of NIS 7.62 per share. No options were issued to consultants in 2013 and 2014.

The options to consultants generally vest over four years and may be exercised for periods of between five and ten years. As of December 31, 2015, 59,890 options to consultants were outstanding, with a weighted average exercise price of NIS 21.9 per share and a weighted average contractual life of 1.68 years.

Company management estimates the fair value of the options granted to consultants based on the value of services received over the vesting period of the applicable options. The value of such services (primarily in respect of clinical advisory services) is estimated based on the additional cash compensation the Company would need to pay if such options were not granted. The value of services recorded in 2013, 2014 and 2015 amounted to $40,000 each year.

NOTE 11 – 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 2013, and 26.5% in 2014 and 2015. The corporate tax rates for 2016 and thereafter are currently set at 25%. Capital gains are generally subject to tax at the same rate as the corporate tax rate.

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 two years, followed by five years at the Benefited Enterprise tax rate of 25%, commencing in the first year in which BioLineRx generates taxable income after setting off losses for Israeli tax purposes from prior years (see c. below). The seven-year period may not extend beyond 12 years from the beginning of the Benefited Enterprise's election year. BioLineRx received Benefited Enterprise status with respect to Eligible Projects in the 2009 and 2012 tax years, so depending on when the Benefited Enterprise programs begin to generate taxable income, the benefit period could continue through 2023. However, any distribution of income derived from exempt income sourced in the Benefited Enterprise programs will result in such income being subject to a rate of corporate tax no greater than 25%.

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 16%, whether or not distributed. 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 25%.

NOTE 11 – TAXES ON INCOME (cont.)

c. Tax loss carryforwards

As of December 31, 2014 and 2015, the tax loss carryforwards of BioLineRx were approximately $135 million and $152 million, respectively. The tax loss carryforwards have no expiration date.

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

d. Tax assessments

In accordance with Israeli tax regulations, the tax returns filed by BioLineRx and BIJ Ltd. through the 2011 tax year are considered final.

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,					
	2013		2014		2015	
		USD in thousands		USD in thousands		USD in thousands
Loss before taxes	25%	(17,024)	26.5%	(11,076)	26.5%	(14,400)
Theoretical tax benefit		(4,256)		(2,935)		(3,816)
Disallowed deductions (tax exempt income):						
Gain on adjustment of warrants to fair value		(358)		(915)		(342)
Share-based compensation		211		280		305
Other		18		15		14
Increase in taxes for tax losses and timing differences incurred in the reporting year for which deferred taxes were not created		4,385		3,555		3,839
Taxes on income for the reported year		-		-		-

NOTE 12 – LOSS PER SHARE

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

	Year ended December 31,		
	2013	2014	2015
	In USD thousands		
Loss attributed to ordinary shares	(17,024)	(11,076)	(14,400)
Number of shares used in basic calculation (in thousands)	22,488	32,434	51,406
	in USD		
Basic loss per ordinary share	(0.76)	(0.34)	(0.28)
Diluted loss per ordinary share	(0.76)	(0.34)	(0.28)

NOTE 13 – COMMITMENTS AND CONTINGENT LIABILITIES

a. Commitments

1) Agreement with the State of Israel for operation of the Incubator

Pursuant to an agreement with the State of Israel, the Company operated the Incubator from January 1, 2005 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.

As of December 31, 2015, 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 13 – 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 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 participation by the OCS in the project to the total project costs incurred by the Company. As of December 31, 2015, the contingent liability for potential royalties payable by the Company for OCS grants received (other than BL-8040 – see below) amounts to $0.2 million.

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 $2.7 million as of December 31, 2015. 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 13 – 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 on a broad basis worldwide, and if the Company decides not to initiate or continue a patent registration proceeding in a given country, the Company is required to notify the applicable licensor to this effect and the licensor is entitled to take action for registration of the patent in such country.

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) payments through the early stages of development (i.e. through the end of phase 2) of up to $150,000; (c) payments of up to $2,000,000 upon the achievement of milestones necessary for advancing to phase 3; (d) payments of up to $5,000,000 from the end of a successful phase 3 trial through approval of the therapeutic compound; and e) royalties on sales of the final product resulting from development under the license or including any component thereof, ranging between 3%-5% of the Company's net sales of the product, although in specific instances the royalty rate has been higher or lower than this range. In instances where the Company has outlicensed the product for further development, the Company pays a percentage of the net consideration received from the licensee ("Sublicense Receipts") to the upstream licensor that generally range from 20% to 29.5% of such consideration , although in specific instances the percentage paid has been higher or lower than this range. These Sublicense Receipts generally take the place of most or all of the milestone and royalty payments set forth in (b) through (e) above.

NOTE 13 – 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) In August 2014, the Company entered into an operating lease agreement in connection with the lease of new premises. Payments under the new lease commenced in June 2015 and will expire in June 2020. The monthly lease fee is approximately $27,000 (including maintenance fees and parking). 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 guarantees provided to secure the Company's liability under the lease agreements, see Note 13b.

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 $240,000. 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 15b.

NOTE 13 – 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. Amounts recognized as a reduction of research and development expenses in 2013 related to the EDP program were $669,000.

b. Contingent liabilities

Guarantees and liens:

To secure the Company's lease obligation on its premises, the Company has provided a bank guarantee in the amount of $100,000 for the benefit of the lessor, which was outstanding as of December 31, 2015. As of December 31, 2014, the Company had pledged several dollar-denominated bank deposits in the aggregate amount of $166,000 to secure the lease on its premises.

See Note 9a regarding equipment pledged as collateral to secure a bank loan.

NOTE 14 – TRANSACTIONS AND BALANCES WITH RELATED PARTIES

Transactions with related parties

Expenses (income):

	Year ended December 31,		
	2013	2014	2015
	In USD thousands		
Participation in EDP project funding*	(669)	-	-
Benefits to related parties:			
Compensation and benefits to senior management, including benefit component of option grants	1,590	2,084	1,843
Number of individuals to which this benefit related	5	5	5
Compensation and benefits to directors, including benefit component of option grants	192	218	233
Number of individuals to which this benefit related	6	7	7

* This amount relates to a grant received from Pan Atlantic, in accordance with the EDP Agreement as detailed in Note 13a(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,		
	2013	2014	2015
	In USD thousands		
Salaries and other short-term employee benefits	1,271	1,704	1,412
Post-employment benefits	121	130	120
Other long-term benefits	16	30	27
Share-based compensation	374	438	517
	1,782	2,302	2,076

NOTE 15 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

a. Other receivables

	December 31,	
	2014	2015
	In USD thousands	
Institutions	250	255
Income receivables	-	26
Other	7	10
	257	291

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,	
	2014	2015
	In USD thousands	
1) Trade:		
Accounts payable:		
In Israel	558	374
Overseas	1,096	1,536
	1,654	1,910
2) Other:		
Payroll and related expenses	361	209
Accrual for vacation and recreationpay	277	213
Accrued expenses	610	705
Other	4	10
	1,252	1,137

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

NOTE 15 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (cont.)

d. Research and development expenses – net

	Year ended December 31,		
	2013	**2014**	**2015**
	In USD thousands		
Payroll and related expenses, including vehicles	3,545	3,771	3,754
Depreciation and amortization	226	253	414
Write-off of intellectual property	38	97	-
Research and development services	7,078	6,050	5,455
Professional fees	1,082	682	772
Materials	17	18	39
Overseas travel	13	12	2
Lab, occupancy and telephone	878	940	926
Other	63	43	127
	12,940	11,866	11,489
Less – OCS participation in research and development costs - see also Notes 13a(1) and (2)	(63)	-	-
Less – participation in research and development costs by a related party - see Note 14	(669)	-	-
	12,208	11,866	11,489

e. Sales and marketing expenses

	Year ended December 31,		
	2013	**2014**	**2015**
	In USD thousands		
Payroll and related expenses, including vehicles	486	668	690
Marketing	554	799	243
Overseas travel	96	122	70
	1,136	1,589	1,003

NOTE 15 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (cont.)

f. General and administrative expenses

	Year ended December 31,		
	2013	**2014**	**2015**
	In USD thousands		
Payroll and related expenses, including vehicles	1,900	2,283	2,003
Professional fees	1,159	884	1,053
Office supplies and telephone	15	14	13
Office maintenance	18	17	30
Insurance	142	146	155
Depreciation	91	16	27
Other	339	440	423
	3,664	3,800	3,704

g. Non-operating income, net

	Year ended December 31,		
	2013	**2014**	**2015**
	In USD thousands		
Issuance costs	(271)	(103)	-
Changes in fair value of warrants	1,432	3,454	1,292
Cost reimbursement related to prior year	-	-	153
Initial commitment and finder’s fees associated with LPC agreement	-	(290)	-
	1,161	3,061	1,445

h. Financial income

	Year ended December 31,		
	2013	**2014**	**2015**
	In USD thousands		
Income from interest and exchange differences on deposits	720	3,566	457

i. Financial expenses

	Year ended December 31,		
	2013	**2014**	**2015**
	In USD thousands		
Exchange differences	1,877	428	91
Bank commissions	20	20	15
	1,897	448	106

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 OTC rights to BL-5010 in the United States and the rest of the world, as well as the non-OTC rights on a global basis. Under 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 – OTHER OUT-LICENSING AGREEMENTS

a. Agreement with Bellerophon

In 2009, the Company entered into an out-licensing agreement with Bellerophon BCM, LLC ("Bellerophon"), 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. 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) may reach up to $282,500,000, subject to the achievement of certain milestones. The Company has received payments totaling $17,000,000 since 2009. Approximately 50% of the remaining payments are subject to development and regulatory milestones and the rest are subject to commercialization milestones. The abovementioned 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).

In July 2015, Bellerophon reported top-line results from the clinical trial it had been conducting, which showed no statistically significant difference between patients treated with BL-1040 versus placebo for both the primary and the secondary endpoints of the study. The Company has not yet received formal notification from Bellerophon about its plans regarding the future of its development program for BL-8040.

The Company is required to pay to the licensors of the BL-1040 compound 28% of all consideration received under the agreement.

b. CTTQ Agreement

In June 2014, 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. In January 2016, CTTQ notified the Company of its intention to terminate the agreement, which will take effect in April 2016.

NOTE 19 – EVENT SUBSEQUENT TO THE BALANCE SHEET DATE

In January 2016, the Company announced a collaboration with MSD, known as Merck in the US and Canada, in the field of cancer immunotherapy. The Company plans to sponsor and conduct a Phase 2 study investigating the Company's BL-8040 oncology compound in combination with KEYTRUDA®, MSD's anti-PD-1 therapy, in patients with pancreatic cancer. The study is planned to commence by mid-2016. Upon completion of the study, or at any earlier point, both parties will have the option to expand the collaboration to include a pivotal registration study.

BioLineRx Ltd.

Amended and Restated 2003 Share Incentive Plan
(as approved effective as of January 7, 2016)

(In compliance with Amendment No. 132 of the Israeli Tax Ordinance, 2002)

1. Name

This plan, as amended from time to time, shall be known as the "BioLineRx Ltd. Amended and Restated 2003 Share Incentive Plan" (the "**Plan**").

2. Purpose

The purpose and intent of the Plan is to provide incentive: (i) to retain, in the employ of the Company and its Affiliates (as defined below), persons of training, experience and ability, (ii) to attract new employees, directors, consultants, service providers and other entities, the services of which shall be considered valuable to the Company by the Board of the Company, (iii) to encourage the sense of proprietorship of such persons, and (iv) to stimulate the active interest of such persons in the development and financial success of the Company by providing them with opportunities to purchase shares in the Company, pursuant to the Plan.

3. Definitions

For purposes of the Plan and related documents, including the Incentive Agreement, the following definitions shall apply:

3.1. "**Affiliate**" means any "employing company" within the meaning of Section 102(a) of the Ordinance.

3.2. "**Approved 102 Award**" means an Award granted pursuant to Section 102(b) of the Ordinance and held in trust by a Trustee (as defined in Section 7) for the benefit of Grantee.

3.3. "**Approved 102 Security**" means an Approved 102 Award and/or an Approved 102 Share.

3.4. "**Approved 102 Share**" means a Share issued pursuant to Section 102(b) of the Ordinance or a Share derived from an Approved 102 Award, and held in trust by a Trustee (as defined in Section 7) for the benefit of a Grantee.

3.5. "**Articles**" means the Articles of Association of the Company, and any subsequent amendments or replacements thereto.

3.6. "**Award**" means an Option, a Performance Stock Unit award or a Restricted Stock Unit award granted under the Plan.

3.7. "**Board**" means the Board of Directors of the Company.

3.8. "**Capital Gain Security (CGS)**" as defined in Section 6.4.

3.9. "**Cause**" means (i) commitment of a serious breach of trust, including, but not limited to, theft, embezzlement, self-dealing; (ii) prohibited disclosure to unauthorized persons or entities of confidential or proprietary information of, or relating to, the Company and/or its Affiliates; (iii) the engaging by Grantee in any prohibited business or activities competitive to the business of the Company and/or its Affiliates; or (iv) any other action or omission which may be defined as Cause "justifiable cause" or the like in the respective Grantee's employment, consulting or service agreement with the Company or an Affiliate, as applicable, or under applicable law.

3.10. "**Chairman**" means the chairman of the Committee.

3.11. "**Committee**" means a share award / share incentive compensation committee appointed by the Board, as may be fixed from time to time by the Board.

3.12. "**Companies Law**" means the Israeli Companies Law 5759-1999, as now in effect or as hereafter amended.

3.13. "**Company**" means BioLineRx Ltd.

3.14. "**Controlling Shareholder**" shall have the meaning ascribed to it in Section 32(9) of the Ordinance.

3.15. "**Date of Grant**" means, the date of grant of a Security, as determined by the Board and set forth in Grantee's Incentive Agreement.

3.16. "**Employee**" means a person who is employed by the Company or its Affiliates, including an individual who is serving as a director or an office holder, but excluding Controlling Shareholder(s).

3.17. "**Exercise Price**" means the price for each Share subject to an Award.

3.18. "**Expiration Date**" means the date upon which an Option shall expire, as set forth in Section 10.2.

3.19. "**Fair Market Value**" means as of any date, the value of a Share determined as follows:

(i) If the Shares are listed on any established stock exchange or a national market system, including without limitation the NASDAQ National Market system, or the NASDAQ SmallCap Market of the NASDAQ Stock Market, the Fair Market Value shall be the closing sales price for such Shares (or the closing bid, if no sales were reported), as quoted on such exchange or system for the last market trading day prior to time of determination, as reported in the Wall Street Journal, or such other source as the Board or the Committee deems reliable. Without derogating from the above, to the extent the rules of the security exchange on which the Shares are registered require so, the Fair Market Value shall be determined in accordance with the average value of the Shares during the thirty (30) trading days preceding the date of determination, as reported on such securities exchange records, or any other source the Board deems reliable.

(ii) Otherwise, the Fair Market Value shall be determined in good faith by the Board of Directors.

(iii) In addition, for the purpose of determining the tax liability pursuant to Section 102(b)(3) of the Ordinance, if at the Date of Grant the Company's shares are listed on any established stock exchange or a national market system, the Fair Market Value of a Share at the Date of Grant shall be determined in accordance with the average value of the Company's shares on the thirty (30) trading days preceding the Date of Grant.

(iv) If the Shares are regularly quoted by a recognized securities dealer but selling prices are not reported, the Fair Market Value shall be the mean between the high bid and low asked prices for the Shares on the last market trading day prior to the day of determination, or;

(v) In the absence of an established market for the Shares, the Fair Market Value thereof shall be determined in good faith by the Board or the Committee.

3.20. "**Grantee**" means a person who receives or holds a Security under the Plan.

3.21. "**Issuance Price**" means the price for each share issued to a Grantee.

3.22. "**Non-Employee**" means a consultant, adviser or service provider to the Company, who is not an Employee, or a Controlling Shareholder of the Company.

3.23. "**Ordinary Income Security (OIS)**" as defined in Section 6.5.

3.24. "**Option**" means an option to purchase one or more Shares of the Company pursuant to the Plan.

3.25. "**102 Award**" means any Award granted pursuant to Section 102 of the Ordinance to any person who is an Employee.

3.26. "**102 Security**" means a 102 Award and/or a 102 Share.

3.27. "**102 Share**" means a Share issued pursuant to Section 102 of the Ordinance or a Share issued upon the exercise or vesting of a 102 Award, as applicable, to any person who is an Employee.

3.28. "**3(i) Award**" means an Award granted pursuant to Section 3(i) of the Ordinance to any person who is a Non- Employee.

3.29. "**3(i) Security**" means a 3(i) Award and/or a 3(i) Share.

3.30. "**3(i) Share**" means a Share issued pursuant to Section 3(i) of the Ordinance or a Share derived from a 3(i) Award, to any person who is a Non-Employee.

3.31. "**Incentive Agreement**" means the share award agreement or share incentive agreement between the Company and a Grantee that sets out the terms and conditions of a Security.

3.32. "**Ordinance**" means the Israeli Income Tax Ordinance [New Version] 1961, as now in effect or as hereafter amended.

3.33. "**Performance Criteria**" means the criteria that the Committee selects for purposes of establishing the Performance Goal or Performance Goals for a Performance Period. The Committee shall define in an objective fashion the manner of calculating the Performance Criteria it selects to use for such Performance Period for such Employee or Non-Employee.

3.34. "**Performance Goals**" means, for a Performance Period, the goals established in writing by the Committee for the Performance Period based upon the Performance Criteria. Depending on the Performance Criteria used to establish such Performance Goals, the Performance Goals may be expressed in terms of overall Company performance or the performance of a division, business unit or an individual. The Committee, in its discretion, may adjust or modify the calculation of Performance Goals for such Performance Period in order to prevent the dilution or enlargement of an entitlement (a) in the event of, or in anticipation of, any unusual or extraordinary corporate item, transaction, event, or development, or (b) in recognition of, or in anticipation of, any other unusual or nonrecurring events affecting the Company, or the financial statements of the Company, or in response to, or in anticipation of, changes in applicable laws, regulations, accounting principles, or business conditions.

3.35. "**Performance Period**" means the one or more periods of time, which may be of varying and overlapping durations, as the Committee may select, over which the attainment of one or more Performance Goals will be measured for the purpose of determining the right to, and the vesting of, a Stock Unit.

3.36. "**Performance Stock Unit**" means a right granted pursuant to Section 13.2, to receive Shares, the entitlement to which is contingent upon achieving certain Performance Goals established by the Committee.

3.37. "**Plan**" means this BioLineRx Ltd. Amended and Restated 2003 Share Incentive Plan.

3.38. "**Restricted Stock Unit**" means a right granted pursuant to Section 13.1 to receive Shares subject to vesting conditions as shall be set forth in the Incentive Agreement, such that upon vesting, a Share of the Company shall be automatically issued to the Participant.

3.39. "**Section 102**" means section 102 of the Ordinance as now in effect or as hereafter amended.

3.40. "**Security**" means an Award or a Share.

3.41. "**Share**" means an Ordinary Share of the Company, nominal value NIS 0.01 per share, of the Company.

3.42. "**TASE**" means the Tel-Aviv Stock Exchange.

3.43. "**TASE Directives**" means the directives, rules and regulations published by the TASE, as established from time to time.

3.44. "**Transaction**" means (i) a merger, consolidation or reorganization of the Company with or into any other corporation resulting in such other corporation being the surviving entity or the direct or indirect parent of the Company or resulting in the Company being the surviving entity and a change in the ownership of shares of the Company, such that another person or entity owning fifty percent (50%) or more of the outstanding voting power of the Company's securities by virtue of the transaction, or (ii) the sale or transfer of all or substantially all of the outstanding shares of the Company, (iii) or the sale or transfer of all or substantially all of the assets of the Company.

3.45. "**Unapproved 102 Award**" means an Award granted pursuant to Section 102(c) of the Ordinance.

3.46. "**Unapproved 102 Security**" means an Unapproved 102 Award and/or an Unapproved 102 Share.

3.47. "**Unapproved 102 Share**" means a Share issued pursuant to Section 102(c) of the Ordinance or a Share issued upon the exercise of an Unapproved 102 Award.

3.48. "**Vesting Dates**" means, as determined by the Board or by the Committee, the date as of which Grantee shall be entitled to exercise the Options or part of the Options or be issued Shares derived from Awards.

4. Administration

4.1. The Plan will be administered by the Board or by a Committee. If a Committee is not appointed, the term Committee, whenever used herein, shall mean the Board. The Board shall appoint the members of the Committee and may, from time to time, remove members from, or add members to, the Committee and shall fill vacancies in the Committee however caused.

4.2. The Committee shall select one of its members as its Chairman and shall hold its meetings at such times and places as it shall determine. Actions taken by a majority of the members of the Committee, at a meeting at which a majority of its members is present, or acts reduced to or approved in writing by all members of the Committee, shall be the valid acts of the Committee. The Committee may appoint a Secretary, who shall keep records of its meetings and shall make such rules and regulations for the conduct of its business as it shall deem advisable.

4.3. Subject to the general terms and conditions of the Plan, the Committee shall have the full authority in its discretion, from time to time and at any time to: (i) designate Grantees to whom Securities shall be granted; (ii) determine the number of Shares to be covered by each Award; (iii) determine the time or times at which the same shall be granted; (iv) determine the Exercise Price of the Awards and the Vesting Dates; (v) determine the Fair Market Value of the Shares; (vi) make an election as to the type of Approved 102 Securities; (vii) designate the type of Securities; (viii) determine any conditions on which the Awards may be exercised, the Awards may be granted and on which such Shares shall be paid for; and (ix) make all other determinations necessary or desirable for, or incidental to, the administration of the Plan.

4.4. Notwithstanding the above, the Committee shall not be entitled to grant Awards or issue Shares that are not underlying Awards to Grantees, however, it will be authorized to issue Shares underlying Awards which have been granted by the Board and duly exercised pursuant to the provisions herein in accordance with section 112(a)(5) of the Companies Law.

4.5. The Committee may, from time to time, adopt such rules and regulations for carrying out the Plan as it may deem necessary. Without limiting the generality of the foregoing, the Committee may adopt special appendices and/or guidelines and provisions for persons who are residing in or employed in, or subject to, the taxes of, any domestic or foreign jurisdictions, to comply with applicable laws, regulations, or accounting, listing or other rules with respect to such domestic or foreign jurisdictions.

4.6. No member of the Board or of the Committee shall be liable for any act or determination made in good faith with respect to the Plan or any Security granted thereunder. Subject to the Company's decision and to all approvals legally required, each member of the Board or the Committee shall be indemnified and held harmless by the Company against any cost or expense (including counsel fees) reasonably incurred by him or her, or any liability (including any sum paid in settlement of a claim with the approval of the Company) arising out of any act or omission to act in connection with the Plan unless arising out of such member's own willful misconduct or bad faith, to the fullest extent permitted by applicable law. Such indemnification shall be in addition to any rights of indemnification the member may have as a director or otherwise under the Company's Articles, any agreement, any vote of shareholders or disinterested directors, insurance policy or otherwise.

4.7. The interpretation and construction by the Committee of any provision of the Plan or of any Security thereunder shall be final and conclusive unless otherwise determined by the Board. The Committee may correct any defect, supply any omission or reconcile any inconsistency in the Plan or in any agreement relating thereto in the manner and to the extent it shall deem necessary to effectuate the purpose and intent of the Plan.

4.8. As long as the Company's securities are traded on the TASE, the Plan or any Securities granted or issued thereunder, shall be subject to the TASE Directives, as amended from time to time. If, as a result of any amendments or changes to the TASE Directives, any provision of the Plan or any grant document thereunder is incompliant with the TASE Directives, such provision shall be deemed amended as required in order to comply with the applicable TASE Directives, as shall be determined by the Board or Committee.

4.9. It is expressly intended that the Plan shall be administered in accordance with, and subject to the Company's Executive Compensation Policy for executive officers and directors, as shall be in effect from time to time. The Committee shall ensure that actions taken under the Plan, including without limitation, the grant of awards and administration and interpretation of the Plan, shall be made in accordance with such Executive Compensation Policy, as in effect from time to time.

5. Eligible Grantees

5.1. The persons eligible for participation in the Plan as Grantees shall include any Employees and/or Non-Employees of the Company or of any Affiliate; provided, however, that (i) Employees may only be granted 102 Securities; (ii) Non-Employees may only be granted 3(i) Securities; and (iii) Controlling Shareholders may only be granted 3(i) Securities. Notwithstanding the foregoing, employees and service providers of non-Israeli affiliates of the Company shall be entitled to participate in the Plan and receive grants of Securities hereunder in accordance with the terms of an Incentive Agreement and/or country-specific appendixes governing the grant of such Securities in a form approved by the Committee.

5.2. The grant of a Security to a Grantee hereunder, shall neither entitle such Grantee to participate, nor disqualify her/him from participating, in any other grant of Securities pursuant to the Plan or any other Share incentive plan of the Company.

6. Designation of Securities Pursuant to Section 102

6.1. The Company may designate Securities granted to Employees pursuant to Section 102 as Unapproved 102 Securities or as Approved 102 Securities.

6.2. The grant of Approved 102 Securities may be made under the Plan only following its adoption by the Board as described in Section 19, and shall be conditioned upon the filing of the Plan with the Israeli Tax Authorities.

6.3. Approved 102 Securities may either be classified as Capital Gain Securities ("**CGS**") or Ordinary Income Securities ("**OIS**").

6.4. Approved 102 Securities elected and designated by the Company to qualify under the capital gain tax treatment in accordance with the provisions of Section 102(b)(2) shall be referred to herein as CGS.

6.5. Approved 102 Securities elected and designated by the Company to qualify under the ordinary income tax treatment in accordance with the provisions of Section 102(b)(1) shall be referred to herein as OIS.

6.6. The Company's election of the type of Approved 102 Securities as CGS or OIS granted to Employees (the "**Election**"), shall be appropriately filed with the Israeli Tax Authorities before the Date of Grant of any Approved 102 Securities.

Such Election shall become effective beginning the first Date of Grant of an Approved 102 Security under the Plan and shall remain in effect until at least the end of the year following the year during which the Company first granted Approved 102 Securities. The Election shall obligate the Company to grant only the type of Approved 102 Security it has elected, and shall apply to all Approved 102 Security granted during the period indicated herein, all in accordance with the provisions of Section 102(g) of the Ordinance. For the avoidance of doubt, such Election shall not prevent the Company from granting Unapproved 102 Securities simultaneously.

6.7. All Approved 102 Securities must be held in trust by a Trustee, as described in Section 7.

6.8. For the avoidance of doubt, the designation of Unapproved 102 Securities and Approved 102 Securities shall be subject to the terms and conditions set forth in Section 102 of the Ordinance and the regulations promulgated thereunder.

6.9. With regards to Approved 102 Securities, the provisions of the Plan and/or the Incentive Agreement shall be subject to the provisions of Section 102 and the Tax Assessing Officer's permit, and the said provisions and permit shall be deemed an integral part of the Plan and of the Incentive Agreement. Any provision of Section 102 and/or the said permit which is necessary in order to receive and/or to keep any tax benefit pursuant to Section 102, which is not expressly specified in the Plan or the Incentive Agreement, shall be considered binding upon the Company and the Grantees.

6.10. Approved 102 Securities will be deemed granted on the date approved by the Board and stated in a written or electronic notice by the Company, provided that effective as of such date or within the requisite period thereafter, the Approved 102 Securities have been deposited with a Trustee in accordance with the requirements of Section 102. Securities will only qualify as Approved 102 Securities if deposited with the Trustee within the term and in compliance with all conditions required by the Israeli Tax Authorities, as amended and updated from time to time.

7. Trustee

7.1. Anything herein to the contrary notwithstanding, Approved 102 Securities granted under the Plan and/or other shares received subsequently following any realization of rights with respect to such Securities, including without limitation bonus shares, shall be granted by the Company to a trustee designated by the Board and approved by the Israeli Tax Authorities in accordance with the provisions of Section 102(a) of the Ordinance (the "**Trustee**"), and held for the benefit of the Grantees for such period of time as required by Section 102 or any regulations, rules (including the Income Tax Rules (Tax Benefits in Stock Issuance to Employees), 2003) or orders or procedures promulgated thereunder (the "**Holding Period**"). In the event that the requirements for Approved 102 Securities are not met, then the Approved 102 Securities may be treated as Unapproved 102 Securities, all in accordance with the provisions of Section 102 and regulations promulgated thereunder.

7.2. Notwithstanding anything to the contrary, the Trustee shall not release any Approved 102 Shares prior to the full payment of Grantee's tax liabilities arising from Approved 102 Securities which were granted to Grantee.

7.3. With respect to any Approved 102 Securities, subject to the provisions of Section 102 and any rules or regulation or orders or procedures promulgated thereunder, a Grantee shall not sell or release from trust any Approved 102 Share and/or any share received subsequently following any realization of rights, including without limitation, bonus shares, until the lapse of the Holding Period required under Section 102 of the Ordinance. Notwithstanding the above, if any such sale or release occurs during the Holding Period, the sanctions under Section 102 of the Ordinance and under any rules or regulation or orders or procedures promulgated thereunder shall apply to and shall be borne by such Grantee.

7.4. Upon receipt of Approved 102 Securities, Grantee will sign an undertaking to release the Trustee from any liability in respect of any action or decision duly taken and bona fide executed in relation with the Plan, or any Approved 102 Security granted to Grantee thereunder.

7.5. For the avoidance of doubt, nothing contained herein shall prevent the Company from granting Unapproved 102 Securities and/or 3(i) Securities to a trustee designated by the Board, to be held for the benefit of Grantees, all in accordance with the terms and conditions specified by the Board.

8. Reserved Shares

The Company has reserved sufficient authorized but unissued Shares for purposes of the Plan and any other present or future share incentive plans of the Company, subject to adjustments as provided in Section 15. All Shares under the Plan or under any other present or future share incentive plans, in respect of which the right of a Grantee hereunder or thereunder to hold or purchase the same shall, for any reason, terminate, expire or otherwise cease to exist, shall again be available for issuance and/or grant through Securities under the Plan and such other share incentive plans.

9. Grant of Securities

Each Security granted pursuant to the Plan shall be evidenced by a written Incentive Agreement between the Company and Grantee, in such form as the Board or the Committee shall from time to time approve. Each Incentive Agreement shall state, inter alia, the number of Shares covered thereby, the type of Security granted thereunder (whether a CGS, OIS, Unapproved 102 Security, 3(i) Security, or other designation), the dates when the Award may be exercised (if applicable) or Award granted, the Exercise Price (if applicable), and such other terms and conditions as the Committee at its discretion may prescribe, such as, without limitation, vesting or reverse vesting dates, provided that they are consistent with the Plan.

10. Term and Vesting of Options

10.1. Subject to the provisions of this Plan, Options granted to a Grantee under the Plan shall vest and become exercisable following the vesting dates and for such number of Shares as set forth in such Grantee's Incentive Agreement, as determined by the Committee. As well, subject to the Plan, Shares issued to a Grantee shall be released from reverse vesting as set forth in the Grantee's Incentive Agreement, as determined by the Committee. A Security may be subject to such other terms and conditions on the time or times when it may be exercised or released from reverse vesting, as applicable, as the Committee may deem appropriate. The vesting or reverse vesting provisions of individual Securities may vary.

10.2. Options, to the extent not previously exercised, shall terminate forthwith upon the earlier of: (i) ten (10) years from the Date of Grant (unless otherwise specified in the Option Agreement); (ii) the expiration in accordance with Section 16; and (ii) the expiration of any extended period in any of the events set forth in Section 14.

11. Issuance Price and Exercise Price of Options

The Issuance Price or Exercise Price per Share issued or covered by each Option, as applicable, shall be determined by the Committee in its sole and absolute discretion; provided, however, that such Issuance Price or Exercise Price shall not be less than the nominal value of the Shares issued or of the Shares into which such Option is exercisable, as applicable. Each Incentive Agreement will contain the Issuance Price or Exercise Price determined for each Grantee.

12. Exercise of Options

12.1. Options shall be exercisable pursuant to the terms under which they were awarded and subject to the terms and conditions of the Plan.

12.2. The exercise of an Option shall be made by a written notice of exercise (the "**Notice of Exercise**") delivered by Grantee to the Company at its principal executive office, specifying the number of Shares to be purchased and accompanied by the payment of the Exercise Price, and containing such other terms and conditions as the Committee shall prescribe from time to time.

12.3. Anything herein to the contrary notwithstanding, but without derogating from the provisions of Section 14, if any Option has not been exercised and the Shares covered thereby not paid for until the Expiration Date, the Grantee's right to such Option and his/her right to acquire the underlying Shares of such Option shall terminate, all interests and rights of the Grantee in and to the same shall ipso facto expire, and, in the event that in connection therewith any Approved 102 Options are still held by the Trustee as aforesaid, the trust with respect thereto shall ipso facto expire and all of such Approved 102 Options shall again be subject for grant as provided in Section 8.

12.4. Each payment for Shares shall be in respect of a whole number of Shares, and shall be effected in cash or by a cashier's check payable to the order of the Company, or such other method of payment acceptable to the Company.

12.5. For the avoidance of doubt, Grantees shall not have any of the rights or privileges of shareholders of the Company in respect of any Shares, nor shall they be deemed to be a class of shareholders or creditors of the Company for purpose of the operation of sections 350 and 351 of the Companies Law or any successor to such section, until registration of Grantee as holder of such Shares in the Company's register of shareholders in accordance with the provisions of the Plan, but in case of Options and Shares held by the Trustee, subject to the provisions of Section 7.

12.6. In accordance with the applicable TASE Directives, and as long as the Company's Shares are traded on TASE, no exercise of Options will be permitted on the record date for the following events: (a) distribution of bonus shares; (b) rights offering; (c) the distribution of dividends; (d) unification of capital; (e) stock split; or (f) reduction in capital (any of the foregoing "**Company Event**"). In addition, if the "X Date" (as such term is defined in the TASE Directive) occurs prior to the record date of such Company Event, no exercise of Options will be permitted on such X Date.

13. Restricted Stock Units; Performance Stock Units

13.1. **Restricted Stock Units**. Restricted Stock Units may be granted in such amounts and subject to such terms and conditions as determined by the Committee. At the time of grant, the Committee shall specify the date or dates on which the Restricted Stock Units shall become fully vested and non-forfeitable, and may specify such conditions to vesting as it deems appropriate. At the time of grant, the Committee may specify whether any payment or no payment is due with respect to the issuance of Shares upon vesting of Restricted Stock Units. The Company shall issue one unrestricted, fully transferable Share for each Restricted Stock Unit scheduled to be paid out on a vesting date and not previously forfeited.

13.2. **Performance Stock Units**. Restricted Stock Units that are linked to any one or more of the Performance Goals (in addition to or in lieu of time-based vesting terms) determined appropriate by the Committee, in each case on a specified date or dates or over any period or periods determined by the Committee, shall be designated as Performance Stock Units. In making such determinations, the Committee shall consider (among such other factors as it deems relevant in light of the specific type of award) the contributions, responsibilities and other compensation of the Grantee.

13.3. **Term**. Except as otherwise provided herein, the term of any Award of Performance Stock Units or Restricted Stock Units shall be set by the Committee in its discretion.

14. Termination of Engagement

14.1. Subject to the provisions of Section 14.2, unless otherwise provided in the Grantee's Incentive Agreement, in the event that a Grantee ceases, for any reason, to be employed by or to provide services to the Company or an Affiliate, all Awards granted to such Grantee will immediately expire upon such cessation. For the avoidance of doubt, unless expressly stated otherwise in the Grantee's Incentive Agreement, in case of such cessation of employment or service, the unvested portion of the Grantee's Award shall not continue to vest and shall immediately expire.

14.2. Notwithstanding anything to the contrary hereinabove and unless otherwise determined in the Grantee's Incentive Agreement, an Option may be exercised after the date of cessation of Grantee's employment or service with the Company or any Affiliates during an additional period of time beyond the date of such cessation, but only with respect to its vested portion at the time of such termination, as follows:

14.2.1 If the Grantee's termination of employment or service is due to such Grantee's death or "Disability" (as hereinafter defined), then any of such Grantee's vested Options (to the extent exercisable at the time of the Grantee's termination of employment or service) shall be exercisable by the Grantee's legal representative, estate of other person to whom the Grantee's rights are transferred by will or by laws of descent of distribution for a period of twelve (12) months following such death or termination of employment or service due to "Disability" (but in no event after the Expiration Date), and shall thereafter terminate.

For purposes hereof, "**Disability**" shall mean the inability, due to illness or injury, to engage in any gainful occupation for which the individual is suited by education, training or experience, which condition continues for at least six (6) consecutive months or an aggregate of six (6) months in any twelve (12)-month period.

14.2.2 If the Grantee's termination of employment or service is for any reason other than for Cause, then any of such Grantee's vested Options (to the extent exercisable at the time of the Grantee's termination of employment or service) shall be exercisable for a period of ninety (90) days following such termination of employment or service (but in no event after the Expiration Date), and shall thereafter terminate; provided, however, that if the Grantee dies within such ninety-day period, such Options shall be exercisable by the Grantee's legal representative, estate or other person to whom the Grantee's rights are transferred by will or by laws of descent of distribution for a period of twelve (12) months following the Grantee's death (but in no event after the Expiration Date), and shall thereafter terminate.

14.2.3 In the event of termination for Cause, any Option held by such Grantee (whether or not vested) shall terminate immediately and the Grantee shall have no further rights to purchase Shares pursuant to such Option.

14.3. With respect to Unapproved 102 Securities, if the Grantee ceases to be employed by the Company or any Affiliate, the Grantee shall extend to the Company and/or its Affiliate a security or guarantee for the payment of tax due at the time of sale of Shares, all in accordance with the provisions of Section 102 and the rules, regulation or orders promulgated thereunder.

15. Adjustment Upon Changes in Capitalization

Subject to any required action by the shareholders of the Company, the number and type of Shares covered by each outstanding Award, and the number of Shares which have been authorized for issuance under the Plan but which have not been issued or as to which no Awards have yet been granted or which have been returned to the Plan upon cancellation or expiration of an Award or otherwise, as well as the Exercise Price, shall be proportionately adjusted for any increase or decrease in the number of issued Shares resulting from a stock split, stock dividend, combination, exchange of shares or reclassification of the Shares, all only if such triggering event generally applies to all Shares. The conversion of any convertible securities of the Company shall not be deemed to have been "effected without receipt of consideration." Notwithstanding the above, if the Company distributes bonus shares, the exercise price of the Awards shall not be adjusted, however, the number of Shares covered by each outstanding Award and the number of Shares which have been authorized for issuance under the Plan but as to which no Awards have yet been granted or which have been returned to the Plan upon cancellation or expiration of an Award, shall be proportionately adjusted to the increase. Any adjustment shall be made by the Committee, whose determination in that respect shall be final, binding and conclusive. Except as expressly provided herein, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number or price of Shares subject to the Plan.

16. Consequences of a Transaction, Dissolution, Right Issue or Distribution of Dividend.

16.1. **Dissolution; Transaction**. Upon the occurrence of any kind of Transaction or voluntarily liquidation or dissolution of the Company ("**Dissolution**"), any unexercised vested Awards and any unvested Awards existing at that time shall be automatically terminated.

16.2. Notwithstanding the aforesaid, in case of a Transaction that involves sale, transfer or disposal of the securities of the Company (including by way of a merger in which the Company is the surviving entity), the Grantee's Awards then outstanding may be assumed or substituted for an appropriate number of shares of each class of shares or other securities and/or assets of the successor company in such Transaction (or a parent or subsidiary or another affiliate of such successor company) (the "**Successor Company**") as were distributed to the shareholders of the Company in respect of the Transaction. Furthermore, if the consideration received by the shareholders of the Company in respect of the Transaction was not solely common stock (or its equivalent) of the Successor Company, then the Committee may stipulate that the consideration to be received upon the exercise of Awards shall be solely common stock (or its equivalent) of the Successor Company. As well, the Committee may stipulate that in lieu of any assumption of Awards for shares or other securities of the Successor Company, such Awards will be substituted for any other type of asset of the Successor Company as may be fair under the circumstances, including, but not limited to, cash amounts. In the case of such assumption and/or substitution of shares, appropriate adjustments shall be made to the Exercise Price of the Awards to reflect such action, and all other terms and conditions of the Awards, such as the vesting periods, shall remain in force.

16.3. The Company may notify all holders of vested but unexercised Awards, at least 10 (ten) business days before the estimated day of closing of a Transaction or of Dissolution (as shall be determined by the Committee) of such expected event, and such holders shall be required to advise the Company within 7 (seven) days of such notice, whether they wish to exercise their vested Awards, in accordance with the procedures set forth in this Plan (regardless of whether or not actual closing of the Transaction or the Dissolution occurs after more than such 7-day period). Such exercise may be contingent on actual closing of the Transaction or actual occurrence of the Dissolution. Upon the expiration of such 7-day period, no exercise of the Awards shall be allowed unless specifically authorized by the Committee. With respect to a Transaction, the provisions of this Section 16.3 shall not apply in the event of an assumption or substitution under Section 16.2, including in the event the Awards are substituted for cash consideration.

16.4. If the Board determines in good faith that, in the context of a Transaction, certain Securities have no monetary value and thus do not entitle the holders of such Securities to any consideration under the terms of the Transaction, the Board may determine that such Securities shall terminate effective as of the effective date of the Transaction. Without limiting the generality of the foregoing, the Board may provide for the termination of any Award, effective as of the effective date of the Transaction, that has an exercise price that is greater than the per share Fair Market Value at the time of such Transaction, without any consideration to the holder thereof.

16.5. It is the intention that the Committee's authority to make determinations, adjustments and clarifications in connection with the treatment of Securities shall be interpreted as widely as possible, to allow the Committee maximal power and flexibility to interpret and implement the provisions of the Plan in the event of a Transaction or Dissolution, provided that the Committee shall determine in good faith that a Grantee's rights are not thereby adversely affected without the Grantee's express written consent. Without derogating from the generality of the foregoing, the Committee shall have the authority, at its sole discretion, to determine that the treatment of Securities, whether vested or unvested, in a Transaction or Dissolution may differ among individual Grantees or groups of Grantees, provided that the overall economic impact of the different approaches determined by the Committee shall be substantively equivalent as of the date of the closing of the Transaction or determination of Dissolution.

16.6. **Rights Issue**. In the event that the Company offers all the shareholders of the Company securities of the Company by way of a rights issue, the exercise price of the Awards shall not be adjusted, however, the number of Shares resulting from the exercise of the Awards which have yet to be exercised on the date determining the right to acquire the aforesaid securities shall be adjusted to the benefit component of the rights issue as such is expressed by the ratio between the closing price of the Company's shares on the TASE on the last trading day prior to the X Date to the share's base price prior to the grant of such rights ("**X-rights**").

16.7. **Distribution of Dividends**. In the event of distribution of dividends, in cash of in kind, to all shareholders of the Company (including by way of court approved distribution pursuant to Section 303 of the Companies Law, or other applicable law), the exercise price of outstanding Awards not yet exercised on the date determining the right to receive such dividend shall be adjusted and reduced by the gross dividend amount distributed by the Company per share (or its value in the event of dividend in kind). Other than the adjustments in the exercise price detailed herein, the distribution of dividend by the Company, in cash of in kind, will not affect the number of Shares covered by each outstanding Award and/or will not require the Company to make any other adjustments with respect to Awards and or the Shares covered by each Award.

17. Transferability; Restrictions

17.1. No Award shall be assignable or transferable by the Grantee to whom granted otherwise than by will or the laws of descent and distribution, and an Award may be exercised during the lifetime of the Grantee only by such Grantee or by such Grantee's guardian or legal representative. The terms of such Award shall be binding upon the beneficiaries, executors, administrators, heirs and successors of such Grantee. The provisions of this Section 17.1 applying to Awards shall apply to any Shares subject to reverse vesting, mutatis mutandis.

17.2. Anything herein to the contrary notwithstanding, if, upon a Transaction, all or substantially all of the shares of the Company are to be exchanged for securities of another company, then Grantee shall be obliged to exchange all Shares such Grantee was issued or purchased under the Plan, in accordance with the instructions then issued by the Board, whose determination shall be final.

17.3. Grantee acknowledges that, Grantee's right to sell the Shares may be subject to certain limitations (including a lock-up period), in connection with any registration of the offering of any securities of the Company under the securities laws of any jurisdiction, as will be required by the Company or its underwriters; and Grantee unconditionally agrees and accepts any such limitations.

17.4. By exercising an Award and/or by being issued a Share hereunder, Grantee agrees not to sell, transfer or otherwise dispose any of the Shares so purchased by Grantee except in compliance with the United States Securities Act of 1933, as amended, and the rules and regulations thereunder or any other applicable law, and Grantee further agrees that all certificates evidencing any of such shares shall be appropriately legended to reflect such restriction. Nothing herein shall be deemed to require the Company to register the Shares under the securities laws of any jurisdiction. The Company shall not register any transfer of Shares not made in accordance with the provisions of the Plan, the Company's Articles and any applicable law.

18. Shareholders Rights

18.1. The Grantee shall have no rights of a shareholder with respect to the Shares subject to the Plan until the Grantee shall have exercised the Award (if applicable), paid the Exercise Price thereof (if applicable) and become the record holder of the Shares.

18.2. With respect to all exercised Awards or Shares issued under the Plan, the Grantee shall be entitled to receive dividends in accordance with the number of such Shares, and subject to any applicable taxation on distribution of dividends, and when applicable subject to the provisions of Section 102 and the rules, regulations or orders promulgated thereunder.

19. Term and Amendment of the Plan

19.1. The Plan shall be effective as of the day it was adopted by the Board, and shall expire on such date that is twenty (20) years following the Board adoption of the Plan.

19.2. Subject to applicable laws, the Board may, at any time and from time to time, but when applicable, after consultation with the Trustee, terminate or amend the Plan in any respect. In no event, unless allowed under this Plan, may any action of the Company alter or impair the rights of a Grantee, without his consent, under any Security previously granted to him. Termination of the Plan shall not affect the Committee's ability to exercise the powers granted to it hereunder with respect to Securities granted under the Plan prior to the date of such termination.

20. Tax Consequences

20.1. All tax consequences and/or obligations regarding other compulsory payments arising from the issuance of Shares, the grant or exercise of any Award, from the payment for, or the subsequent disposition of, Shares covered thereby or from any other event or act (of the Company, its Affiliates, the Trustee or the Grantee) hereunder, shall be borne solely by the Grantee, and the Company and/or its Affiliates, and/or the Trustee shall withhold taxes according to the requirements under the applicable laws, rules, and regulations, including withholding taxes at source. The Grantee shall indemnify the Company and/or its Affiliates and/or the Trustee, as applicable, and hold them harmless against and from any and all liability for any such tax (and compulsory payment, if any) or interest or penalty thereon, including without limitation, in respect of Approved 102 Securities, liabilities relating to the necessity to withhold, or to have withheld, any such tax (and compulsory payment, if any) from any payment made to the Grantee.

20.2. The Company or any of its Affiliates and the Trustee may make such provisions and take such steps as it/they may deem necessary or appropriate for the withholding of all taxes required by law to be withheld with respect to Securities granted under the Plan and the exercise, sale, transfer or other disposition thereof, including, but not limited, to (i) deducting the amount so required to be withheld from any other amount then or thereafter payable to a Grantee, including by deducting any such amount from a Grantee's salary or other amounts payable to the Grantee, to the maximum extent permitted under law and/or (ii) requiring a Grantee to pay to the Company or any of its Affiliates the amount so required to be withheld as a condition of the issuance, delivery, distribution or release of any Shares and/or (iii) by causing the exercise of Awards and/or sale of Shares held by or on behalf of the Grantee to cover such liability. In addition, the Grantee will be required to pay any amount, including penalties, that exceeds the tax to be withheld and transferred to the tax authorities, pursuant to applicable tax laws, regulations and rules.

20.3. The Company and/or, when applicable, the Trustee, shall not be required to release any Share certificate to a Grantee until all required payments have been fully made.

20.4. With respect to Unapproved 102 Securities, if the Grantee ceases to be employed by the Company or any Affiliate, the Grantee shall extend to the Company and/or its Affiliate a security or guarantee for the payment of tax due at the time of sale of Shares to the satisfaction of the Company, all in accordance with the provisions of Section 102 and the Income Tax Rules (Tax Benefits in Stock Issuance to Employees), 2003.

21. Miscellaneous

21.1. Continuance of Employment or Hired Services: Neither the Plan nor the grant of a Security hereunder shall impose any obligation on the Company or any Affiliate thereof to continue the employment or service of any Grantee, and nothing in the Plan or in any Security granted pursuant hereto shall confer upon any Grantee any right to continue in the employ or service of the Company or an Affiliate thereof, or restrict the right of the Company or an Affiliate to terminate such employment or service at any time.

21.2. Lock up: The Grantee will be subject to a lock-up period of up to ninety (90) days beginning on the effective date of any underwritten registration of the Company's securities (except to the extent that the relevant shares of the Grantee are part of such underwritten registration), or any longer period of time which may be required by the underwriters of such subsequent underwritten registration, or as shall be binding on all other shareholders of the Company.

21.3. Governing Law and Jurisdiction: The Plan and all instruments issued hereunder or in connection herewith, shall be governed by, and interpreted in accordance with, the laws of the State of Israel. The competent courts in Tel Aviv shall have sole and exclusive jurisdiction over any matters pertaining to the Plan.

21.4. Multiple Agreements: The terms of each Security may differ from other Securities granted under the Plan at the same time, or at any other time. The Committee may also grant more than one Security to a given Grantee during the term of the Plan, either in addition to, or in substitution for, one or more Securities previously granted to that Grantee. The grant of multiple Securities may be evidenced by a single Incentive Agreement or multiple Incentive Agreements, as determined by the Committee.

21.5. Non-Exclusivity of the Plan: The adoption of the Plan by the Board shall not be construed as amending, modifying or rescinding any previously approved incentive arrangement or as creating any limitations on the power of the Board to adopt such other incentive arrangements as it may deem desirable, including, without limitation, the granting of stock awards otherwise than under the Plan, and such arrangements may be either applicable generally or only in specific cases.

Exhibit 4.40

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

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

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

RECITALS

A. BioLineRx is developing the BioLineRx Compound (as defined below) for the treatment of certain tumor types.

B. Merck is developing the Merck Compound (as defined below) for the treatment of certain tumor types.

C. BioLineRx desires to sponsor a clinical trial in which the BioLineRx Compound and the Merck Compound would be dosed concurrently or in combination.

D. Merck and BioLineRx, consistent with the terms of this Agreement, desire to collaborate as more fully described herein, including by providing the Merck Compound and the BioLineRx Compound for the Study (as defined below).

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

1. Definitions.

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

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

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

1.3 "**Alliance Manager**" has the meaning set forth in Section 3.10.

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

1.5 "**BioLineRx**" has the meaning set forth in the preamble.

1.6 [Deleted]

1.7 "**BioLineRx Class Compound**" means any small or large molecule that [*]

1.8 "**BioLineRx Compound**" means BioLineRx's BL-8040, a short synthetic peptide, which is a CXCR4 inhibitor.

1.9 "**BioLineRx Inventions**" is defined in Section 10.2.

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

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

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

1.13 "**Clinical Quality Agreement**" has the meaning set forth in Section 8.2.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.32 "**Force Majeure**" has the meaning set forth Section 16.

1.33 "**GAAP**" has the meaning set forth in Section 6.12.

1.34 "**GCP**" means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the testing of the Compounds.

1.35 "**Government Official**" means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any Person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organization such as the World Bank or United Nations; (e) any officer or employee of a political party or any Person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office; who, when such Government Official is acting in an official capacity, or in an official decision-making role, has responsibility for performing regulatory inspections, government authorizations or licenses, or otherwise has the capacity to make decisions with the potential to affect the business of either of the Parties.

1.36 "**HIPAA**" has the meaning set forth in the definition of Applicable Law.

1.37 "**IND**" means any Investigational New Drug Application filed or to be filed with the FDA as described in Title 21 of the U.S. Code of Federal Regulations, Part 312, and/or the equivalent application in the jurisdictions outside the United States, including an "Investigational Medicinal Product Dossier" filed or to be filed with Regulatory Authorities in the European Union.

1.38 "**Indirect Manufacturing Costs**" has the meaning set forth in Section 6.12.

1.39 "**Inventions**" means all inventions and discoveries, whether or not patentable, that are made, conceived, or first actually reduced to practice by or on behalf of a Party, or by or on behalf of the Parties together, (i) in the design or performance of the Study, or in the design or performance of any Phase III registration study for the Combination performed pursuant to Section 3.14, or (ii) through use of any unpublished Clinical Data or Sample Testing Results.

1.40 "**Joint Development Committee**" or "**JDC**" has the meaning set forth in Section 3.10.

1.41 "**Joint Patent Application**" has the meaning set forth in Section 10.1.3.

1.42 "**Joint Patent**" means a patent that issues from a Joint Patent Application.

1.43 "**Jointly Owned Invention**" has the meaning set forth in Section 10.1.1.

1.44 "**Know-How**" means any proprietary invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, that is not generally known or otherwise in the public domain.

1.45 "**Liability**" has the meaning set forth in Section 14.2.1.

1.46 "**Manufacture**," "**Manufactured**," or "**Manufacturing**" means all activities related to the manufacture of a Compound, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply, as applicable.

1.47 "**Manufacturer's Release**" or "**Release**" has the meaning ascribed to such term in the Clinical Quality Agreement.

1.48 "**Manufacturing Costs**" has the meaning set forth in Section 6.12.

1.49 "**Manufacturing Site**" means the facilities where a Compound is Manufactured by or on behalf of a Party, as such Manufacturing Site may change from time to time in accordance with Section 8.7.

1.50 "**Merck**" has the meaning set forth in the preamble.

1.51 [Deleted]

1.52 "**Merck Compound**" means pembrolizumab, a humanized anti-human PD-1 monoclonal antibody [*]

1.53 "**Merck Inventions**" is defined in Section 10.3.

1.54 "**NDA**" means a New Drug Application, Biologics License Application, Worldwide Marketing Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the United States Federal Food, Drug and Cosmetic Act, or similar application or submission for a marketing authorization of a product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.

1.55 "**Non-Conformance**" means, with respect to a given unit of Compound, (i) a deviation from an approved cGMP requirement with respect to the applicable Compound, such as a procedure, Specification, or operating parameter, or a circumstance that requires an investigation to assess impact to the quality of the applicable Compound or (ii) that such Compound failed to meet the applicable representations and warranties set forth in Section 2.3. Classification of the Non-Conformance is detailed in the Clinical Quality Agreement.

1.56 "**Non-Filing Party**" has the meaning set forth in Section 10.1.3.

1.57 "**Opting-out Party**" has the meaning set forth in Section 10.1.3.

1.58 "**Other Party**" has the meaning set forth in Section 14.2.3.

1.59 "**Party/Parties**" has the meaning set forth in the preamble.

1.60 "**PD-1 Antagonist**" means any small or large molecule that [*].

1.61 "**Permitted Use**" has the meaning set forth in Section 3.7.

1.62 "**Person**" means any individual, sole proprietorship, partnership, corporation, business trust, joint stock company, trust, unincorporated organization, association, limited liability company, institution, public benefit corporation, joint venture, entity or governmental entity.

1.63 "**Pharmacovigilance Agreement**" has the meaning set forth in Section 5.1.

1.64 "**Project Manager**" has the meaning set forth in Section 3.10.

1.65 "**Protocol**" means the written documentation that describes the Study and sets forth specific activities to be performed as part of the Study conduct, to be finalized and agreed upon within sixty (60) calendar days after the Effective Date pursuant to Section 4.1.

1.66 "**Regulatory Approvals**" means, with respect to a Compound, any and all permissions (other than the Manufacturing approvals) required to be obtained from Regulatory Authorities and any other competent authority for the development, registration, importation, sale and distribution of such Compound in the United States, Europe or other applicable jurisdictions for use in the Study.

1.67 "**Regulatory Documentation**" means, with respect to the Compounds, all submissions to Regulatory Authorities in connection with the development of such Compounds, including all INDs and amendments thereto, NDAs and amendments thereto, drug master files, correspondence with regulatory agencies, periodic safety update reports, adverse event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including documents that include Clinical Data).

1.68 "**Regulatory Authorities**" has the meaning set forth in the definition of Applicable Law.

1.69 "**Related Agreements**" means the Pharmacovigilance Agreement and the Clinical Quality Agreement.

1.70 "**Right of Reference**" means the "right of reference" defined in 21 CFR 314.3(b), including with regard to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to a Party's Compound, only to the extent necessary for the conduct of the Study in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder.

1.71 "**SAEs**" has the meaning set forth in Section 5.1.

1.72 "**SADRs**" has the meaning set forth in Section 5.1.

1.73 "**Samples**" means biological specimens collected from subjects participating in the Study, including urine, blood and tissue samples.

1.74 "**Sample Testing**" means the analyses to be performed by each Party using the applicable Samples, as described in the Data Sharing and Sample Testing Schedule (Schedule I).

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

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

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

1.78 "**Study Completion**" has the meaning set forth in Section 3.11.

1.79 "**Subcontractors**" has the meaning set forth in Section 2.4.

1.80 "**Term**" has the meaning set forth in Section 6.1.

1.81 "**Territory**" means anywhere in the world.

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

1.83 "**VAT**" has the meaning set forth in Section 8.16.

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

2 Scope of the Agreement.

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

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

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

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

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

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

3 Conduct of the Study.

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

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

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

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

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

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

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

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

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

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

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

3.12 [*]

3.13 [*]

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

4 Protocol and Related Documents.

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

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

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

b) [*]

c) [*]

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

5 Adverse Event Reporting.

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

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

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

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

6 Term and Termination.

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

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

6.3 *Material Breach*. Either Party may terminate this Agreement if the other Party commits a material breach of this Agreement, and such material breach continues for [*] after receipt of written notice thereof from the non-breaching Party describing such breach and demanding its cure; provided that if such material breach cannot reasonably be cured within [*], the breaching Party shall be given a reasonable period of time to cure such breach; provided further, that if such material breach is incapable of cure, then [*] the non-breaching Party may terminate this Agreement effective after the expiration of such [*] period.

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

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

6.6 *[Deleted]*

6.7 *Return of Merck Compound*. In the event that this Agreement is terminated, or in the event BioLineRx remains in possession (including through any Affiliate or Subcontractor) of Merck Compound at the time this Agreement expires, BioLineRx shall, at Merck's sole discretion, promptly either return or destroy all unused Merck Compound pursuant to Merck's instructions. If Merck requests that BioLineRx destroy the unused Merck Compound, BioLineRx shall provide written certification of such destruction. [*].

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

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

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

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

6.12 *Merck's Manufacturing Costs*. Provided the Parties do not otherwise dispute the circumstances of termination, in the event of termination by Merck pursuant to [*], Merck shall be entitled to reimbursement by BioLineRx for [*] incurred by Merck for its Compound Delivered for the Study. [*]

6.13 [*]

7 Costs of Study.

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

8 Supply and Use of the Compounds.

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

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

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

8.4 *Provision of Compounds.*

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

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

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

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

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

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

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

8.8 *Product Testing; Noncompliance*.

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

8.8.2 *Non-Conformance.*

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

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

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

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

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

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

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

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

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

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

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

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

9 Confidentiality.

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

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

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

10 Intellectual Property.

10.1 *Joint Ownership and Prosecution*.

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

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

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

b. [*]

c. [*]

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

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

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

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

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

10.4 [deleted]

11 Reprints; Rights of Cross-Reference.

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

12 Publications; Press Releases.

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

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

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

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

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

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

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

13 Representations and Warranties; Disclaimers.

13.1 [*]

13.2 *Compounds*.

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

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

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

13.4 *Anti-Corruption*

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

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

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

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

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

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

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

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

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

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

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

14 Insurance; Indemnification; Limitation of Liability.

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

14.2 *Indemnification*.

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

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

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

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

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

15 Use of Name.

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

16 Force Majeure.

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

17 Entire Agreement; Modification.

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

18 [*]

19 Invalid Provision.

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

20 No Additional Obligations.

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

21 Governing Law

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

22 Dispute Resolution.

22.1 *Negotiation*. The Parties shall attempt in good faith to settle all disputes arising out of or in connection with this Agreement in an amicable manner. Any dispute that is not an Excluded Dispute arising between the Parties relating to, arising out of, or in any way connected with this Agreement, or any term or condition hereof, or the performance by either Party of its obligations hereunder (a "**Dispute**"), whether before or after expiration or termination of this Agreement, which is not resolved by the Parties within [*] days after written notice of such Dispute is first given by one Party to the other Party in writing, will be referred to a senior executive (at Vice President level or above) designated by BioLineRx and a senior executive (at Vice President level or above) designated by Merck who are authorized to resolve such Dispute on behalf of their respective companies ("**Senior Executives**"). The Senior Executives will meet (or confer by telephone or video conference) within [*] days after the end of the initial [*] period referred to above, at a time and place acceptable to both Senior Executives. [*]

[*]

23 Notices.

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

If to BioLineRx, to:

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

With a copy to:

General Counsel
BioLineRx Ltd.
Same address as above

If to Merck, to:

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

With a copy to:

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

24 Relationship of the Parties.

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

25 Counterparts and Due Execution.

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

26 Construction.

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

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the respective authorized representatives of the Parties have executed this Agreement as of the Effective Date.

BioLineRx Ltd.

By: _____

_____
Name

_____
Title

Merck Sharp & Dohme B.V.

By: _____

_____
Name

_____
Title

Appendix A

PROTOCOL SUMMARY [Merck draft dated December 27]

[*]

Appendix B

DELIVERY SCHEDULE

[*]

Appendix C

INITIAL PRESS RELEASE

For Immediate Release
DRAFT: January 8, 2016

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

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

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

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

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

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

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

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

About Pancreatic Cancer

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

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

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

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

For more information on BioLineRx, please visit www.biolinerx.com 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 future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. These and other factors are more fully discussed in the "Risk Factors" sections of recent annual reports filed by the parties to this release. In addition, any forward-looking statements represent the parties' views only as of the date of this release and should not be relied upon as representing their views as of any subsequent date. The parties do not assume any obligation to update any forward-looking statements unless required by law.

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Schedule I

DATA SHARING AND SAMPLE TESTING SCHEDULE

[*]

SCHEDULE 2.4

Potential BioLineRx Subcontractors
(in accordance with Section 2.4)

[*]

Employment Agreement

This Employment Agreement (this "**Agreement**") is entered into on this 1st day of March, 2016 by and between **BioLineRx Ltd.**, a company organized under the laws of the State of Israel, with its offices at Modi'in Technology Park, 2 HaMa'ayan Street, Modi'in 7177871 ("**BioLine**"), and **Dr. Merril Gersten**, whose address is 13472 Calle Colina, Poway, California 92064 ("**Executive**").

WHEREAS, BioLine desires to employ Executive and Executive desires to enter into such employment, on the terms and conditions hereinafter set forth.

NOW THEREFORE, in consideration of the mutual covenants and conditions hereinafter set forth, the parties agree as follows:

1. **Employment**.

1.1. Executive shall serve in the position described in **Exhibit A** commencing on the date indicated in that exhibit (the "**Commencement Date**"). Executive shall be under the direct supervision of the Chief Executive Officer of BioLine or any individual designated by BioLine at its sole discretion (the "**Supervisor**"). Executive shall perform the duties, undertake the responsibilities and exercise the authority as determined from time to time by the Supervisor diligently, conscientiously and in furtherance of BioLine's best interests. Executive's duties and responsibilities hereunder may also include other services performed for affiliates of BioLine.

1.2. During the Employment Period (as defined in Section 5), Executive shall honestly, diligently, skillfully and faithfully serve BioLine, and undertakes to devote all of Executive's efforts and the best of her qualifications and skills to promoting the business and affairs of BioLine, and shall at all times act in a manner suitable of her position and status in BioLine.

1.3. Executive agrees and undertakes to inform BioLine, immediately after becoming aware of any matter that may in any way raise a conflict of interest between Executive and BioLine. Executive shall not receive any payment, compensation or benefit from any third party in connection, directly or indirectly, with the execution of Executive's position in BioLine.

1.4. Executive will be employed on a full time basis. Executive shall not undertake or accept any other paid or unpaid employment or occupation or engage in any other business activity except with the prior written consent of BioLine, which shall not be unreasonably withheld.

1.5. Executive hereby confirms and declares that her position is one that requires a special measure of personal trust and loyalty. Accordingly, the provisions of the Hours of Work and Rest Law, 1951 shall not apply to Executive, and Executive shall not be entitled to any compensation for working more than the maximum number of hours per week set forth in said law or any other applicable law.

1.6. Executive may also work outside of regular working hours and outside of regular working days, as may be required by BioLine from time to time.

1.7. The parties hereby confirm that this is an agreement for personal services and that the relationship between the parties shall not be subject to any general or special collective employment agreement or any custom or practice of BioLine with respect to any of its other employees or contractors.

2. **Place of Performance**. Executive shall be based at BioLine's facilities in Modi'in. In addition, Executive may be required to perform work at such other places as are appropriate to the functions being performed by BioLine. Executive acknowledges and agrees that her position may involve significant domestic and international travel.

3. **Executive's Representations and Warranties**. Executive represents and warrants that the execution and delivery of this Agreement and the fulfillment of all its terms: (i) will not constitute a default under or conflict with any agreement or other instrument to which Executive is a party or by which Executive is bound; and (ii) do not require the consent of any person or entity. Further, with respect to any past engagement Executive may have had with third parties and with respect to any allowed engagement Executive may have with any third party during the term of her engagement with BioLine (for purposes hereof, such third parties shall be referred to as "**Other Employers**"), Executive represents, warrants and undertakes that: (a) Executive's engagement with BioLine is and will not be in breach of Executive's undertakings towards Other Employers, and (b) Executive will not disclose to BioLine, or use, in provision of any services to BioLine, any proprietary or confidential information belonging to any Other Employers. Executive further represents and warrants that: (y) she does not suffer from any medical condition that may prevent from complying with duties and obligations under this Agreement; and (z) to Executive's best knowledge, the employment by BioLine will not cause any hazard to Executive's health.

4. **Proprietary Information; Confidentiality and Non-Competition**. By executing this Agreement, Executive agrees to the provisions of BioLine's Proprietary Information, Confidentiality and Non-Competition Agreement attached as **Exhibit B** hereto. The terms of Executive's employment are personal and confidential, and Executive undertakes to refrain from disclosing such terms to any third party, other than her consultants, immediate family or as otherwise required by Israeli, United States and California law or injunction.

5. **Period of Employment**. Executive's employment by BioLine commences on the Commencement Date and shall then continue, unless terminated in accordance with the provisions of this Agreement. The time during which Executive shall be employed by BioLine shall be referred to as the "**Employment Period**".

5.1. Death or Disability. Executive's employment will terminate upon the death of the Executive, and BioLine may terminate Executive's employment after having established Executive's disability. For purposes of this Agreement, "disability" means a physical or mental infirmity which impairs Executive's ability to substantially perform Executive's duties under this Agreement which continues for a period of at least ninety (90) consecutive days. Upon termination for disability, Executive shall be entitled to severance pay required by law, in accordance with the terms of this Agreement.

5.2. Termination at Will. Either party may terminate the employment relationship hereunder at any time by giving the other party prior written notice, as set forth in Exhibit A (the "**Notice Period**").

5.3. Termination for Cause. In the event of a termination for Cause (as defined below), BioLine may immediately terminate the employment relationship effective as of the time of notice of the same, and without payment in lieu of prior notice. "**Cause**" means (i) a material breach of trust including but not limited to theft, embezzlement, self-dealing, prohibited disclosure to unauthorized persons or entities of confidential or proprietary information of or relating to BioLine or its affiliates, unless required by law or injunction, and the engaging by Executive in any prohibited business competitive to the business of BioLine; (ii) any willful failure to perform or failure to perform competently any of Executive's fundamental functions or duties hereunder, which was not cured within thirty (30) days after receipt by Executive of written notice thereof; (iii) any breach of this Agreement by Executive; and (iv) any other cause justifying termination or dismissal without severance payment under applicable law.

5.4. Notice Period; End of Relations. During the Notice Period, the employment relationship hereunder shall remain in full force and effect and there shall be no change in Executive's position with BioLine, the Salary, social benefits or in any other obligations of either party hereunder. At the option of BioLine, Executive shall during such period either continue with Executive's duties or remain absent from BioLine's premises. However, BioLine, at its own discretion, may terminate this Agreement and the employment relationship at any time immediately upon a written notice and pay Executive an amount equal to the Salary referred to in Section 6 below including any and all social benefits that would have been paid to Executive during the Notice Period in lieu of the prior notice. In any event of the termination of this Agreement, Executive shall (a) immediately return all company property, equipment, materials and documents and (b) cooperate with BioLine and use Executive's best efforts to assist with the integration into BioLine's organization of the person or persons who will assume the Executive's responsibilities. Under no circumstances will Executive have a lien over any property provided by or belonging to BioLine.

5.5. Without derogating from all of BioLine's rights according to the provisions of this Agreement and the law, upon the termination of this Agreement, BioLine shall have the right to deduct from any payment to be paid to Executive any sum owed by Executive to BioLine by a written document.

6. **Salary**.

6.1. BioLine shall pay or cause to be paid to Executive during the term of this Agreement a gross monthly salary in the amount set forth in Exhibit A per month (the "**Base Salary**").

6.2. The Salary will be paid no later than the ninth day of each calendar month after the month for which the Salary is paid, after deduction of any and all taxes and charges applicable to Executive, as may be in effect or which may hereafter be enacted or required by law. Executive shall notify BioLine of any change which may affect Executive's tax liability.

7. **Relocation Costs Loan**

In order to assist in the costs related to Executive's relocation, BioLine agrees to provide Executive with a loan in the amount of $15,000 under the following terms:

7.1. The loan shall be provided within seven days after the date that this Agreement is signed, and shall bear linkage to the Israeli consumer price index and annual interest at the lowest rate allowed in accordance with the rules for employee loans currently in effect as established by the Israeli Income Tax Authority.

7.2. After completion of one year of employment, 33% of the loan (including accrued interest) shall be forgiven.

7.3. After completion of two years of employment, 100% of the loan (including accrued interest) shall be forgiven.

7.4. If Executive decides to terminate the employment arrangement prior to completion of two years of employment, the balance amount of loan then in effect (including linkage and accrued interest) shall become payable within 30 days of termination, and Executive hereby agrees that the balance amount shall be deducted from Executive's Salary and/or any other payment due to Executive by BioLine. If BioLine decides to terminate the employment arrangement, other than for Cause as defined herein, the entire loan balance (including linkage and accrued interest) shall be immediately forgiven.

Executive will be responsible for all income taxes that may be payable upon forgiveness of the loan and accrued interest.

8. **Insurance and Social Benefits**.

Executive shall be entitled to the following benefits:

8.1. Manager's Insurance/Pension Fund. During the Employment Period, BioLine will insure Executive under a "Manager's Insurance Scheme" or pension fund as agreed to by the parties (collectively the "**Policy**"). In the case of a Manager's Insurance Scheme, BioLine will pay an amount equal to 13⅓% of the Salary towards such Policy, of which 5% shall be for pension payments and 8⅓% shall serve to cover severance compensation. In addition, BioLine shall deduct from the Salary an amount equal to 5% of the Salary and forward the same to the Policy. In the case of a pension fund, BioLine will pay an amount equal to 14⅓% of the Salary towards such Policy, of which 6% shall be for pension fund payments and 8⅓% shall serve to cover severance compensation, and in addition, BioLine shall deduct from the Salary an amount equal to 5.5% of the Salary and forward the same to the Policy. Any tax payable in respect of such contributions to the Policy shall be borne and paid by Executive. The percentages listed above will be subject to adjustment in accordance with changes in applicable law from time to time.

8.2. Executive hereby agrees and acknowledges that all of the payments that BioLine shall make to the abovementioned Policy shall be instead of any severance pay to which Executive or Executive's successors shall be entitled to receive from BioLine with respect to the salary from which these payments were made and the period during which they were made, in accordance with Section 14 of the Severance Pay Law 5723-1963 (the "**Law**"). The parties hereby adopt the General Approval of the Minister of Labor and Welfare, published in the Official Publications Gazette No. 4659 on June 30, 1998, attached hereto as **Exhibit C**. BioLine hereby waives in advance any claim it has or may have to be refunded any of the payments made to the manager's insurance policy, unless (i) Executive's right to severance pay is invalidated by a court ruling on the basis of Sections 16 or 17 of the Law (and in such case only to the extent it is invalidated), or (ii) Executive withdrew funds from the manager's insurance policy for reasons other than an "Entitling Event". An "Entitling Event" means death, disability or retirement at the age of sixty (60) or more.

8.3. Disability Insurance. In addition to the foregoing, during the Employment Period BioLine will bear the cost of disability insurance with an insurance company (*Ovdan Kosher Avoda*). The amount paid by BioLine for such insurance shall be as generally accepted, but shall not exceed 2.5% of the Salary.

8.4. Advanced Study Fund. During the Employment Period, BioLine will maintain for the Executive an advanced study fund (*Keren Hishtalmut*) recognized by the Israeli Income Tax Authorities, such that BioLine and Executive shall contribute to such fund an amount equal to 7.5% of the Salary and 2.5% of the Salary, respectively. Any tax payable in respect of such contributions to such fund shall be borne and paid by Executive. All payments and contributions of BioLine with respect to these benefits shall be limited to the Salary and up to the highest amount recognized by the tax authorities.

8.5. Convalescence. During the Employment Period, Executive shall be entitled to receive convalescence allowance (*Dmei Havra'a*) pursuant to applicable law.

8.6. Sick Leave. Executive shall be entitled to be absent from work each year due to illness for the number of days allowed pursuant to the Sick Pay Law 5736 - 1976, and shall be entitled to fully paid sick leave upon presentation of appropriate medical documentation regarding said illness. Any amounts paid to Executive on account of the disability insurance indicated in subsection 8.3 will be on account of sick leave payment.

8.7. Vacation. During the Employment Period, Executive shall be entitled to vacation in the number of working days per year as set forth in Exhibit A, as adjusted in accordance with applicable law. A "working day" shall mean Sunday to Thursday inclusive, and the use of said vacation days will be coordinated with BioLine. Executive shall be entitled to accumulation and redemption of vacation days in accordance with BioLine's policies, which may be amended from time to time in BioLine's sole discretion.

For the avoidance of any doubt, due to the Company's request that Executive move to Israel by early May 2016, she may therefore be required to return to the US one or more times during the first year of employment to finalize her relocation. Therefore, the Company will not unreasonably withhold its consent to allow Executive's request for vacation.

8.8. Health Insurance. Beginning on the Commencement Date, the Company will provide Executive with private medical insurance and shall give Executive a summary of the insurance policy in English. Such insurance will be provided to Executive until the earlier of: (i) her making *aliyah* and becoming eligible for health insurance coverage in Israel and (ii) 18 months from the Commencement Date.

8.9. Mobile Phone; Computer. During the Employment Period, Executive shall be entitled to receive a mobile phone and a laptop computer. Executive shall use the mobile phone and computer (together hereinafter: the "**Equipment**") in a standard and reasonable manner, and in accordance with BioLine's policies. The Executive hereby agrees that any amount due by Executive to BioLine in connection with the Equipment (including, e.g., compensation for loss or damage of the Equipment) shall be deducted from Executive's Salary.

8.10. Automobile. During the Employment Period, for purposes of performance of Executive's duties and tasks, BioLine shall make available to Executive a company vehicle of a type to be chosen by BioLine in accordance with its policy which may be amended from time to time (the "**Company Car**"). Before delivery of the Company Car, Executive shall sign BioLine's Vehicle Agreement, the form of which is attached hereto as **Exhibit G.** Executive shall use the Company Car in accordance with the Vehicle Agreement as well as with BioLine's car policy then in effect. For the avoidance of doubt, Executive agrees that the cost of the leasing and the cost of the use of the Company Car shall not constitute a component of Executive's Salary, including with regard to social benefits or any other right to which Executive is entitled by virtue of this Agreement or under law.

9. **BioLine Property**. Executive acknowledges and agrees that the Equipment, email account and any other device or system providing for transmittal and storage of information which are placed at Executive's disposal by BioLine during the Employment Period are and shall remain the property of BioLine. Executive confirms her understanding that BioLine may review email correspondence and other information transmitted and stored by using the equipment stated above, and BioLine reserves the right to copy, store, present to others, and use such information. Executive acknowledges and agrees that any messages and data sent from, received by, or stored in or upon BioLine's computers and communications systems are the sole property of BioLine, regardless of the form or content of these messages and data. Executive should not consider messages and data sent from, received by, or stored in or upon BioLine's computer and communications systems to be private and should not send, receive, or store sensitive personal or private information using these systems. Executive is deemed to have consented, subject to any applicable law, to any reasonable use, transfer and disclosure of all messages and data contained or sent via the BioLine's computer and communications systems, including electronic mail. Executive shall fully comply with BioLine's policies regarding its computers and network, as may be in effect from time to time.

10. **Expenses**. Executive shall be reimbursed for all direct business expenses borne by Executive, in accordance with BioLine's policies as determined by BioLine from time to time, provided that such expenses were approved by Executive's Supervisor in advance. As a condition to reimbursement, Executive shall be required to provide BioLine with all invoices, receipts and other evidence of expenditures as may be reasonably required by BioLine from time to time.

11. **Equity Compensation**. Subject to the approval of the Board of Directors of BioLine and the execution of the requisite agreements, Executive shall be granted (a) options to purchase Ordinary Shares par value NIS 0.10 each of BioLine, in the amount set forth in Exhibit A, and (b) performance stock units in the amount set forth in Exhibit A, all to be granted pursuant to, and in accordance with, the terms and conditions of the share incentive plan adopted by BioLine.

12. **Code of Business Conduct and Ethics; Internal Policies.** Executive shall at all times comply with the Code of Business Conduct and Ethics attached hereto as **Exhibit D**, the Policy regarding Securities Trades by Company Personnel attached hereto as **Exhibit E**, the Company's Internal Enforcement Policy attached hereto as **Exhibit F**, and all other internal policies and procedures of BioLine, as shall be updated from time to time. Updates to Exhibits D, E and F, and copies of BioLine's internal policies and procedures, can be obtained at BioLine's human resources office. Executive represents that she has read Exhibits D, E and F, will acquaint herself with BioLine's other internal policies and procedures and agrees to comply with their terms, including any amendments and updates thereto.

13. **General**.

13.1. The laws of the State of Israel shall apply to this Agreement and the sole and exclusive place of jurisdiction in any matter arising out of or in connection with this Agreement shall be the Tel Aviv Regional Labor Court. The provisions of this Agreement are in lieu of the provisions of any collective bargaining agreement, and therefore, no collective bargaining agreement shall apply with respect to the relationship between the parties hereto (subject to the applicable provisions of law).

13.2. This Agreement constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof, and supersedes all prior written or oral agreements with respect to the subject matter hereof. This Agreement may not be modified except by written instrument signed by a duly authorized representative of each party. No failure, delay of forbearance of either party in exercising any power or right hereunder shall in any way restrict or diminish such party's rights and powers under this Agreement, or operate as a waiver of any breach or nonperformance by either party of any terms of conditions hereof. If it shall be determined under any applicable law that a certain provision set forth in this Agreement is invalid or unenforceable, such determination shall not affect the remaining provisions of this Agreement.

13.3. This Agreement may be assigned by BioLine. Executive may not assign or delegate her duties under this Agreement without the prior written consent of BioLine. This agreement shall be binding upon the heirs, successors and permitted assignees of Executive. The provisions of this Agreement shall survive the termination of the Employment Period and the assignment of this Agreement by BioLine to any successor or other assignee.

13.4. The parties agree that this Agreement constitutes, among other things, notification in accordance with the Notice to Executives (Employment Terms) Law, 2002.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first set forth above.

BioLineRx Ltd.	**Executive**
By: _____	Name: _____
Name: _____	Signature: _____
Title: _____	

Exhibit A
Particulars of Employment

1.	Name of Executive:	Merril Gersten
2.	Address of Executive:	13472 Calle Colina Poway, California 92064
3.	Position in BioLine:	Chief Scientific Officer
4.	Commencement Date:	May 10, 2016
5.	Notice Period:	60 days
6.	Base Salary:	NIS 52,000
7.	Equity Compensation	100,000 stock options, subject to Board approval 50,000 performance stock units (PSUs), subject to Board approval
8.	Vacation Days Per Year:	20
9.	Manager's Insurance/Pension Fund	Yes
10.	Disability Insurance	Yes
11.	Advanced Study Fund	Yes
12.	Mobile Phone	Yes
13.	Computer	Yes
14.	Car	Yes, senior manager level

_____ _____

BioLine Executive

Exhibit B

Proprietary Information, Confidentiality and Non-Competition Agreement

1. **General**.

1.1. All capitalized terms herein shall have the meanings ascribed to them in the Employment Agreement to which this Exhibit B is attached (the "**Employment Agreement**"). For purposes of any undertaking of Executive toward BioLine, the term BioLine shall include all subsidiaries and affiliates of BioLine.

1.2. Executive's obligations and representations and BioLine's rights under this Exhibit B (this "**Agreement**") shall apply as of the Commencement Date of the employment relationship between BioLine and Executive, and as of the first time in which Executive became engaged with BioLine, regardless of the date of execution of the Employment Agreement.

1.3. Executive's undertakings hereunder shall remain in full force and effect after termination of this Agreement or the Employment Agreement, or any renewal thereof.

2. Executive acknowledges that he/she has received or may receive information of a confidential and proprietary nature regarding the activities and business of BioLine, its subsidiaries or affiliates, all whether in oral, written, graphic, or machine-readable form, or in any other form, including, but not limited to, (i) patents and patent applications and related information, (ii) trade secrets and industrial secrets, and (iii) drugs, compounds, molecules, building blocks, chemical libraries, reaction protocols for chemical libraries, chemical structures, chemical design and model relationship data, chemical databases, assays, samples, media and other biological materials, procedures and formulations for producing any such materials, products, processes, ideas, know-how, trade secrets, drawings, inventions, improvements, formulas, equations, methods, developmental or experimental work, research or clinical data, discoveries, developments, designs, techniques, instruments, devices, computer software and hardware related to the current, future or proposed products and services, and including, without limitation, information regarding research, development, new service offerings or products, marketing and selling, business plans, forecasts, business methods, budgets, finances, licensing, collaboration and development arrangements, prices and costs, buying habits and practices, contact and mailing lists and databases, vendors, customers and clients, and potential business opportunities, and personnel (collectively, "**Confidential Information**"). Confidential Information may also include information furnished to BioLine by third parties, which, for purposes of this Agreement, shall all be deemed Confidential Information of BioLine. Notwithstanding the aforesaid, information that is in the public domain, through no act or omission of Executive shall not be deemed Confidential Information. The Confidential Information and all right, title and interest therein will remain at all times the exclusive property of BioLine (or any third party entrusting its own Confidential Information to BioLine).

3. At all times during the Employment Period and thereafter, Executive will hold all Confidential Information in strictest confidence and will not disclose, use, or make any copies thereof, unless required to by law or injunction. Executive hereby assigns to BioLine any rights that Executive may have or acquire in such Confidential Information and recognize that all Confidential Information shall be the sole property of BioLine and its assigns or licensors, as applicable.

4. Executive represents that he/she has assigned to BioLine all inventions, original works of authorship, developments, improvements, and trade secrets which were conceived, developed, made or reduced to practice by Executive prior to the date of the this Agreement or the Commencement Date, whichever is earlier (collectively referred to as "**Prior Inventions**"), in which Executive has or purports to have any ownership interest in or a license to use, and which relate to BioLine's current or proposed business, products or research and development. Notwithstanding the foregoing, this Agreement will not be deemed to require assignment of any invention which was developed entirely on Executive's own time without using BioLine's equipment, supplies, facilities, or Proprietary Information and which is not related to the BioLine's actual business, research or development. In addition, the Agreement will not apply with respect to inventions, if any, that were reduced to practice, made or conceived by Executive not in connection with Executive's relationship with BioLine and have been fully disclosed to BioLine prior to Executive's engagement with BioLine ("**Excluded Inventions**"). All Excluded Inventions existing as of the date hereof are listed in Schedule 1 hereto. If, in the course of Executive's employment, Executive incorporates an Excluded Invention into a product, process or machine of BioLine, BioLine is hereby granted and shall have a nonexclusive, royalty-free, irrevocable, perpetual, worldwide license (with rights to sublicense through multiple tiers of sublicenses) to make, have made, modify, use and sell such Excluded Invention. Notwithstanding the foregoing, Executive agrees that: (i) Executive will not incorporate, or permit to be incorporated, Excluded Inventions in any Inventions of BioLine without the BioLine's prior written consent, (ii) Executive's failure to obtain such prior consent shall not affect the grant of the license relating to the Excluded Inventions as specified in this Section 4.

5. Executive will promptly disclose and describe to BioLine all inventions, improvements, designs, concepts, techniques, methods, processes, know how, and trade secrets, whether or not patentable, copyrightable or protectable as trade secrets that are made, developed, conceived or first reduced to practice or created by Executive, whether alone or jointly with others, during Executive's employment with BioLine (i) which relate to BioLine's business or actual or demonstrably anticipated research or development, (ii) which are developed in whole or in part on BioLine's time or with the use of any of BioLine's Confidential Information or other information, equipment, supplies, facilities or trade secret information, or (iii) which result directly or indirectly from any work performed by Executive for BioLine (the "**Inventions**," and each an "**Invention**").

6. Executive hereby assigns and agrees to assign in the future (when any such Inventions or Proprietary Rights (defined below) are first reduced to practice or first fixed in a tangible medium, as applicable) to BioLine or its designee(s) all of Executive's right, title and interest in and to any and all Inventions (and all Proprietary Rights with respect thereto) whether or not patentable or registrable under copyright or similar statutes. Executive further specifically assigns to BioLine all original works of authorship, including any related moral rights, which are made by Executive (solely or jointly with others) during the Employment Period which are protectable by copyright pursuant to applicable copyright law. Executive also agrees to assign all of her right, title and interest in and to any particular Invention to any third party, including without limitation government agency, as directed by BioLine. Executive hereby waives and irrevocably quitclaims to BioLine any and all claims, of any nature whatsoever, that Executive now has or may hereafter have for infringement of any and all rights in Inventions and Proprietary Rights. To the extent any moral rights cannot be assigned under applicable law and to the extent the following is allowed by the laws in the various countries where moral rights exist, Executive hereby waives such moral rights and consent to any action of BioLine that would violate such moral rights in the absence of such consent.

   The term "**Proprietary Rights**" shall mean: (i) patents, whether in the form of utility patents or design patents and all pending applications for such patents; (ii) trademarks, trade names, service marks, designs, logos, trade dress, and trade styles, whether or not registered, and all pending applications for registration of the same; (iii) copyrights or copyrightable material, including moral rights, including but not limited to books, articles and publications, whether or not registered, and all pending applications for registration of the same; and (iv) all other intellectual property rights throughout the world.

7. Executive specifically acknowledges and agrees that Executive's duties with BioLine will entail the invention and development of new ideas, technologies, products and other confidential and proprietary information, and that the creation of any such intellectual property is an inherent part of Executive's duties with BioLine. Executive expressly agrees that the consideration paid to Executive pursuant to her Employment Agreement constitutes the sole consideration to which Executive may be entitled to for the assignment of any and all Inventions or Proprietary Rights made, developed, conceived or first reduced to practice or created by Executive (or with her assistance or contribution) including, without limitation, in accordance with Section 134 of the Patent Law, 5727-1967 (the "Patent Law"), and Executive shall not be entitled to receive any additional consideration in this respect whatsoever. Without derogating from the aforesaid, it is hereby clarified that the level of Executive's compensation and consideration has been established based upon the aforementioned waiver of rights to receive any such additional royalties, consideration or other payments. The above will apply to any "Service Inventions" as defined in the Patent Law. It being clarified that under no circumstances will Executive be deemed to have any Proprietary Right in any Service Invention, notwithstanding the provision or non-provision of any notice of an invention or BioLine's response to any such notice, under Section 132(b) of the Patent Law. This Agreement is expressly intended to be an agreement with regard to the terms and conditions of consideration for Service Inventions in accordance with Section 134 of the Patent Law.

8. Executive will assist BioLine in every proper way to obtain, and from time to time enforce, any Proprietary Rights relating to any Inventions in any and all countries. To that end Executive will execute, verify and deliver such documents and perform such other acts (including appearances as a witness) as BioLine may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Proprietary Rights and the assignment thereof. In addition, Executive will execute, verify and deliver assignments of such Proprietary Rights to BioLine or its designee. Executive's obligation to assist BioLine with respect to Proprietary Rights relating to any such Inventions in any and all countries shall continue indefinitely beyond termination of the Employment Period for any reason (the "**Termination Date**"), but BioLine shall compensate Executive at the rate of $350 per hour after the Termination Date for the time actually spent by Executive at BioLine's request on such assistance.

9. If BioLine is unable for any reason, after reasonable effort, to secure Executive's signature on any document needed in connection with the actions specified in the preceding paragraph, Executive hereby irrevocably designates and appoints BioLine and its duly authorized officers and agents as Executive's agent and attorney in fact, which appointment is coupled with an interest, to act for and in Executive's behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by Executive. Executive hereby waives and holds BioLine harmless from any and all claims, of any nature whatsoever, which Executive now or may hereafter have for infringement of any Proprietary Rights assigned hereunder to BioLine.

10. Executive agrees to keep and maintain adequate and current records (in the form of notes, sketches, drawings and in any other form that may be required by BioLine) of all Confidential Information developed by Executive and all Inventions made by Executive during the Employment Period to BioLine, which records shall be available to and remain the sole property of BioLine at all times.

11. During the Employment Period, Executive will not improperly use or disclose any confidential information or trade secrets, if any, of any former employer or any other person to whom Executive has an obligation of confidentiality, and Executive will not bring onto the premises of BioLine any unpublished documents or any property belonging to any former employer or any other person to whom Executive has an obligation of confidentiality unless consented to in writing by that former employer or person.

12. Upon the earlier of (i) a written request by BioLine; or (ii) the expiration or termination of the employment, Executive shall promptly return to BioLine all Confidential Information, together with any and all copies or excerpts thereof and any and all other information directly or indirectly derived therefrom. Return or destruction of the Confidential Information as required hereunder shall not affect Executive's remaining obligations pursuant to this Agreement.

13. **Non-Competition; Non-Solicitation**.

13.1. In consideration of Executive's terms of employment, which include special compensation for Executive's undertakings under this Section 12, and in order to enable BioLine to effectively protect its Proprietary Information, Executive undertakes that during the Employment Period and for a period of twelve (12) months from the Termination Date, Executive will not directly or indirectly: (i) carry on or hold an interest in any company, venture, entity or other business (including, without limitation, as a shareholder other than a minority interest in a publicly traded company) which directly competes with the products or services of BioLine (a "**Competing Business**") ; (ii) act as a consultant, employee or officer or in any managerial capacity in a Competing Business, or supply in direct competition with BioLine services to any person who, to Executive's knowledge, was provided with services by BioLine any time during the twelve (12) months immediately prior to the Termination Date; (iii) solicit, canvass or approach or endeavor to solicit, canvass or approach any person who, to Executive's knowledge, was provided with services by BioLine at any time during the twelve (12) months immediately prior to the Termination Date, for the purpose of offering services or products which directly compete with the services or products supplied by BioLine at the Termination Date; or (iv) employ, solicit or entice away or endeavor to solicit or entice away from BioLine any person employed by BioLine any time during the twelve (12) months immediately prior the Termination Date with a view to inducing that person to leave such employment and to act for another employer in the same or a similar capacity.

13.2. Insofar as the protective covenants set forth in this Agreement are concerned, Executive specifically acknowledges, stipulates and agrees as follows: (i) the protective covenants are reasonable and necessary to protect the goodwill, property and Proprietary Information of BioLine, and the operations and business of BioLine; and (ii) the time duration of the protective covenants is reasonable and necessary to protect the goodwill and the operations and business of BioLine, and does not impose a greater restraint than is necessary to protect the goodwill or other business interests of BioLine. Nevertheless, if any of the restrictions set forth in this Agreement is found by a court having jurisdiction to be unreasonable or overly-broad as to geographic area, scope or time or to be otherwise unenforceable, the parties intend for the restrictions set forth in this Agreement to be reformed, modified and redefined by such court so as to be reasonable and enforceable and, as so modified by such court, to be fully enforced.

14. Executive represents that Executive's performance of all the terms of the Employment Agreement and this Agreement does not and will not breach any agreement to keep in confidence information acquired by Executive in confidence or in trust prior to Executive's relationship with BioLine. Executive has not entered into, and agrees that he/she will not enter into, any agreement either written or oral in conflict herewith.

15. Executive hereby consents that if Executive leaves the employ of BioLine, BioLine may notify any new employer of Executive's rights and obligations under this Agreement.

16. Executive acknowledges that any violation or threatened violation of this Agreement may cause irreparable injury to BioLine, entitling BioLine to seek injunctive relief in addition to all other legal remedies.

17. Executive recognizes and agrees that: (i) this Agreement is necessary and essential to protect the business of BioLine and to realize and derive all the benefits, rights and expectations of conducting BioLine's business; (ii) the area and duration of the protective covenants contained herein are in all things reasonable; and (iii) good and valuable consideration exists under the Employment Agreement, for Executive's agreement to be bound by the provisions of this Agreement.

18. The terms of paragraphs 13.1 through 13.3 of the Employment Agreement shall apply to this Agreement.

19. EMPLOYEE ACKNOWLEDGES THAT HE/SHE HAS READ THIS AGREEMENT CAREFULLY, UNDERSTANDS ITS TERMS AND HAS BEEN GIVEN THE OPPORTUNITY TO DISCUSS IT WITH INDEPENDENT LEGAL COUNSEL.

Schedule 1 to Exhibit B

LIST OF PRIOR INVENTIONS
AND EXCLUDED INVENTIONS
(SECTION 4)

Modeling of the IL2 receptor
Modeling of the myeloid-T cell switch
Analysis of data relating to neuronal differentiation
Analysis of data relating to Alzheimer's Disease

Exhibit C

General Approval Regarding Payments by Employers to a Pension Fund and Insurance Fund in lieu of Severance Pay under the Severance Pay Law 5723-1963

By virtue of my power under Section 14 of the Severance Pay Law, 5723-1963 (hereinafter: the "**Law**"), I certify that payments made by an employer commencing from the date of the publication of this approval for the sake of his employee to a comprehensive pension provident fund that is not an insurance fund within the meaning set forth in the Income Tax Regulations (Rules for the Approval and Conduct of Provident Funds), 5724-1964 (hereinafter: the "**Pension Fund**") or to managers' insurance which includes the possibility to receive annuity payments under an insurance fund as aforesaid, (hereinafter: the "**Insurance Fund**"), including payments made by the employer by a combination of payments to a Pension Fund and an Insurance Fund (hereinafter: "**Employer's Payments**"), shall be made in lieu of severance pay due to said employee with respect to the salary from which said payments were made and for the period they were paid (hereinafter: the "**Exempt Salary**"), provided that all the following conditions are fulfilled:

(1) The Employer's Payments –

(a) to the Pension Fund are not less than 14⅓% of the Exempt Salary or 12% of the Exempt Salary if the employer pays, for the sake of his employee, in addition thereto, payments to supplement severance pay to a severance pay provident fund or to an Insurance Fund in the employee's name, in the amount of 2⅓% of the Exempt Salary. In the event that the employer has not paid the above mentioned 2⅓% in addition to said 12%, his payments shall come in lieu of only 72% of the employee's severance pay;

(b) to the Insurance Fund are not less than one of the following:

(i) 13⅓% of the Exempt Salary, provided that, in addition thereto, the employer pays, for the sake of his employee, payments to secure monthly income in the event of disability, in a plan approved by the Commissioner of the Capital Market, Insurance and Savings Department of the Ministry of Finance, in an amount equivalent to the lower of either an amount required to secure at least 75% of the Exempt Salary or in an amount of 2½% of the Exempt Salary (hereinafter: "Disability Insurance Payment");

(ii) 11% of the Exempt Salary, if the employer paid, in addition, the Disability Insurance Payment; and in such case, the Employer's Payments shall come in lieu of only 72% of the employee's severance pay. In the event that the employer has made payments in the employee's name, in addition to the foregoing payments, to a severance pay provident fund or to an Insurance Fund in the employee's name, to supplement severance pay in an amount of 2⅓% of the Exempt Salary, the Employer's Payments shall come in lieu of 100% of the employee's severance pay.

(2) No later than three months from the commencement of the Employer's Payment, a written agreement was executed between the employer and the employee, which includes:

(a) the employee's consent to an arrangement pursuant to this approval, in an agreement specifying the Employer's Payments, the Pension Fund and the Insurance Fund, as the case may be; said agreement shall also incorporate the text of this approval;

(b) an advance waiver by the employer of any right which he may have to a refund of monies from his payments, except in cases in which the employee's right to severance pay was denied by a final judgment pursuant to Section 17 of the Law, and in such a case or in cases in which the employee withdrew monies from the Pension Fund or Insurance Fund, other than by reason of an entitling event; for these purposes an "Entitling Event" means death, disability or retirement at or after the age of 60.

(3) This approval shall not derogate from the employee's right to severance pay pursuant to any law, collective agreement, extension order or employment agreement with respect to compensation in excess of the Exempt Salary.

15th Sivan 5758 (June 9th, 1998).

Exhibit D

BioLineRx Ltd. Code of Business Conduct and Ethics

Effective as of January 1, 2011

POLICY STATEMENT

It is the policy of BioLineRx Ltd. (the "Company") to conduct its affairs in accordance with all applicable laws, rules and regulations of the jurisdictions in which it does business. This Code of Business Conduct and Ethics (this "Code") applies to the Company's employees, officers and directors. This Code is designed to promote:

- honest and ethical conduct by all of the Company's employees, officers and directors, including the ethical handling by such persons of actual or apparent conflicts of interest between personal and professional relationships;

- full, fair, accurate, timely and understandable disclosure in the reports and documents the Company files with, or submits to, the U.S. Securities and Exchange Commission ("SEC") or the Israeli Securities Authority ("ISA"), and in other public communications made by the Company;

- compliance with applicable governmental laws, rules and regulations;

- the prompt internal reporting to the appropriate person of violations of this Code; and

- Accountability for adherence to this Code.

All directors, officers and employees of the Company are subject to this Code and are expected to adhere to and comply with those principles and procedures set forth in this Code that apply to them. The Company will take such disciplinary or preventative action as it deems appropriate to address any existing or potential violation of this Code brought to its attention.

APPROVALS AND WAIVERS

Certain provisions of this Code require you to act, or to refrain from acting, unless prior approval is received from the appropriate person. Employees requesting approval pursuant to this Code should request such approval in writing from the Compliance Officer. Approvals relating to Executive Officers and Directors must be obtained from the Company's Board of Directors. All other approvals may be granted by the Compliance Officer, or such officer's designee.

Other provisions of this Code require you to act, or to refrain from acting, in a particular manner and do not permit exceptions based on obtaining an approval. Waiver of those provisions relating to Executive Officers, senior financial officers and Directors may only be granted by the Board of Directors.

RESPONSIBILITY FOR COMPLIANCE

Your responsibility

You are obligated to adhere to this policy in the performance of your job responsibilities. When faced with a situation that requires an evaluation of what is, and what is not, proper business conduct, begin by applying the following criteria:

- Is the course of conduct legal?
- Is the course of conduct in accordance with the guidelines set forth in this Code and with Company policies and procedures?
- Would you or the Company be compromised or embarrassed if the situation were known by your co-workers or the public?
- Does the intended course of conduct have the appearance of impropriety?

If you are unable to answer "yes" to the first two questions and "no" to the second two questions with certainty, seek advice through the channels described under the section entitled "To seek advice or report non-compliance."

Remember that failure to report a violation of this Code is itself a violation.

To seek advice or report non-compliance

If you suspect non-compliance, or have a question as to any aspect of this Code, including its interpretation, application or compliance therewith, regarding yourself or any other employee of BioLineRx, you must seek the advice of the appropriate Company authority, such as your immediate supervisor, human resources manager or General Counsel. If for any reason you feel uncomfortable discussing your concerns or questions with these individuals, or if you are dissatisfied with their responses, seek advice from the Internal Auditor. If you prefer, you may correspond anonymously with the Internal Auditor through our confidential mailbox: biolinerx@deloitte.co.il.

The Company Compliance Team:

Nurit Benjamini **Audit Committee Chairperson** **email: nurit378@gmail.com** **Tel: 052-644-0745**	**Linur Dloomy, CPA (Deloitte)** **Internal Auditor** **e-mail: LDloomy@deloitte.co.il** **Tel: 052-583-9635**

Disciplinary action

The Company intends to prevent the occurrence of conduct not in compliance with the Code, applicable laws or regulations, or other policies, procedures and guidelines prepared by our Company and its business units and to halt any such conduct that may occur as soon as reasonably possible after its discovery. Allegations of non-compliance with the Code will be investigated whenever necessary and evaluated at the proper level(s). Those found to be in violation of this Code are subject to appropriate disciplinary action, up to and including termination of employment. Criminal misconduct may be referred to the appropriate legal authorities for prosecution.

When in doubt . . .

If you think you are being asked to behave or conduct business in an illegal, unethical or otherwise inappropriate manner, or you suspect others of such behavior, immediately report your concerns through the channels described above. You will ***not*** be penalized for reporting what you believe, in good faith, to be a breach of the Code; even if it later turns out that a violation has not occurred.

THE EMPLOYMENT RELATIONSHIP

Terms of employment

BioLineRx employees are generally employed by the Company either pursuant to an employment contract or other arrangement. Subject to applicable law, both the employee and the employer are legally allowed to terminate the employment at will. This BioLineRx Code may be revised from time to time at the Company's discretion and is not a contract of employment.

Anti-discrimination and anti-harassment

BioLineRx hires, pays, promotes and makes other employment decisions based upon lawful factors, such as qualifications and performance, and without regard to race, sex, color, religion, age, national origin, sexual orientation, disability or any other basis that is protected under applicable law.

Drug and alcohol abuse and drug-free workplace

BioLineRx prohibits the illegal use, sale, purchase, transfer, possession or presence in one's system of drugs, other than medically prescribed drugs, while on the Company's premises.

Workplace violence

BioLineRx does not tolerate workplace violence or threats of violence committed by or against employees or property.

Conflict of interest and opportunities for personal gain

All Directors, officers and employees must avoid relationships, activities or interests that conflict or appear to conflict with the interests of the Company. Directors, officers and all employees have an obligation to promptly disclose to their supervisor or local internal auditor any relationship, activity or interest that could possibly involve or appear to involve an actual or potential conflict of interest. If you are unsure whether something is a conflict of interest you are obligated to promptly disclose it to your supervisor.

Related Party Transactions

All Directors, officers and employees should immediately inform a representative of the Finance Department or General Counsel at the outset of negotiations or contacts regarding a potential transaction between an entity or a person related to a Director, officer or employee of BioLineRx or its subsidiaries and BioLineRx or its subsidiaries and in any event prior to completion of any such transaction (without regard to size or materiality).

Acceptance and giving entertainment or gifts

You may never accept bribes, kickbacks, or other types of unusual payments from any organization or individual seeking to do business with, doing business with, or competing with BioLineRx. You may accept gifts or entertainment of nominal value as part of the normal business process if public knowledge of your acceptance would cause the Company no conceivable embarrassment. In accordance with foreign laws, you are prohibited from directly or indirectly authorizing, offering, promising or giving anything of value to a foreign governmental official as a means of influencing or inducing the official to obtain or retain business for BioLineRx.

Fraud

You may not engage in fraudulent conduct. “Fraud” is the deliberate practice of deception in order to receive unfair or unlawful gain.

Financial reporting

All financial and other records of the Company are required to accurately and fairly reflect the Company’s assets, liabilities, revenues and expenses.

Outside employment or consulting

Employment as a consultant, officer, or manager of another business organization requires prior written management approval. Outside employment or consulting must never interfere with your job performance, utilize Company property or facilities, involve the implicit or explicit sponsorship of the Company, or create the possibility of adverse publicity for the Company.

Political activity and contributions

Requiring anyone at BioLineRx to make a personal or corporate contribution to any candidate, political party, or holder of any governmental office is prohibited. You are free to participate in lawful political activity.

Company records and accounts

All Company records and accounts are the property of BioLineRx. Company records and accounts must be maintained at all times in reasonable detail and in a manner that accurately reflects all business and financial transactions, including the disposition of assets. The destruction or falsification of a document in order to impede a litigation, governmental investigation, audit or examination is prohibited and may lead to prosecution for obstruction of justice.

Protection of the Company's Property

All employees should endeavor to protect the Company's property, plant and other tangible and intangible assets. Company property should not be used for non-Company business, though incidental personal use may be permitted.

Expense accounts

The Company recognizes its responsibility to reimburse you for legitimate business expenses. Those expenses should be within reasonable limits and commensurate with the nature of the business assignment. You are expected to fully and clearly document business expenses and comply with the travel policy, which applies to your business unit/locale.

Employee privacy

Company information about employees is confidential and only those with a legitimate, work-related need may access such information. BioLineRx will not release any information about you to entities outside the Company without your written authorization or unless required to do so by applicable law, pursuant to a summons, subpoena or court order, or as deemed appropriate by the Company.

Proprietary information and intellectual property

Proprietary business, technical, personal information or any trade secret of the Company and its employees, customers and suppliers is considered confidential and must be safeguarded. Intellectual property developed by you or by others for the Company, or for which the Company has secured rights from others, should be used only for the benefit of the Company. Accordingly, all intellectual property rights derived from confidential information or other materials made, originated or developed by the employees shall belong exclusively to the Company, and the employees who are the inventors or developers of such intellectual property rights shall have no rights or benefits therein or deriving therefrom. You may not disclose proprietary information of the Company, its employees, customers, former employees, former customers or suppliers. These prohibitions continue even if you cease being employed by the Company for any reason.

Corporate data security

Corporate data refers to all information collected, created, processed and/or maintained in the normal course of BioLineRx's business. The data may be in manual form (examples include verbal, handwritten, typed onto hard copy, microfilmed, photocopied or computer printouts), electronic form (examples include e-mails, voice-mails, computer memory, magnetic tape, cassette, disk, or diskette), or BioLineRx specific information included in computer applications programs, personal computing software, or operating system software.

All BioLineRx employees and any other person having physical or electronic access to corporate data are responsible for safeguarding corporate data by knowing and keeping such corporate data confidential.

Electronic communications

You may not access or use BioLineRx's electronic and wire communications systems without appropriate authority. No individual shall use the passwords or codes of another individual in order to gain access to that individual's e-mail, voice mail, or Internet communications on BioLineRx's systems unless first authorized to do so by that individual or the Company. These systems are provided for Company business, and only occasional personal use of the systems is permissible. Occasional personal use means minimal and infrequent use that does not interfere with BioLineRx business or job performance. BioLineRx's systems may not be used to access or transmit material that could embarrass, harass, or offend other persons.

External communications

Requests for financial or business information, for interviews with any BioLineRx employee including comments or responding to requests relating to BioLineRx or its business, or the issuance of any press releases by any BioLineRx employee must be referred to the Company's Chief Financial Officer.

Public disclosure requirements

All reports and submissions ("Reports") of BioLineRx to the SEC, NASDAQ, the Israel Securities Authority and the Tel Aviv Stock Exchange must comply with applicable legal and exchange requirements and may not contain material misstatements or omit material facts.

RELATIONSHIPS WITH BUSINESS ENTITIES AND AUTHORITIES

Product quality

We are committed to making safe quality products for our sublicensees and future users of our products. We expect each BioLineRx employees to contribute to these standards by providing high quality work, being fully familiar with applicable laws and regulations that are pertinent to their areas of responsibility and participating in training programs provided by the Company covering broad ranges of activities. Employees are also encouraged to exert diligence in identifying and preventing practices that could impair product quality, safety or compliance with law.

Economic Sanctions

BioLineRx employees must comply with the applicable laws and regulations relating to economic and trade sanctions and embargoes against certain countries or entities. This includes refraining from indirect facilitation of a prohibited transaction.

Foreign corrupt practices and anti-boycott laws

In accordance with local and/or foreign laws, BioLineRx employees are prohibited from directly or indirectly authorizing, offering, promising or giving anything of value to a foreign governmental official as a means of influencing or inducing the official to obtain or retain business for BioLineRx. BioLineRx employees also are required to comply with applicable corrupt practices laws and anti-boycott laws that prohibit participation in certain foreign boycotts.

Securities laws compliance/insider trading

All BioLineRx employees must strictly obey all laws that prohibit the trading of securities based on prior knowledge of "material," "non-public" information about BioLineRx. You may not trade BioLineRx stock, nor recommend to others that they trade BioLineRx stock, until such information has been publicly disclosed. These restrictions also apply to any trading, including securities of other companies, based on material, non-public information about customers, competitors or business partners of BioLineRx, either when trading BioLineRx securities or the securities of these other companies as well.

Unfair trade practices and fair dealing

All BioLineRx employees must comply with applicable laws in their place of employment and the laws of other applicable jurisdictions that prohibit unfair or deceptive business acts and practices, as well as unfair competition

Environmental protection

As a Company we are committed to full compliance with all applicable environmental protection laws and expect your individual cooperation

Health and safety

Employees must observe safe practices on their jobs, report any injury or accident at work promptly and follow Company security and emergency policies and procedures.

Exhibit E

BIOLINERX LTD.

STATEMENT OF COMPANY POLICY

SECURITIES TRADES BY BIOLINERX LTD. PERSONNEL

BioLineRx Ltd. (the "Company") has adopted the following Policy regarding trading by Company personnel in the Company's securities. The Policy applies to *all* Company personnel, including directors, officers, employees and consultants of the Company and its subsidiaries.

The Need for a Policy

This Policy has been developed:

- to educate all Company personnel;
- to set forth guidelines for courses of action;
- to protect the Company and all of its personnel against legal liability; and
- to preserve the reputation of the Company and its personnel for integrity and ethical conduct.

Since the Company is a public company with its ordinary shares traded on the Tel Aviv Stock Exchange and its American Depositary Shares on the Nasdaq Capital Market, transactions in the Company's securities are subject to both Israeli and United States federal securities laws and regulations. These laws and regulations make it illegal for an individual to buy or sell securities of the Company while aware of "inside information." The U.S. Securities and Exchange Commission (SEC) and the Israel Securities Authority (ISA) take insider trading very seriously and devote significant resources to uncovering the activity and to prosecuting offenders. Liability may extend not only to the individuals who trade on "inside information," but also to their "tippers," people who leak the inside information to the individuals who trade. The Company and "controlling persons" of the Company may also be liable for violations by Company employees.

In addition to responding to the statutes and regulations, we are adopting this Policy to avoid even the appearance of improper conduct on the part of anyone employed by or associated with the Company (not just "insiders").

The Consequences

The consequences of insider trading violations can be severe. The following are examples under U.S. law applicable to the Company:

For **individuals** who trade on inside information (or tip information to others):

- a civil penalty of up to three times the profit gained or loss avoided;
- a criminal fine (no matter how small the profit) of up to $5 million; and
- a jail term of up to twenty years.

For a **company** (as well as possibly any supervisory person) that fails to take appropriate steps to prevent illegal trading:

- a civil penalty of the greater of $1 million or three times the profit gained or loss avoided as a result of the employee's violation; and
- a criminal penalty of up to $25 million.

Any of the above consequences – or even an SEC or ISA investigation that does not result in prosecution – can tarnish one's reputation and irreparably damage a career. In addition, if an employee violates this Policy, Company-imposed sanctions, including dismissal for cause, could result from failing to comply with the Company's policy or procedures.

Our Policy

It is the Company's policy that no Company personnel nor any related persons may buy or sell securities of the Company while aware of material nonpublic information or engage in any other action to take advantage of, or pass on to others, that information.

This Policy also applies with equal force to information relating to any other company, including our collaborators, partners, suppliers, customers and others, obtained by Company personnel during the course of his or her service to or employment by the Company.

Transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) are no exception. Even the appearance of an improper transaction must be avoided to preserve our reputation for adhering to the highest standards of conduct.

Policy Administrator. This Policy shall be administered by the "Policy Administrator," who shall initially be the Chief Financial and Operating Officer. The Policy Administrator may, however, change from time to time, and you are encouraged to consult the copy of this Policy that is included on the Company's website to obtain current information concerning the Policy Administrator.

Material Non-Public Information. Material non-public information (*i.e.*, "inside information") is any information that:

- is not generally known to the public, and
- which, if publicly known, would likely affect either the market price of the Company's securities or a person's decision to buy, sell or hold the Company's securities.

Information "generally known to the public" is information released to the press or the industry and after public investors and the market have had a reasonable period of time to evaluate and react to the information. All other information is regarded as non-public.

Examples of Material Information. Common examples of information that will frequently be regarded as material are:

- quarterly or annual earnings results;
- projections of future results or sales;
- earnings or losses;
- news of a pending or proposed merger, acquisition or tender offer;
- an important financing transaction;

- significant clinical or regulatory developments;
- the entry into or termination of a significant collaboration, joint venture or strategic alliance;
- changes in management;
- significant new products or discoveries;
- plans regarding strategy or significant capital investments;
- impending bankruptcy or financial liquidity problems;
- criminal charge or government investigations;
- internal financial information which departs from what the market would expect; and
- the gain or loss of any significant contract or agreement.

Either positive or negative information may be material. We emphasize that this list is merely illustrative.

Twenty-Twenty Hindsight. Remember, if your securities transactions become the subject of scrutiny, they will be viewed after-the-fact with the benefit of hindsight. As a result, before engaging in any transaction, you should carefully consider how regulators and others might view your transaction in hindsight.

Transactions by Family Members and Others in Your Household. These restrictions also apply to your "immediate family members" – that is, a spouse, parent, child or sibling and any other family member who shares the same address as, or is financially dependent on you. Employees are expected to be responsible for the compliance of all family members with this Policy. Employees are also expected to be responsible for the compliance of other persons who live in their household, whether or not related, with this Policy.

Tipping Information to Others. Whether the information is proprietary information about the Company or information that could have an impact on our stock price, Company personnel must not pass the information on to others. The above penalties apply, whether or not you derive any monetary benefit from another person's actions. *Inside information is often inadvertently disclosed or overheard in casual, social conversations. Care must be taken to avoid such disclosures.*

When Information is Public. As you can appreciate, it is also improper for Company personnel to trade the Company's securities immediately after the Company has made a public announcement of material information. Since the Company's shareholders and the investing public should be afforded time to receive information and to act upon it, as a general rule you should not engage in any transactions until the beginning of the second business day after the information has been released. Thus, if an announcement is made on a Monday, Wednesday generally would be the first day on which you should trade. If an announcement is made on a Friday, Tuesday generally would be the first day on which you should trade. However, if the information released is complex, such as a prospective major financing or other transaction, it may be necessary to allow additional time for the information to be absorbed by investors. In such circumstances, you will be notified by the Policy Administrator regarding a suitable waiting period before trading.

Prevention of Insider Trading by Others. If you become aware of a potential insider trading violation, you must immediately advise the Policy Administrator. You should also take steps, where appropriate, to prevent persons under your supervision or control from using inside information for trading purposes.

Confidentiality. Serious problems could be caused for the Company by the unauthorized disclosure of internal information about the Company, whether or not for the purpose of facilitating improper trading in the securities of the Company. Company employees should not discuss internal company matters or developments with anyone outside of the Company, except as required in the performance of regular corporate duties.

This prohibition applies specifically (but not exclusively) to inquiries about the Company that may be made by the financial press, investment analysts or others in the financial community. It is important that all such communications on behalf of the Company be through an appropriately designated officer under carefully controlled circumstances. Unless you are expressly authorized to the contrary, if you receive any inquiries of this nature, you should decline comment and refer the inquirer to the Chief Financial and Operating Officer.

Nothing in this Policy is meant to limit or change the obligations of confidentiality and non-use of non-public information that directors, officers, employees and consultants of the Company by virtue of their positions or their agreements with the Company. Such obligations also apply in the context of any electronic chat room or electronic bulletin board, including participation under a pseudonym.

Additional Prohibited Transactions

Since we believe it is generally improper and inappropriate for Company personnel to engage in short-term or speculative transactions involving the Company's securities, it is our policy that such personnel should not engage in any of the following activities with respect to the Company's securities:

- Trading in the Company's securities on a short-term basis. Any ordinary shares of the Company purchased in the open market should be held for a minimum of 60 days.
- Short sales of the Company's securities.
- Use of the Company's securities to secure a margin or other loan, except in limited cases with the prior approval of the Policy Administrator.
- Transactions in straddles, collars, or other similar risk reduction devices, except in limited cases with the prior approval of the Policy Administrator.
- Transactions in publicly-traded options relating to the Company's securities (i.e., options that are not granted by the Company), except in limited cases with the prior approval of the Policy Administrator.

Trading Blackouts Applicable to all Company Personnel

While it is never permissible to trade based on material non-public information, we are implementing procedures to help prevent inadvertent violations and avoid even the appearance of an improper transaction (which could result, for example, where Company personnel engage in a trade while unaware of a pending major development).

Prohibited Periods for Trading. No person to whom this Policy is applicable may trade in the Company's securities during the following periods:

- the periods starting on the 15th day after the close of each fiscal quarter and ending at the beginning of the second business day after the release of the Company's financial results for each quarter and, in the case of the fourth quarter, financial results for the year end; and

- any other periods as determined by the Company. You will be notified by e-mail when you may not trade in the Company's securities during such periods, and you will also be notified when trading restrictions are lifted.

There are no restrictions on exercising options **without a sale**. **Selling** the shares held as a result of exercising options is subject to the restrictions set forth above.

Pre-Clearance of Trades

In order to ensure and maintain compliance with this Policy, all transactions in the Company's securities (acquisitions, dispositions, transfers, etc.), including the execution of Trading Plans (as defined below), by directors, members of Executive Management, financial team members and designated employees must be pre-cleared in advance by the Policy Administrator. If you are a member of one of the groups listed above and you contemplate a transaction in the Company's securities, you must contact the Policy Administrator or other designated individual prior to executing the transaction. The Policy Administrator will use his reasonable best efforts to provide approval or disapproval as soon as practicable. You must wait until receiving pre-clearance to execute the transaction. Neither the Company nor the Policy Administrator shall be liable for any delays that may occur due to the pre-clearance process. If the transaction is pre-cleared by the Policy Administrator, it must be executed by the end of the second business day after receipt of pre-clearance. Notwithstanding receipt of pre-clearance of a transaction, if you become aware of material nonpublic information after receiving the pre-clearance but prior to the execution of the transaction, you may not execute the transaction.

Please note that such pre-clearance does not provide the insider with immunity from investigation or suit; it is the responsibility of the individual to comply with the applicable securities laws and regulations.

Exception for Trading Plans

Notwithstanding the restrictions and prohibitions on trading in the Company securities as set forth in this Policy, persons subject to this Policy are permitted to effect transactions in Company securities pursuant to approved trading plans established under Rule 10b5-1 under the Securities Exchange Act of 1934 ("Trading Plans"), including transactions during the prohibited periods discussed above. Rule 10b5-1 requires that these transactions be made pursuant to a plan that was established while the person was not in possession of material non-public information. In order to comply with this Policy, the Company must pre-approve any such Trading Plan prior to its effectiveness. Company personnel seeking to establish a Trading Plan should contact the Policy Administrator.

Application of this Policy to Persons Who Cease to be Associated with the Company

The laws against insider trading continue to apply to anyone who has material non-public information about the Company. Therefore, even if an individual ceases to be employed by or associated with the Company, that person is prohibited by law from trading any securities of the Company for so long as he or she possesses material non-public information.

Company Assistance

Any person who has any questions about specific transactions or this Policy in general may obtain additional guidance from the Policy Administrator. Remember, however, the ultimate responsibility for adhering to the Policy and avoiding improper transactions rests with you. In this regard, it is imperative that you use your best judgment.

Certifications

As a condition to continuing employment, all employees will be required to certify their understanding of and intent to comply with this Policy. Members of the Board of Directors, Senior Management and other personnel may be required to certify compliance on an annual basis.

Certification

The undersigned hereby certifies that he/she has read and understands, and agrees to comply with, the Company's Statement of Company Policy regarding Securities Trades by Company Personnel, a copy of which was distributed with this Certification.

Date: _____ Signature _____

Name: _____
(Please Print)

Exhibit F

BIOLINERX LTD.

Intra-Organizational Enforcement Plan
Pursuant to and in accordance with the Law for the Improvement of Internal Enforcement Proceedings in the Israel Securities Authority, 5770-2010

This plan was approved by the Board of Directors of the Company on December 22, 2012 and has been updated as of October 2013.

2. Senior officer declaration

2.1 CEO's message

The status of BioLineRx as a public company confers on it both advantages and responsibility. The main market for trading the Company's shares is the Tel Aviv Stock Exchange. Therefore, we are subject to the Israeli Securities Law and the enforcement thereof by the Israel Securities Authority ("ISA"). When the ISA learns of breaches of the law, it has the power to sue companies and individuals in criminal proceedings and (after amendments to the law from 2011) to impose fines and other sanctions without the need to apply to the courts.

The administrative enforcement plan is intended to help us comply with the law, to correctly address violations and to demonstrate to the ISA that we treat seriously anything that is related to the offering of our shares. Understanding the plan and enforcing it in day-to-day life provides a solid basis for the investors' trust in particular and for the Company's public reputation in general.

Similarly to our code of business and ethics, this plan is intended for each and every Company employee, manager and Board member.

I request and expect your personal commitment to the enforcement of the procedure and full cooperation in its application.

This procedure is a living procedure which may change from time to time pursuant to relevant laws and regulations and according to the lessons learned during the assimilation of the plan.

I trust each and every one of you to comply with both the written plan and its spirit.

Dr. Kinneret Savitsky
CEO

3. General information on an administrative enforcement plan

3.1 Improvement of Internal Enforcement Proceedings in the ISA Law, 5770-2010

The Law for the Improvement of Internal Enforcement Proceedings in the Israel Securities Authority, 5770-2010 (the "**Law**"), which was approved by the Knesset in January 2011, constitutes a significant change that requires reporting companies to immediately address the requirements of the new Law. The main parts of the Law regulate the establishment of an administrative committee that will deal with violations in the area of securities. If the committee reaches the conclusion that it was proven at the level of proof which is customary in civil law (a probability of more than 50%) that a violation was committed, it will be authorized to institute various means of enforcement against the violating party.

The committee will deal with various violations that are related to the Securities Law, 5728-1968 (the "**Securities Law**") and other relevant laws. The common feature of such violations is that the *mens rea* that is set forth therein is at most that of negligence.

The means of enforcement that the committee will be authorized to impose will be significant fines, a demand to pay damages to the party injured by the violation, a payment to the State treasury which derives from profits that were generated as a result of the violation, a demand to institute acts to remedy the violation and prevent its recurrence, a prohibition on holding office in certain bodies, a suspension or revocation of a license and suspended punishment.

As is known, the Law establishes, *inter alia*, the strict responsibility of the CEO, due to which enforcement measures can be imposed as set forth in the Law.

(a) "The CEO of the corporation and a partner other than a limited partner, are obligated to supervise and institute any and all reasonable means under the circumstances of the case to prevent the commission of a violation by the corporation or partnership, as the case may be, or by any of their employees."

(b) If a violation is committed the presumption is that the CEO of the corporation or a partner other than a limited partner in the partnership, as the case may be, has breached his obligation pursuant to Subsection (a) **and may be subject to one or more of the means of enforcement** as specified below…unless he proves that he has fulfilled his obligation pursuant to Subsection (a):

(c) If the corporation has established **adequate procedures to prevent a violation** as provided in Subsection (b), **appointed an officer** on its behalf to supervise the compliance therewith, including with regard to providing guidance to the corporation's employees for the compliance therewith, and **instituted reasonable steps to remedy the violation and prevent the recurrence thereof**, the presumption is that the CEO or the partner, as the case may be, **has fulfilled his obligation** as provided in Subsection (a).

According to commentators, all the provisions of Subsection (c) lead to an *internal enforcement plan*. So, too, thought the Israel Securities Authority (the "**ISA**"), when in August 2011 it released a ***Document on criteria for recognition of an internal enforcement plan in the area of securities and investment management*** (the "**ISA Document**") and set forth that:

"**The application** in practice of an efficient enforcement plan by the corporation **may be viewed favorably by the ISA with respect to the corporation or individuals therein in the context of its discretion in respect of the exercise of its powers** of enforcement pursuant to the law."

The ISA's Document sets forth the standards that will be examined by the ISA when deliberating and deciding whether an efficient enforcement plan exists at a corporation. **Based on the requirements of the Law, the ISA's Document and the understanding of the Company's management, the relevant information and instructions have been incorporated into the enforcement plan document that is set forth below.**

3.2 What is an enforcement plan

This internal enforcement plan document is a document that is unique to the Company which set forth the activities to be undertaken in order to prevent the violations listed in the schedule to the administrative enforcement law.

3.3 Objectives of an enforcement plan

The creation, implementation and assimilation of a correct and suitable enforcement plan can constitute a dual safety mechanism for the Company and the individuals therein:

ü **Minimization of the possibility of the occurrence of a violation**

Through the establishment of clear procedures, presentation of standards for conduct and implementation of controls for the application thereof in the day-to-day activity, ensuring that any and all individuals taking part in the Company's relevant activity are aware of their obligation and the manner of their compliance therewith.

ü **Immediate effect on the examining entity in the event that a violation occurs**

As stated in the Law and in the ISA's Document, an enforcement plan is an indication that the Company (its managers and directors) has done everything within its power to try to prevent violations. Such a plan will provide a defense to their benefit whereby they have instituted any and all reasonable measures to prevent the offence for a body which is examining and/or dealing with an occurrence of a violation.

The primary objective of the enforcement plan is to ensure the proper activity of the Company in accordance with any and all regulatory obligations and desired standard of conduct insofar as the same are relevant to the Securities Law and the regulations promulgated thereunder.

The plan intends to establish existing proper conduct, to create a compilation of information and procedures that are relevant to the organization and to assimilate the conduct which is desired and required of each and every one of the Company's employees and officers and to promote an organizational culture of compliance with and respect for the Law.

All employees and/or officers should be able to consult the document if and when they encounter an issue pertaining to the content of the plan and to find answers with regard to the conduct that is appropriate and expected of them, whether it is a procedure which offers guidance on how to act or a referral to consultation with a relevant body.

3.4 Applicability of the enforcement plan

This plan applies to BioLineRx (the "**Company**") by virtue of its being a public company whose shares are listed on the Tel Aviv Stock Exchange. The plan applies to all of the Company's echelons, i.e. the Company's employees, senior officers, managers and directors. It is important to emphasize that the plan also applies to the employees of any and all subsidiaries of the Company in view of their involvement with the operations of the parent company.

3.5 Prohibition on insurance and indemnification

The Law explicitly contains a prohibition on insurance and/or indemnification in respect of violations of the Law.

The Law establishes that a proceeding to impose a pecuniary sanction, an administrative proceeding or an arrangement proceeding cannot be insured. A pecuniary sanction imposed on a corporation, its controlling shareholder or an employee in a proceeding as aforesaid cannot be indemnified or paid, either directly or indirectly.

However, an employee can be indemnified or insured for payment to the party injured by the violation and additionally for expenses that he shall have incurred in relation to a proceeding that was conducted in the matter of the employee, irrespective of the results of the proceeding.

In November 2011, the Company's articles of association and letters of insurance and indemnification of the officers were updated accordingly, such that a provision was set forth that permits the insurance and/or indemnification pursuant to the provisions of the Securities Law.

3.6 Documentation and provision of documents for inspection and storing of documents

The Law and the schedules include a reference to the issue of providing documents for inspection. As part of the enforcement plan and its procedures, the Company is obligated to make available for inspection any and all relevant documents (for example, a prospectus that was authorized for publication, a registration document or any and all reports, opinions, approvals, reports or notices that were filed) at its head office.

Relevant procedures shall specify the responsibility for the fulfillment of the right of inspection insofar as will be required.

4. Organizational structure and division of functions and responsibility

4.1 Organizational structure for the issue of administrative enforcement (areas of responsibility, reporting chain, decision making, etc.)

4.1.1 Responsibility of the Board of Directors and its committees

4.1.1.1 Formulation and adoption of the Company's internal enforcement plan

As the body responsible for outlining the Company's policy and supervising its performance and acts, the Board of Directors (including its committees) plays a central and decisive role in the **formulation and adoption of the Company's internal enforcement plan** and it bears the overall responsibility for the supervision over the actual performance thereof.

Pursuant to the ISA's requirement that the Board of Directors determine which body is responsible for the supervision over the performance of the enforcement plan (the "**Responsible Body**"), whether the Board of Directors itself or the Audit Committee or any other committee thereof, the Board of Directors determined that the Audit Committee shall be the Responsible Body as aforesaid.*

Such responsibility of the Audit Committee as the Responsible Body shall be applied through:

1. Special-purpose meetings for the presentation of the subject.

2. Presentation, discussion and approval of the outline of the enforcement plan project.

3. Presentation of the findings of the mapping of the existing situation (compliance survey) and deliberation on the recommendations deriving therefrom.

4. Presentation, discussion and approval of the procedures comprising the internal enforcement plan.

5. Approval of the final plan.

The Audit Committee shall be involved in the implementation of the plan during the usual conduct of business as specified below.

The Audit Committee, including all of the members thereof, will take an active part in all stages of the formulation and adoption of the plan:

- Setting the enforcement plan into motion
- Mapping of the existing situation
- Formulation of the plan and its procedures
- Formulation of the assimilation plan
- Ongoing monitoring

This Plan was approved by the Audit Committee on March 21, 2012 and by the Board of Directors on March 22, 2012.

4.1.1.2 Implementation of the plan

The Responsible Body shall oversee the enforcement plan and ensure that it is executed by way of receiving periodic reports from the Enforcement Officer and management, discussing them same and examining the means of action employed by the Company as arising therefrom. The Audit Committee shall ensure that the Audit Committee and management review the need to update and refresh the plan once a year.

The implementation of the plan shall be performed *inter alia* through ongoing reporting as specified above and through the assimilation plan as the same is specified in Chapter 11 of this plan.

4.1.1.3 Supervision of the enforcement plan

The Responsible Body, i.e. the Audit Committee, shall supervise the plan's performance. To this end, the internal auditor's audit plan for 2013, includes follow-up of the implementation of the administrative enforcement plan.

4.1.1.4 Handling violations of the enforcement proceedings

The Responsible Body shall ensure that the provisions of the enforcement procedures are applied in practice. In addition, the Responsible Body shall ensure that violations of the plan will be appropriately handled, the deficiencies corrected, conclusions drawn, and in the appropriate cases, measures taken against the violating parties.

(*) Relevant quotations from the minutes of the Board of Directors and Audit Committee are attached hereto, marked as Annex A.

The manner of contact and reporting is specified in Chapter 7 of this plan and was approved by the Audit Committee and Board of Directors as part of the plan's approval. The Company shall approve in each procedure separately, insofar as necessary, the required sanctions and disciplinary action.

4.1.1.5 Reporting to the Board of Directors and the Audit Committee

The Audit Committee as the Responsible Body or a body authorized thereby shall report as needed and at least annually to the Board of Directors on the implementation of the enforcement plan and related issues at the Committee's discretion.

A report to the Board of Directors may include but is not limited to supervision of the implementation of the plan through demanding periodic reports on the approval of the enforcement plan, updating the plan and its procedures, appointing relevant bodies, and the results of the supervision of the implementation and effectiveness of the plan.

4.1.2 Responsibility of the CEO/management – steering committee

The ISA's Document provided that the CEO is the officer with supervisory responsibility to ensure the compliance of the Company and its employees with the securities laws through the shaping of the internal enforcement mechanisms.

Management is responsible for the shaping and formulation of the enforcement plan and its presentation for the Audit Committee's approval. In addition it is responsible for the ongoing implementation of the plan.

Management shall act through the Enforcement Officer, Adv. Norman Kotler, as appointed on February 5, 2012, and through the Chief Financial & Operating Officer, Philip Serlin, CPA.

As part of the fulfillment of such obligation, the CEO has appointed a **steering committee** to shape the internal enforcement mechanisms. The steering committee includes the following:

Chief Financial & Operating Officer

Executive Director of Finance and Reporting

General Counsel and Internal Enforcement Officer

The steering committee is responsible for shaping the enforcement mechanisms, performing the compliance survey, writing the enforcement and assimilation plan and obtaining the suitable approvals from the relevant bodies.

4.1.3 Responsibility of the Chief Financial & Operating Officer

The Chief Financial & Operating Officer, as management's representative, is responsible for leading and managing the process of writing the enforcement plan and determining the mechanisms included therein.

Such power includes review and approval of the compliance survey, the enforcement plan and the procedures included therein.

The Chief Financial & Operating Officer as the direct supervisor of the Enforcement Officer shall supervise his activity as the officer responsible for internal enforcement.

4.1.4 Responsibility of the General Counsel and Internal Enforcement Officer

The General Counsel of the Company, as the officer in charge of the compliance culture and proper corporate governance in the Company and as the officer responsible for the compliance of the Company, its officers, managers and employee with the laws and regulations that apply to them, is involved in shaping, implementing and ensuring the compliance with the enforcement plan and examining the suitability of the mechanisms set forth in the enforcement plan and its procedures to the laws that apply to the Company.

The General Counsel shall take an active part in the deliberations of the steering committee of which he is a member, and by virtue of his appointment as the Internal Enforcement Officer (also to be referred to in this plan as the "Officer") at the Company shall act to fulfill his obligations.

Responsibility

The Officer shall in practice lead the implementation of the enforcement plan. Powers shall be conferred on the Officer, enabling him to carry out the processes and mechanisms included in the enforcement plan and that are *inter alia* specified in the standards in the ISA Document and in Chapter 6 of this plan, "Appointment of the Enforcement Officer".

The Officer's responsibilities and the acts for the implementation of the enforcement plan are specified in the assimilation plan in Chapter 11.

For any question or query on the issue of the enforcement plan, please contact the Officer:

Adv. Norman Kotler
E-mail: normank@biolinerx.com
Tel. 02-5489139

Determination of a work plan for the fulfillment of all of his obligations pursuant to this plan

The Officer shall be responsible to add as an annex

4.1.5 Internal auditor's responsibility

The Internal Audit Law, 5752-1992, provides that the internal auditor of the Company is, *inter alia*, the body responsible for the examination of issues such as: the propriety of the actions of the Company and the officers, the fulfillment of the provisions that are binding on the Company and the carrying out of decision-making processes according to proper procedures and, consequently, contributes to the Company's compliance and enforcement mechanisms.

In accordance with his or her in-depth familiarity with internal control at the Company, the internal auditor shall take an active part in the deliberations and shaping of the enforcement plan insofar as will be required.

Ongoing supervision:

One of the roles of the internal auditor in the context of an enforcement plan is supervising the activity of the Officer and the enforcement plan (as defined in the ISA Document).

In order to perform such role, the auditor shall set include a periodic audit in his or her work plan, which may include:

Examining the relevance and effectiveness of the enforcement plan, the effectiveness of the Officer's actions, examining the compliance with the enforcement plan and its procedures once every four years, handling irregular cases that were identified, completing the acts required in the enforcement plan within the required timelines.

5. Guiding principles/issues addressed

BioLine is a dual-listed company that is listed on the Tel Aviv Stock Exchange and on NASDAQ in the U.S.

The Company's reporting obligations derive mainly from the requirements of the U.S. Securities and Exchange Commission ("**SEC**"), and the reports deriving from its compliance with SEC's requirements are also published in the ISA's reporting system.

Pursuant to an examination of the violations in the Fifth and Seventh Schedules to the Law, and an examination of the relevance to the Company by the General Counsel and the Officer, the following issues were found to be relevant to the enforcement plan.

5.1 Prospectus/annual report process

Corporations publish a prospectus as part of the process of offering securities or bonds. In addition, under U.S. law, the Company is required to file an annual report with the SEC. The process of preparation of the annual report is similar to the one related to the preparation of a prospectus. The purpose of the prospectus and the annual report is to provide to the general public and to the reasonable investor in particular information that is essential to the decision to purchase the Company's securities.

In view of the Company's dual listing, it is obligated to institute a process with regard to a prospectus or annual report (and which is relevant to the process at the main stock exchange) upon the completion of which, the Company shall be able to publish a full, reliable and up-to-date prospectus or report that is approved by any and all relevant bodies and meets all of the regulatory requirements.

The process shall be regulated in the context of a procedure or a checklist, specifying the acts that are required and which shall be updated from time to time and as necessary.

5.2 Reports to the SEC and ISA

The purpose of the reports to the ISA is to update the investors and supervisory bodies on the Company's condition and on developments or changes in its activity that may be relevant to the investing public. The Company's reports are based on the reports to the SEC and which are required thereby.

All of the reports must include full, reliable and current information and to fulfill any and all relevant regulatory requirements.

A reporting obligation exists in various cases which affects the content and manner of reporting. This plan deals with three issues that arise from the obligations that apply as a result of the Fifth and Seventh Schedules

5.2.1 Periodic reports – In addition to an extensive annual report, a public company is required to release financial statements on a quarterly basis. In the Company's case, the structure and content of the reports are audited and supervised according to international accounting standards and the rules of the SEC.

Establishing an internal procedure regarding periodic reporting will assist the Company in minimizing the risks related to the deadline for and appropriateness of the periodic reporting, and the fulfillment and enforcement thereof will assist in the prevention of failures on the part of employees and officers with regard to the subject, directly or indirectly.

5.2.2 Immediate reports – BioLine, as a dual public company, is required to immediately report (according to SEC's reporting rules) material events which may have an effect on the price of the Company's securities. The identification of the need to report, the decision on the need to report, the weighing of conflicting interests, the timing and content of the report, requires the Company to have an orderly process, which includes the identification of information which may have to be reported, the consultation with regard to the need to report, and the actual reporting, all within the timeframes prescribed in by applicable regulations.

The purpose of establishing a process and determining rules of activity and conduct is to provide current, accurate and full reporting to the SEC, the ISA and the public, on issues that are regulated in the securities laws and the regulations thereunder.

Establishing an internal procedure regarding immediate reports will assist the Company in minimizing the risks related to the deadline for and appropriateness of the periodic reporting, and the fulfillment and enforcement thereof will assist in the prevention of failures on the part of employees and officers with regard to the subject, directly or indirectly.

5.3 Prohibition on the use of inside information

Inside information is "information on developments in the company, changes in its condition, expected developments or changes, or other information about the company, which is unknown to the public and which, were it to become known to the public, would result in a material change in the price of the Company's security or the price of another security of which the Company's security is a basic asset." It was determined in the legislation that the use of inside information for the purpose of a securities transaction or its transmission to another, are prohibited by law.

Each corporation is required to adopt rules and guidelines in order to fulfill Chapter H1 of the Securities Law including all of its provisions, as well as the U.S. laws which relate to such issue, all in order to prevent the use of inside information by the Company's employees and other bodies.

It is necessary to put in place a process to cover the identification of the sensitive information, clarify the prohibition to use the same and assimilate it among any and all persons who come into contact with such information.

Establishing an internal procedure regarding the use of inside information will assist the Company in minimizing the risks related to the deadline for and appropriateness of the periodic reporting, and the fulfillment and enforcement thereof will assist in the prevention of failures on the part of employees and officers with regard to the subject, directly or indirectly.

5.4 Transactions with interested parties

Interested party transactions are transactions entered into between one of the interested parties of the company (or between a company affiliated with that party or a person related to it) and the company. Such transactions contain a potential for a conflict of interests that is higher than in ordinary transactions. Therefore, applicable laws and regulations set forth conditions to the approval of such type of transactions, *inter alia*, the manner of approval thereof by various organs of the corporation (including, under circumstances set forth in the law, an approval by a general meeting of a majority of the shareholders of the company from among the those shareholders who do not have a personal interest in relation to the transaction), and the disclosure to the public of the terms and conditions of the transaction.

In view of the regulatory requirements concerning the identification of such transactions, the manner of approval thereof and reporting thereon, a controlled process should be put in place concerning the subject, in order to reduce the related risks and assist in the prevention of failures in the matter.

5.5 Procedure for period end closing

In accordance with the Companies Law, 5759-1999, the Securities Law and U.S. securities laws, public companies must abide by all disclosure rules and prepare proper financial statements covering all accounting operations. Companies must therefore operate in accordance with orderly and well-defined work procedures, and generate reports conform to accepted accounting practices, according to the provisions of the law. The procedure for period end closing, which is in the advanced stage of drafting, intended to set in order the preparation of the Company's financial statements.

6. Appointment of an Internal Enforcement Officer

6.1 Appointment of an Officer

The Officer shall have the skills, knowledge and experience that are appropriate for his position and areas of responsibility and shall be a manager in the Company who is familiar with the Company's activity and the business and regulatory environment in which it operates.

The Company's management and the Audit Committee shall ensure that the Officer is given the powers and provided with suitable resources such that they will enable him to fulfill his duties and exercise his powers (as will be specified below) in an optimal manner.

6.2 The appointment and approval (and change) process

The candidacy of the Officer shall be presented to the Audit Committee together with management's recommendation to appoint him as the Officer, after the presentation of his skills and experience. For the purpose of management and implementation of the internal enforcement plan, on February 5, 2012, the Audit Committee appointed Adv. Norman Kotler for the position of Internal Enforcement Officer.[1]

As set forth in the ISA Document, it was determined that the appointment of a new officer and/or removal of the Officer from his position require the management's recommendation and the approval of the Audit Committee.

6.3 Powers

The Officer's first and foremost authority is to implement the internal enforcement plan and lead the actual acts of enforcement pursuant to the plan,the requirements of the Law and the recommendations of the ISA and/or any other relevant body.

The Officer's powers include but are not limited to the powers listed in the ISA Document:

6.3.1 Ongoing supervision:

The Company, through the Officer, shall ensure on an ongoing basis that the plan is actually implemented in order to achieve its goals as specified above.

Such supervision shall be performed through:

Formulation of periodic reports which include the means and actions that were taken in order to ensure the implementation of the plan, suspicionsof violations that were raised and how they were addressed, examination of relevance, updates and progress of assimilation of the plan, etc.

Presentation of the reports to the Company's management and/or Audit Committee and/or Board of Directors and deliberation on the data reported by the forum to be determined.

Reporting of issues requiring immediate attention to the Company's management and/or Audit Committee and/or Board of Directors.

Documentation of the processes related to formulation of the plan, and the means that were instituted to implement the plan and to handle violations, as well as documentation, provision of documents for inspection and preservation of documents pursuant to the provisions of the Law.

6.3.2 Investigating suspected violations:

In any case of a suspected violation brought to his knowledge, the Officer shall act to investigate the facts together with a special-purpose team to be appointed by the Chief Financial & Operating Officer, and if it transpires that there was a failure and a violation has occurred, he shall examine the reasons for the failure.

6.3.3 Remedying the violation:

The Officer shall act to remedy the discovered violation or failure as soon as possible and in accordance with the guidelines and approvals of the relevant bodies (the committee, managers and officers that are affected by the change, etc.)

6.3.4 Reporting the violation:

The Officer shall report the failure to the CEO, Chief Financial & Operating Officer, and according to the severity of the case, also to the chairman of the Audit Committee/Board of Directors, all according to the reporting requirements in this plan.

Insofar as the CEO and/or Chief Financial & Operating Officer are involved in the failure, the Officer shall contact the chairman of the Audit Committee. Insofar as the members of the Committee are involved in the matter, the Officer shall contact the internal auditor.

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[1]See quote from the minutes of an Audit Committee meeting dated February 5, 2012, which appears in Annex A.

6.3.5 Preventing the recurrence of the violation

The Officer shall introduce new procedures or amendments to existing procedures, as well as controls over them, and approve the same with the relevant bodies. For the sake of clarity, by virtue of his position as the General Counsel of the Company, and for the purpose of performing his role as the Officer, the Officer shall have direct access at all times to any and all offices and documents of the Company and to any and all records and information at the Company, all as required, in his discretion, for his work.

Naturally, any and all inquiries and actions performed at the Company as part of the enforcement plan shall be performed in accordance with the law and without harming or disrupting any investigation or inquiry by law of which the Company is aware.

In any case of doubt whether or not an issue is within the Officer's jurisdiction, the Officer or any other party shall consult with the Audit Committee.

6.4 Supervision over the Officer

As stated above, and as will be further specified below, the Audit Committee is responsible for the appointment and the termination of the appointment of the Officer.

The Chief Financial & Operating Officer is the direct supervisor of the General Counsel and Officer, and authority is conferred on him accordingly.

The supervision over the Officer's activity and the implementation of the enforcement plan is within the responsibility of the internal auditor in the context of his or her ongoing work and at the request of the Audit Committee (such supervision shall be performed pursuant to the audit plan to be approved by the Audit Committee).

6.5 Officer's reporting responsibility

The Officer shall report a failure to the CEO, Chief Financial & Operating Officer, and according to the severity of the case, also to the chairman of the Audit Committee/Board of Directors, all according to the reporting requirements in this plan.

The report to the Chief Financial & Operating Officer shall be performed after an initial inquiry proceeding by the Officer that shall include an initial factual inquiry.

The report to the Chief Financial & Operating Officer shall be performed no later than two working days after having first learned of the suspected violation, and in any event, no later than four days from the date on which the report shall have been made to him.

Insofar as the Chief Financial & Operating Officer and/or CEO are involved in the failing, the Officer shall contact the chairman of the Board of Directors or the Audit Committee. Insofar as members of the Audit Committee are involved in the matter, the Officer shall contact the internal auditor.

7. Contact and reporting

7.1 Possibilities of contact and reporting in the event of a suspected violation

According to requirements and expectations, the Company has set forth internal mechanisms which enable the officers, directors, employees and service providers of the Company to report and warn about deficiencies and failures in relation to the fulfillment of the provisions of the securities laws or violations of the plan.

The reporting mechanisms for administrative enforcement issues shall be identical to those prevailing at the Company (reporting mechanisms upon a breach of the code of ethics, contacting and reporting to the internal auditor, etc.).

a. Employees, officers and directors

In any case of a suspected violation or improper conduct, the Company's employees, officers and directors have the possibility (and sometimes the obligation) to contact their direct supervisor, the internal auditor and/or the chairman of the Audit Committee.

Internal Auditor, Linur Dloomy, CPA	Audit Committee Chairperson, Nurit Binyamini
E-mail: ldloomy@deloitte.co.il	E-mail: Nurit378@gmail.com
Tel. 052-5838635	052-6440745

b. Service providers

The Officer is responsible for adding a method of reporting by external parties.

In order that all relevant parties shall be aware of their reporting obligation and of the various possibilities of reporting a possible suspected violation, this information shall be passed on to all relevant parties in the context of this document, the training programs, the Company's website, engagement agreements, employment documents, etc.

All of the relevant parties shall be familiar with the existence of the enforcement plan, the main parts of the plan and where it may be inspected, as well as the method of reporting and the rights of the reporting party (anonymity/confidentiality/favorable consideration in the event that he is the violating party, etc.).

The Officer shall confirm that once a year the aforesaid information is communicated to relevant bodies in an initiated manner (for example a dedicated e-mail)

The Officer shall confirm that the manner of approaching him is available at all times.

7.2 [*intentionally omitted*]

7.3 External reporting

There are situations in which a violation or a suspected violation of the securities laws requires reporting to the competent authorities (the ISA or the Israeli Police, as the case may require).

Even in those cases in which there is no reporting obligation, voluntary disclosure should be considered, since the ISA Document states that the ISA's enforcement considerations in exercising its powers in respect of corporations and individuals include the factors of voluntary disclosure by the corporation and the corporation's cooperation with the ISA.

Situations where there is a legal obligation to report to the ISA include among others situations in which an item was published which may mislead a reasonable investor or trading was done based on inside information.

In all situations in which there is no reporting obligation, the Officer shall discuss the need to report with the Chief Financial & Operating Officer and outside legal advisors. Their conclusion and the considerations that led thereto shall be brought for deliberation by the Audit Committee which shall be convened for such purpose.

General Counsel together with the Chief Financial & Operating Officer shall report to the competent authorities in accordance with the Company's decision and soon after the date of the decision.

8. Sanctions in events of violation and failure to report

As mentioned above, one of the functions of an enforcement plan is to encourage an organizational culture of compliance with, and respect for, the law. The ISA Document makes clear that "a culture of compliance means that the corporation is obligated to prevent violations of the law and to handle violations and violating parties with the appropriate measures."

8.1 Determination of sanctions in events of violation

In view of the ISA determination that "the Company shall institute suitable measures against violating parties, including, in appropriate cases, disciplinary action in respect of anyone violating the provisions of the securities laws or the provisions of the enforcement plan", the Company shall set forth in each procedure separately, insofar as necessary, the disciplinary action that is required.

9. Findings of a mapping of the existing situation

Pursuant to Chapter 7 in the ISA Document: "Adjustment of the plan to the corporation and the unique circumstances thereof, after the performance of a compliance survey in the area of the securities laws".

A summary of the first survey that was performed by Deloitte – Brightman Almagor Zohar, the Company's consultants for the enforcement plan project, is available in the Officer's files.

10. Relevant procedures

Pursuant to the compliance survey, the Company has formulated the internal procedures that are specified below, while considering the Company's structure, its unique features, and the potential risks and deficiencies in the area of the compliance with the securities laws to which it is exposed. The role of the procedures is to regulate and determine rules of activity and conduct, the purpose of which is to prevent violations of securities laws as well as to create work processes which will address and control such processes.

10.1 Statement of Company Policy – Securities Trades by BioLineRx Ltd. personnel

The draft procedure was approved by the Board of Directors on May 15, 2012. The procedure in its final form was approved by the Company's management on June 6, 2012. The Chief Financial and Operating Officer was appointed as the officer responsible for the procedure.

The procedure is relevant to all of the Company's employees and to those who come into contact with information which may constitute inside information.

10.2 Transactions involving interested and related parties

The procedure was approved for the first time in December 2010. An amendment to the procedure was approved by the Company's management on July 3, 2012 and by the Audit Committee and Board of Directors in November 2012.

The Executive Director of Finance and Reporting and the General Counsel were appointed as the officers responsible for the procedure.

The procedure is mainly relevant to directors, other officers, the finance department and the General Counsel.

10.3 Procedure for prospectus/annual report/other reports to the SEC and ISA (Disclosure Controls)

The procedure was approved by Company management in September 2012 and by the Audit Committee and Board of Directors in November 2012.

The Chief Financial and Operating Officer and the General Counsel were appointed as the officers responsible for the procedure.

The procedure is relevant primarily to the Finance Department and the General Counsel

10.4 Period end closing procedure

(in progress)

Approved on _____

Appointed as procedure officer: Manager of Reporting and Control

The procedure is relevant to the Chief Financial and Operating Officer and the Finance Department

11. Assimilation plan

11.1 Background

An enforcement plan is a mechanism to encourage compliance which is binding on all of a company's employees, managers and officers.

This document is not intended just for display and the familiarity with its content and the implementation hereof are material to the Company.

Therefore, the Company examined various possible mechanisms for the purpose of assimilation of the enforcement plan and the procedures related hereto, and established the selected mechanisms in an assimilation plan that is brought below.

The purpose of the assimilation plan is to promote and ensure the commitment of all of the relevant parties to the plan, their knowledge of the main parts hereof and the actual implementation hereof in all of their activity.

11.2 Presentation of the enforcement plan

After the completion of the enforcement plan and its approval by the relevant bodies, the plan shall be presented to all of the employees and managers at a Company meeting. At such meeting, the CEO of the Company shall present the main parts of the plan, the importance of compliance herewith, the role of the Enforcement Officer and the manner of publication of the plan.

Following the presentation of the plan, the plan and the procedures related hereto shall be posted on the Company's website (path/link) and be sent via e-mail to the distribution list of all of the Company's employees and managers.

A printed copy is to be kept at the offices of the Company's CEO, Enforcement Officer and the Company's auditor.

The Enforcement Officer shall examine the need for updating the general documents of the Company (like, for example, disciplinary code, the employment agreements, code of conduct, etc., as well as specific related procedures – employee initiation procedure, inside information procedure, etc.) in order that they include a reference to the subject of administrative enforcement.

From the ISA Document:

Measures shall be taken in order to ensure the commitment of all echelons of the corporation to the aforesaid procedures, for example, through the establishment of such commitment in the disciplinary code or employment agreements.

11.3 Implementation and assimilation of the enforcement plan

Publication of the enforcement plan

The enforcement plan shall be published on the Company's portal/website and distributed via e-mail to all of the Company's employees.

Following any updates of the enforcement plan, an e-mail shall be sent with a summary of the changes to all of the Company's employees.

Team/forum of assimilation of the administrative enforcement plan

The steering committee referred to in Section 4.1.2 shall arrange for the implementation of the internal enforcement assimilation plan and the approval of any updates or modifications that will be performed.

New employee

Each new employee, upon his or her arrival at the Company and in the context of the employee's initiation process as conducted by HR, shall be given access to the enforcement plan, be required to read the main parts hereof and sign that he or she has read the plan.

During the first month of his employment, the new employee will be required to participate in training by the Internal Enforcement Officer on the subject of administrative enforcement.

New officer

Each new officer shall participate in a talk with the Administrative Enforcement Officer at which the internal enforcement plan will be presented to him. At the end of the meeting, the officer shall sign a document in which he declares that he has read the plan and undertakes to comply with all provisions hereof that are relevant to him. The officer shall also receive a copy of the plan via e-mail or a link to its location on the Company's website.

Assimilation and periodic communication – Company employees and managers

In order to ensure that all employees are aware of the obligations that apply to them by virtue of the Improvement of Internal Enforcement Proceedings in the ISA Law and the enforcement plan, a training session procedure shall be assimilated for all of the Company's employees and managers as well as the Company's officers.

Alternatives:

a. Frontal training sessions shall be held by the Officer on behalf of the Company or by an outside body. The training sessions shall be performed at least once a year. The training sessions shall include a review of the enforcement plan, possible violations and reporting methods.

b. Written training sessions. At least once a year the Officer shall send a presentation via e-mail to the employees that will include an employee guide – a review of the enforcement plan, possible violations and reporting methods. The employee shall be required to send a return e-mail to the Officer in which he confirms that he has read the content of the guide and undertakes to act according thereto.

The course presentation shall be attached as an annex.

Each employee shall complete the course at least once a year.

Every November the Officer shall distribute a request via e-mail to all of the Company's employees and managers to complete the course within one month from the e-mail's distribution date.

Toward the expiration of such period (about one week before the target date) the Officer shall distribute a reminder e-mail to all of the Company's employees and managers. At the end of the period the Officer shall examine the response rate. In each case where an employee/manager shall have failed to fulfill the request, the Officer shall send an e-mail to the aforesaid employees and their managers, informing that they are required to complete the course and the proficiency test within 5 working days. Employees and managers who will fail to fulfill such demand shall be liable for sanctions by the Company pursuant to Chapter 8 of the enforcement plan.

The Enforcement Officer shall confirm that 100% of the Company's employees and managers have participated in the course over the year. At the end of the year, the Enforcement Officer shall issue a report with regard to the administrative enforcement which shall include the percentage of the employees who shall have participated in training in such year.

The course shall be maintained and updated by the Enforcement Officer pursuant to changes in the enforcement plan and/or the assimilation plan.

Assimilation and periodic communication – officers/Board of Directors

The officers and Board of Directors shall participate in frontal training sessions held by the Officer on behalf of the Company or an outside body. The training sessions shall be held at least once a year. The training sessions shall include a review of the enforcement plan, possible violations, reporting methods.

The Enforcement Officer shall confirm that 100% of the Company's officers/Board of Directors have participated in frontal training sessions over the year and if not, he shall arrange to make up the missing sessions towards the end of the year.

11.4 Implementation and assimilation of the related procedures in the enforcement plan

The Enforcement Officer, in collaboration with the relevant bodies (such as HR), shall map the populations that are relevant to the procedures related to the enforcement plan and determine which employees are required to participate in an assimilation process for each of the procedures (the "**Mapping and Classification Process**").

Such process shall be performed at least once a year.

According to the Mapping and Classification Process, the employee shall receive the procedures that are relevant to his areas of responsibility and be required to sign a document whereby he understands their content and is committed to act according thereto. After the signing by him, the direct supervisor and the Officer shall sign in confirmation and receipt of the document. The Enforcement Officer shall also monitor the employees' aforesaid signatures of the procedures to confirm that they comply with the Mapping and Classification Process and that all of the relevant employees have signed their commitment to all of the procedures that are relevant to their functions and areas of responsibility.

The steering committee responsible for the implementation of the enforcement plan shall confirm that 100% of the employees have signed the procedures that were sent to them.

11.5 Assimilation among parties external to the Company

As part of his work plan, the Officer shall define parties external to the Company that are obligated to comply with the enforcement plan and/or the related procedures, and have them sign the relevant procedures to attest that they have read and understood the obligations that apply to them by virtue of the Law, the enforcement plan and the procedures.

Existing engagements

Insofar as necessary, an annex to the contract shall be added to existing engagements in which the external party undertakes to information security and prevention of misuse of inside information in particular, and to the fulfillment of any and all regulatory obligations that apply to such party, including the Improvement of Internal Enforcement Proceedings in the ISA Law in general.

New engagements

Any new engagements with an external party shall be performed after the signing by such party of a confidentiality and engagement agreements. As part of such agreements, the external party shall undertake to maintain information security, prevent misuse of inside information in particular, and in general fulfill any and all regulatory obligations that apply to such party including the Improvement of Internal Enforcement Proceedings in the ISA Law.

11.6 Monitoring of and reporting on the assimilation of the enforcement plan and the related procedures

The Officer shall examine the fulfillment of the assimilation plan and report to the relevant bodies as set forth in Chapter 4 of the enforcement plan.

11.7 Assimilation acts pursuant to the updating of the enforcement plan

Once a year and as necessary the Officer shall examine the need for updating the assimilation plan as it is presented below.

The plan's update shall be approved by the steering committee in the course of a meeting that will be convened to deliberate on the matter.

In respect of each update of the enforcement plan, the Officer shall examine the need to inform all parties about the main changes or the full, updated enforcement plan and shall choose the best suited means of assimilation in order to communicate the changes and/or the updated enforcement plan.

In addition, in respect of each change the Officer shall examine the need for updating the existing assimilation plan and assimilation tools.

The essential elements of the assimilation plan were approved by the Audit Committee and Board of Directors as part of the approval of the enforcement plan.

ANNEX A

Decisions of the Board of Directors and Audit Committee

Audit Committee decision from February 5, 2012:

"RESOLVED, that Norman Kotler, Adv., be appointed the person responsible for implementation of the Company's Administrative Enforcement Plan."

Audit Committee decision from March 21, 2012:

"RESOLVED, to approve the Administrative Enforcement Plan as presented to the Committee and to recommend approval of the Plan by the Board of Directors."

Board of Directors decision from March 22, 2012:

"RESOLVED, to approve the Administrative Enforcement Plan as presented to the Board, with such non-substantive changes that may be subsequently made after further review by management and Deloitte."

Board of Directors decision from November 13, 2013:

"RESOLVED, to ratify the appointment and authorization of the Audit Committee as the "responsible entity" for supervising the implementation of the Company's Internal Enforcement Plan beginning November 24, 2011."

Exhibit G

Vehicle Agreement

This Vehicle Agreement (the "**Agreement**") is entered into on Click here to enter text. by and between **BioLineRx Ltd.**, a company organized under the laws of the State of Israel, with its offices at Modi'in Technology Park, 2 HaMa'ayan Street, Modi'in 7177871 ("**BioLine**"), and Click here to enter text., whose address is Click here to enter text. ("**Employee**").

WHEREAS, BioLine has employed Employee pursuant to a certain Employment Agreement, dated Click here to enter text.; and

WHEREAS, Employee has requested that BioLine provide him/her with a vehicle, and BioLine has agreed to provide Employee with a vehicle pursuant to the terms and conditions set forth herein.

Therefore, the parties agree as follows:

1. BioLine shall provide Employee with the use of a vehicle selected by BioLine. BioLine shall have the sole discretion to determine the type of vehicle provided to Employee in accordance with the then current BioLine car policy. The vehicle, a detailed description of which appears in **Exhibit A** hereto (the "**Vehicle**"), will be provided to Employee no later than Click here to enter text. (the "**Effective Date**") and for a period of up to thirty-six (36) months from the calendar month following the Effective Date (the "**Term**"). Upon receipt of the Vehicle, Employee shall execute the Vehicle Receipt Form attached as **Exhibit B** hereto. Notwithstanding the abovementioned, the Vehicle provided to Employee may have been leased to BioLine prior to the date hereof, in which event, the Term shall be amended accordingly, and this Agreement shall apply to the applicable Term. If Employee receives a vehicle for the interim period before the Effective Date (the "**Temporary Vehicle**"), the terms of this Agreement shall apply to the Temporary Vehicle in full. It is clarified, *however*, that the interim period shall not be considered part of the Term.

2. **Payments by Employee**

   2.1. Employee acknowledges that the benefit he/she receives from the Vehicle is taxable, and agrees to bear all taxes arising out of the use of the Vehicle ("**Vehicle Taxes**"). Employee acknowledges that Vehicle Taxes will be withheld from his/her salary as required by law.

   2.2. Vehicle Taxes may be increased according to changes from time to time in the applicable tax regulations, and Employee's Salary will be reduced accordingly in the event of such regulatory changes.

   2.3. Employee shall be responsible for the following payments:

      2.3.1. Fines and penalty payments including parking tickets and costs related to the imposing of a prohibited use notice (השבתה מינהלית);

      2.3.2. Fuel over the monthly limit specified in Exhibit A, as may be amended from time to time due to changes in the prices of fuel (the "**Fuel Limit**"). Employee will be charged once every six (6) months for use of fuel over the Fuel Limit, which will be calculated in accordance with Employee's average use during the preceding six-month period (e.g., if Employee's Fuel Limit is 1000 liters, and Employee's average monthly use is 1100 liters, Employee will be charged for 600 liters (excess use of 100 multiplied by six months));

      2.3.3. Fines imposed by the leasing company for mileage costs exceeding the annual limit specified in Exhibit A, as may be amended from time to time based on Employee's place of residence (the "**Mileage Limit**");

      2.3.4. Highway 6 expenses (פסקל) and tolls, except for tolls related to business use, as set forth in Section 3.1 below;

2.3.5. Tel Aviv Fast Lane expenses, except for tolls related to business use, as set forth in Section 3.1 below;

2.3.6. Fines and expenses imposed by the leasing company for tolls related to travel on Highway 6 or the Tel Aviv Fast Lane that is not based on subscriptions arranged by Employee;

2.3.7. Insurance deductible, which will be borne by Employee if the damage was caused by Employee, as follows:

a. On the third occurrence of any such damage, Employee shall bear 30% of the insurance deductible.

b. From the fourth occurrence of any such damage and onwards, Employee shall bear 50% of the insurance deductible.

c. Employee will be charged as provided above only if damage was reported to the leasing company in a timely manner. If damage was not reported in a timely manner, and as a result the leasing company charges BioLine for additional events of damage, Employee will bear the full cost of the insurance deductible.

2.3.8. Employee shall bear the cost of any flat tires, except for the first two (2) flat tires per year, as indicated in Section 3.1.1 below; and

2.3.9. It is Employee's responsibility to ensure that the Vehicle has a full tank upon sending the Vehicle to maintenance and repairs. If the Vehicle's tank is not full, and an extra charge is billed for fuel, Employee shall bear the extra fuel charge, provided however that BioLine may decide in its sole discretion to bear such expense if Employee could not have predicted the repair.

2.4. Employee undertakes to pay, upon first demand, all fines and penalty payments, such as parking tickets, etc., within sixty (60) days of receipt of the ticket. If Employee does not pay the required fines, etc., BioLine may withhold such amount from his/her Salary, together with any late penalties or additional payments which may be assessed.

2.5. Employee confirms and represents that he/she is the holder of the Vehicle as of the Effective Date. Consequently, Employee hereby agrees to the assignment of any tickets, fines, penalties, as well as traffic points (נקודות) to Employee, and authorizes BioLine to carry out such assignment vis-a-vis the competent authority if required. Employee has executed the Confirmation and Assignment deed attached as **Exhibit C** hereto.

3. **Payments by BioLine**

3.1. BioLine shall pay or be responsible for the payment of the monthly leasing payment charged by the leasing company for the Vehicle (the "**Lease Payment**"), and for expenses related to the Vehicle, as follows:

3.1.1. Insurance, licensing fees, maintenance and repairs, and the repair cost of two (2) flat tires a year, in accordance with BioLine's car policy;

3.1.2. Insurance deductible of 100% if the damage is caused by a third party, and the following portions of the insurance deductible if the damage is caused by Employee:

a. 100% of the insurance deductible in the first two occurrences;

b. 70% of the insurance deductible in the third occurrence;

c. 50% of the insurance deductible in the fourth occurrence and onwards.

3.1.3. Fuel up to the Fuel Limit;

3.1.4. Mileage costs up to the Mileage Limit;

3.1.5. Reimbursement for Highway 6 tolls in connection with business related travel only, and subject to the installation by Employee of the Highway 6 meter (פסקל), in accordance with BioLine's procedures for reimbursement of expenses;

3.1.6. Reimbursement for Tel Aviv Fast Lane tolls in connection with business related travel only, and subject to Employee's arranging a subscription; and

3.1.7. Other expenses, all as may be decided from time to time by BioLine and in accordance with BioLine's car policy then in effect.

3.2. For the avoidance of doubt, BioLine shall not be responsible for the payment of any fines, penalties or other expenses as set forth in Section 2.3 above.

4. **Operation and Use of the Vehicle**

4.1. The Vehicle shall be the exclusive responsibility of Employee. Employee shall execute the Undertaking to Secure the Vehicle and Security Code in the form attached as **Exhibit D** hereto.

4.2. Employee undertakes to abide by any and all laws and regulations regarding the use of the Vehicle and to operate the vehicle in a cautious manner. Employee further undertakes to notify BioLine immediately if Employee's license is revoked for any reason. Employee will take all appropriate measures to avoid loss of or damage to the Vehicle or to any third party, and shall at all times comply with the then current BioLine car policy. Employee also undertakes to follow any other limitation or requirement set by the terms of the Vehicle's insurance policy.

4.3. Employee undertakes not to (a) transport more passengers or weight than are allowed by the insurance policy, (b) use the Vehicle for any purpose other than for work-related travel or for his/her own personal needs, (c) drive the Vehicle on unpaved roads or in places which are inappropriate for travel by a private vehicle, (d) take or drive the Vehicle to any areas which are outside the area of the State of Israel (including the Sinai Peninsula and the area of the Palestinian Authority), (e) use the Vehicle for towing, for pushing another vehicle or any other object, for competition, for racing, for testing stability or speed or for any other motor sport, (f) use the Vehicle for any illegal use, political purpose or in connection with any organization, strike or riot, or (g) leave the keys in the Vehicle while Employee is not in the Vehicle, or leave the Vehicle without activating the locking mechanism or other means of securing the Vehicle, even for a short time.

4.4. Employee will bear the cost of any expense or damage to the Vehicle or to a third party (a) arising from any breach of the terms and conditions of this Agreement or from negligent use of the Vehicle, or (b) for which the insurance policy does not compensate BioLine. In addition, if a prohibited use notice (השבתה מינהלית) is imposed on the Vehicle, Employee shall fully cooperate with BioLine in order to release the Vehicle from impound, and shall not be entitled to receive a temporary vehicle during such period. Employee shall indemnify and hold BioLine harmless from any third party claims relating to the prohibited use notice (השבתה מינהלית), and will indemnify BioLine for any damages to the Vehicle, or any other damages which BioLine shall incur in connection thereof.

4.5. The persons who are authorized to drive the Vehicle in addition to Employee are the members of Employee's immediate family (spouse and Employee's children) or Employee's 'significant other', for reasonable family use only; provided that each such driver must hold a valid drivers' license. Notwithstanding the foregoing, Employee must request BioLine's explicit consent with respect to any driver who is over the age of 75 or under the age of 23, or any driver who has not held a valid driver's license for at least two years. Without BioLine's written consent, the drivers specified in the preceding sentence are not authorized to drive the Vehicle and will not be covered by the insurance policy. All the terms set forth in this Agreement are deemed to be accepted by all persons who drive the Vehicle.

5. **Care and Treatment of the Vehicle**

5.1. Employee shall treat the Vehicle as if it was his/her own and shall ensure that the Vehicle remains in good condition.

5.2. Employee will notify BioLine and the police if the Vehicle is stolen as soon as he/she becomes aware of the theft.

5.3. Employee will notify BioLine or the person nominated by it of any damage or malfunction of the Vehicle, as soon as he/she becomes aware of the damage or malfunction, and will ensure that any required repairs are made. Employee will also notify BioLine or the person nominated by it of the regularly scheduled maintenance dates of the vehicle. All care, maintenance and repairs to the Vehicle will be made only by the leasing company at its expense, unless Employee is specifically notified otherwise.

5.4. Employee acknowledges that he/she may not make any alterations to the Vehicle's interior or exterior, nor install any accessories in the Vehicle, including, without limitation, a car stereo or cellular speakerphone (דיבורית) without the prior written consent of BioLine. The cost of installing a cellular speakerphone shall be borne by BioLine, *provided however* that Employee is responsible for making the necessary arrangements for the installation of the cellular speakerphone. In addition, Employee acknowledges and undertakes not to add any sticker, sign or other visible notice on the Vehicle, whether including political statements or otherwise. Employee acknowledges that BioLine may, at its discretion require that the Vehicle bear BioLine's logo.

5.5. If an electronic device for measurement of gas (פזומט) is installed, Employee shall, to the extent possible, refuel only in the gas stations supporting the device.

5.6. In the event of an accident, Employee: (a) will immediately notify both BioLine and the leasing company and will forward to them details of the accident in writing; (b) will immediately notify the police and other authorities, to the extent required by law; (c) will not admit or confess to any guilt or responsibility therefor or provide any information not required by law, nor will accept or propose any offers, payments, arrangements or any other obligations in connection with the accident; (d) will file an accident report provided by BioLine and will include all details including the names, addresses, licenses and insurers of all the parties involved, and the license plate numbers of all of the vehicles involved, whether or not any damage was caused to the Vehicle, (e) will not leave the Vehicle at the scene without appropriate cautionary measures, and (f) will notify BioLine and the leasing company of any summons received to appear before a court.

5.7. In the event of a flat tire, Employee (i) shall change the tire to the spare tire, and notify BioLine, in according with BioLine's car policy; (ii) shall be responsible to repair the flat tire as soon as possible, and in no event after traveling more than eighty (80) Kilometers with the spare tire, due to safety restrictions, and if a new tire is required, Employee shall obtain the approval of the HR department prior to the purchase of a new tire. Employee will be reimbursed for the repair in accordance with BioLine's procedures for reimbursement of expenses.

6. **Return of the Vehicle**

6.1. Upon the termination of his/her employment with BioLine for any reason, Employee shall return the Vehicle to BioLine in working order and in good condition, subject only to wear and tear resulting from careful and reasonable use of the Vehicle. Employee shall return the Vehicle together with the car keys and any duplicates thereof provided to Employee, licenses and all other documents, and the Vehicle shall empty and without any object whatsoever belonging to Employee.

6.2. It is hereby clarified, that in no event shall Employee place a lien on the Vehicle (in connection with any alleged debt or obligation of BioLine towards Employee, or for any other reason).

6.3. If, prior to the expiration of the Term, Employee voluntarily terminates his/her employment or BioLine terminates Employee's employment for Cause (as such term is defined in the Employment Agreement), Employee shall reimburse BioLine for any charges or penalties BioLine may suffer due to the early termination of the lease for the Vehicle; *provided*, *however*, that the amount of such penalty shall not exceed (i) the Lease Payment multiplied by three (3) in the event of termination prior to the first anniversary of the Effective Date, (ii) the Lease Payment multiplied by two (2) in the event of termination following the first anniversary of the Effective Date, and prior to the second anniversary of the Effective Date, and (iii) one Lease Payment in the event of termination following the second anniversary of the Effective Date, and prior to the third anniversary of the Effective Date. Such funds will be withheld from Employee's salary.

6.4. Employee shall not be entitled to use a Company Car during unpaid leaves or absences, unless specifically approved by BioLine in writing.

7. **General**

7.1. Employee confirms that he/she understands that any breach of or deviation from the terms of this Agreement will cause insurance coverage to be denied, and that any damage caused by such breach or deviation will be borne by Employee personally.

7.2. Employee confirms and acknowledges that Employee's obligations hereunder shall apply to any replacement vehicle provided to Employee.

7.3. Employee acknowledges and agrees that the procedures set forth herein may be changed from time to time by BioLine, in its sole discretion.

7.4. For the avoidance of doubt, nothing herein shall obligate BioLine to employ Employee or to continue Employee's employment with BioLine, or derogate in any way from BioLine's right to terminate Employee's employment.

7.5. This Agreement constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof, and supersedes all prior written or oral agreements with respect thereto. This Agreement may be assigned by BioLine; Employee may not assign this Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first set forth above.

_____	_____
BioLineRx Ltd.	**Employee**
By: Philip Serlin	Name:
Title: Chief Financial and Operating Officer	Date:

Exhibit A

Vehicle Specifications

Name of Employee:

I.D Number:

Vehicle Details:
Registration No.:
Make:
Model:
Year:
Color:
Accessories: Radio Disk+ Pazomat

Fuel Limit (monthly):

Mileage Limit (annual):
Payment for extra mileage up to Click here to enter text. Kilometers: NIS 0.12 per km.
Payment for extra mileage over Click here to enter text. Kilometers: NIS 0.4 per km.

Temporary Vehicle details:
Model: Similar
Delivery: End of working day.

Insurance Deductible: 800 NIS

Exhibit B

Vehicle Receipt Form

Name of Employee:

I.D Number:

Date:

Vehicle Model:

Registration No.:

Mileage on date of receipt (in kilometers):

I hereby confirm the receipt of the said vehicle, together with the following accessories:

1. Valid License;
2. Valid Insurance Certificate;
3. Vehicle Manual;
4. Maintenance Manual;
5. Car Jack;
6. Tire Wrench;
7. Spare Tire;
8. Car Key + other Security Measures;
9. Triangle Warning Sign;
10. Dustbin; and
11. Sound System (Radio and Disk).

Additional Accessories: Click here to enter text.

Routine vehicle maintenance shall be carried out every 15,000 kilometers.

Comments:

_____

_____

Employee Signature: _____

Exhibit C

Confirmation and Assignment Deed

[deleted]

Exhibit D

Undertaking to Secure the Vehicle and its Coded Immobilizer

1. I the undersigned, Click here to enter text., I.D. no. Click here to enter text., hereby confirm and undertake to BioLine that I and/or any other driver on my behalf authorized to drive the vehicle, model type Click here to enter text., vehicle number Click here to enter text., shall follow all of the instructions below:

   - I will not leave the vehicle without activating the installed security measures;
   - I will not leave the vehicle with the keys inside the vehicle;
   - I will not abandon the car keys;
   - I will not keep the vehicle's coded immobilizer number and/or any other security measures, if such are installed, in proximity to the keys;
   - I will not leave the security code, if such is installed, inside the vehicle or in its proximity;
   - I will not leave a written copy of the security code, if such is installed, in an exposed place in the vehicle; and
   - I will watch over the vehicle while taking all reasonable precautions to avoid loss and/or theft of the vehicle.

2. I hereby confirm that should I act contrary to the foregoing instructions or should I breach any of my obligations to safeguard the vehicle as a reasonable and cautious owner safeguards his own property, I will bear all damage expenses and/or loss caused to BioLine as a result of any action and/or failure to act by me/us, without any condition or restriction.

3. For the avoidance of doubt it is hereby clarified that my signature below, confirming my obligation in accordance with this document, will take precedence over any agreement and/or representation and/or understanding, if there were such, prior to this date.

IN WITNESS WHEREOF:

Employee Signature: _____

Date:

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 10, 2016

/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 10, 2016

/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, 2015 (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 10, 2016

/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, 2015 (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 10, 2016

/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, 333-201326 and 333-208865) and on Form F-3 (Nos. 333-179792, 333-196390 and 333-205700) of BIOLINERX LTD. (the "Company"), of our report dated March 8, 2016, relating to the financial statements of the Company, which appears in this Form 20-F.

Tel-Aviv, Israel
March 10, 2016

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 68125, Israel, P.O Box 452 Tel-Aviv 61003 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.co.il