As filed with the U.S. Securities and Exchange Commission on March 6, 2018

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

FORM 20-F

(Mark One)

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

OR

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

For the fiscal year ended **December 31, 2017**

OR

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

OR

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

Date of event requiring this shell company report

For the transition period from _____ to _____

Commission file number _____

BioLineRx Ltd.

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

Israel
(Jurisdiction of incorporation or organization)

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

Philip A. Serlin
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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. 105,063,437

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

Yes ☐ No ☒

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

Yes ☐ No ☒

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

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

Yes ☒ No ☐

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

Yes ☐ No ☐

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

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

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

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

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

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

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

☐ Item 17 ☐ Item 18

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

Yes ☐ No ☒

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

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

Yes ☐ No ☐

TABLE OF CONTENTS

INTRODUCTION

Certain Definitions

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

- references to "BioLineRx," the "Company," "us," "we" and "our" refer to BioLineRx Ltd., an Israeli company, and its consolidated subsidiaries;
- references to "ordinary shares," "our shares" and similar expressions refer to the Company's ordinary shares, NIS 0.10 nominal (par) value per share;
- references to "ADS" refer to the Company's American Depositary Shares;
- references to "dollars," "U.S. dollars" and "$" are to United States Dollars;
- references to "shekels" and "NIS" are to New Israeli Shekels, the Israeli currency;
- references to the "Companies Law" are to Israel's Companies Law, 5759-1999, as amended; and
- references to the "SEC" are to the 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;
- our ability to integrate new therapeutic candidates and new personnel;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;

- the implementation of our business model and strategic plans for our business and therapeutic candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere;
- competitive companies, technologies and our industry; and
- statements as to the impact of the political and security situation in Israel on our business.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

The following table sets forth our selected consolidated financial data for the periods ended and as of the dates indicated. The following selected historical consolidated financial data for 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 Tel-Aviv Stock Exchange, or the TASE, is equivalent to one ADS traded on The Nasdaq Capital Market, or Nasdaq (prior to the split, the ratio of ordinary shares to ADSs was 10:1).

The selected consolidated statements of operations data for the years ended December 31, 2015, 2016 and 2017, and the selected consolidated balance sheet data as of December 31, 2016 and 2017, 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, 2013 and 2014, and the selected consolidated balance sheet data as of December 31, 2013, 2014 and 2015, have been derived from our audited consolidated financial statements not included in this Annual Report on Form 20-F.

Our consolidated financial statements included in this Annual Report on Form 20-F were prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, and reported in dollars. The amounts in the tables below for the years 2013 and 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 2013 and 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, 2017.

	Year Ended December 31,				
Consolidated Statements of Operations Data:[1] [2]	**2013**	**2014**	**2015**	**2016**	**2017**
	(in thousands of U.S. dollars, except share and per share data)				
Research and development expenses	(12,208)	(11,866)	(11,489)	(11,177)	(19,510)
Sales and marketing expenses	(1,136)	(1,589)	(1,003)	(1,352)	(1,693)
General and administrative expenses	(3,664)	(3,800)	(3,704)	(3,984)	(4,037)
Operating loss	(17,008)	(17,255)	(16,196)	(16,513)	(25,240)
Non-operating income (expenses), net	1,161	3,061	1,445	214	(260)
Financial income	720	3,566	457	480	1,169
Financial expenses	(1,897)	(448)	(106)	(22)	(21)
Net loss	(17,024)	(11,076)	(14,400)	(15,841)	(24,352)
Other comprehensive income (loss):					
Currency translation differences	1,097	(2,834)	–	–	–
Comprehensive loss	(15,927)	(13,910)	(14,400)	(15,841)	(24,352)
Net loss per ordinary share	(0.76)	(0.34)	(0.28)	(0.28)	(0.27)
Number of ordinary shares used in computing loss per ordinary share	22,488,516	32,433,883	51,406,434	56,144,727	89,970,713

	As of December 31,				
Consolidated Balance Sheet Data:	**2013**	**2014**	**2015**	**2016**	**2017**
	(in thousands of U.S. dollars)				
Cash and cash equivalents	8,899	5,790	5,544	2,469	5,110
Short-term bank deposits	9,319	28,890	42,119	33,154	44,373
Property, plant and equipment, net	712	721	2,909	2,605	2,505
Total assets	20,014	36,211	51,302	38,939	60,965
Total liabilities	8,292	4,406	3,692	3,912	8,084
Total shareholders' equity	11,722	31,805	47,610	35,027	52,881

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

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

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

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

Risks Related to Our Financial Condition and Capital Requirements

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

We are a clinical stage biopharmaceutical development company that was incorporated in 2003. Since our incorporation, we have been focused on research and development. Only one of our therapeutic candidates has begun to be commercialized. We, or our licensees, as applicable, will be required to conduct significant additional clinical trials before we or they can seek the regulatory approvals necessary to begin commercial sales of our other therapeutic candidates. We have incurred losses since inception, principally as a result of research and development and general administrative expenses in support of our operations. We recorded net losses of $14.4 million in 2015, $15.8 million in 2016 and $24.4 million in 2017. As of December 31, 2017, we had an accumulated deficit of 199.6 million. We anticipate that we will incur significant additional losses as we continue to focus our resources on prioritizing, selecting and advancing our most promising therapeutic candidates. We may never be profitable and we may never achieve significant sustained revenues.

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

As of December 31, 2017, we held cash and short-term investments of $49.5 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 out-licensing and other collaboration agreements, will be sufficient to meet our requirements into 2020. We have funded our operations primarily through public and private offerings of our securities, payments received under our strategic licensing and collaboration arrangements and interest earned on investments. The adequacy of our available funds to meet our operating and capital requirements will depend on many factors including: the number, breadth, progress and results of our research, product development and clinical programs; the costs and timing of obtaining regulatory approvals for any of our therapeutic candidates; the terms and conditions of in-licensing and out-licensing therapeutic candidates; and costs incurred in enforcing and defending our patent claims and other intellectual property rights.

While we will continue to explore alternative financing sources, including the possibility of future securities offerings and government funding, we cannot be certain that in the future these liquidity sources will be available when needed on commercially reasonable terms or at all, or that our actual cash requirements will not be greater than anticipated. We 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, only one of our products, BL-5010, for the treatment of benign skin lesions, has been approved for marketing and sale. Currently, we have one clinical-stage therapeutic candidate in development: BL-8040 for the treatment of multiple cancer and hematological indications. We also have one therapeutic candidate, AGI-134, in development for solid tumors, that we expect will begin clinical stage development in mid-2018. Our therapeutic candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization of drugs and devices. We may not obtain marketing approval for any other of our therapeutic candidates in a timely manner or at all. In connection with the clinical trials for BL-8040 and 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 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, because some of our clinical trials are investigator-initiated studies (i.e., we are not the study sponsor), we may have less control over these studies. We estimate that clinical trials of our most advanced therapeutic candidates will continue for several years, but they may take significantly longer to complete. Failure can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future therapeutic candidates, including but not limited to:

delays in securing clinical investigators or trial sites for the clinical trials;

delays in obtaining institutional review board and other regulatory approvals to commence a clinical trial;

slower than anticipated patient recruitment and enrollment;

negative or inconclusive results from clinical trials;

unforeseen safety issues;

uncertain dosing issues;

an inability to monitor patients adequately during or after treatment; and

problems with investigator or patient compliance with the trial protocols.

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

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

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

restrictions on such product, manufacturer or manufacturing process;

warning letters from the FDA or other regulatory authorities;

withdrawal of the product from the market;

suspension or withdrawal of regulatory approvals;

refusal to approve pending applications or supplements to approved applications that we or our licensees submit;

voluntary or mandatory recall;

fines;

refusal to permit the import or export of our products;

product seizure or detentions;

injunctions or the imposition of civil or criminal penalties; or

adverse publicity.

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

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

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

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

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

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

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

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

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

We employ a number of methods to identify therapeutic candidates that we believe are likely to achieve commercial success. In certain instances, disease-specific third-party advisors evaluate therapeutic candidates, as we deem necessary. In addition, therapeutic candidates expected to be developed under our collaboration with Novartis Pharma AG, or 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 our main therapeutic candidates, we have in-licensed rights from Biokine Therapeutics Ltd., or Biokine, with respect to our BL-8040 therapeutic candidate; from the University of Massachusetts and from Kode Biotech Limited, or Kode Biotech, with respect to our AGI-134 therapeutic candidate; and from Innovative Pharmaceutical Concepts, Inc., or IPC, with respect to our BL-5010 therapeutic candidate. See "Item 4. Information on the Company — Business Overview — In-Licensing Agreements." Our in-license agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these agreements. The royalty rates and revenue sharing payments vary from case to case but generally range from 20% to 29.5% of the consideration we receive from sublicensing the applicable therapeutic candidate, and a substantially lower percentage (generally less than 5%) if we elect to commercialize the subject therapeutic candidate independently. Due to the relatively advanced stage of development of the compound licensed from Biokine, our license agreement with Biokine provides for royalty payments of 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.

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

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

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

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

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

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

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address the indications for which we are currently developing therapeutic candidates or for which we may develop therapeutic candidates in the future. Specifically, we are aware of other companies which currently market and/or are in the process of developing products that address stem-cell mobilization, acute myeloid leukemia, or AML, solid malignancies and skin lesions.

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

Our contract manufacturers are, and will be, subject to FDA and other comparable agency regulations.

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

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

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

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

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

We may not be successful in recruiting the sales and marketing personnel necessary to sell any of our therapeutic candidates upon approval, if at all, and even if we do build a sales force, 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 rely upon third-party manufacturers to produce therapeutic supplies for the clinical trials, and commercialization, of our therapeutic candidates. If we manufacture any of our therapeutic candidates in the future, we will be required to incur significant costs and devote significant efforts to establish and maintain manufacturing capabilities.

We do not currently have laboratories that are compliant with cGMP and therefore cannot independently manufacture drug products for our current clinical trials. We rely on third-party manufacturers to produce the therapeutic supplies that will enable us to perform clinical trials and, if we choose to do so, commercialize therapeutic candidates ourselves. We have limited personnel with experience in drug or medical device manufacturing and we lack the resources and capabilities to manufacture any of our therapeutic candidates on a commercial scale. The manufacture of pharmaceutical products and medical devices requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products and medical devices often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields and quality control, including stability of the therapeutic candidate.

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

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

reliance on the third party for regulatory compliance and quality assurance;

limitations on supply availability resulting from capacity and scheduling constraints of the third parties;

impact on our reputation in the marketplace if manufacturers of our products, once commercialized, fail to meet customer demands;

the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and

the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

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

Risks Related to Our Industry

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

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

difficulty in large-scale manufacturing;

low market acceptance by physicians, healthcare payors, patients and the medical community as a result of lower demonstrated clinical safety or efficacy compared to other products, prevalence and severity of adverse side effects, or other potential disadvantages relative to alternative treatment methods;

insufficient or unfavorable levels of reimbursement from government or third-party payors;

infringement on proprietary rights of others for which we or our licensees have not received licenses;

incompatibility with other therapeutic products;

other potential advantages of alternative treatment methods;

ineffective marketing and distribution support;

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

lack of cost-effectiveness; or

timing of market introduction of competitive products.

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

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

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

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

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

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

a covered benefit under its health plan;

safe, effective and medically necessary;

appropriate for the specific patient;

cost-effective; and

neither experimental nor investigational.

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

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

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

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

Our business exposes us to significant potential clinical trial and product liability risks that are inherent in the development, manufacturing and sales and marketing of human therapeutic products. Claims could be made against us based on the use of our therapeutic candidates in clinical trials and in marketed products. We currently carry life science liability insurance covering general liability with an annual coverage amount of $30.0 million per occurrence and product liability and clinical trials coverage with an annual coverage amount of $30.0 million each claim and in the aggregate. The maximum indemnity for a single occurrence, claim or circumstances under this insurance is $30.0 million. However, our insurance may not provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage or 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 that are in development or being commercialized. In 2012, we in-licensed the rights to BL-8040 under a license agreement from Biokine. Under the BL-8040 license agreement, we are obligated to make commercially reasonable, good faith efforts to sublicense or commercialize BL-8040 for fair consideration. Agalimmune in-licensed rights to AGI-134 under a license from the University of Massachusetts in 2013 and under a license from Kode Biotech in 2015. Under each of those license agreements, Agalimmune is obligated to use diligent efforts or cause its affiliates and sublicensees to use diligent efforts to develop the respective licensed technology and introduce licensed products into the commercial market. In 2007, we in-licensed the rights to BL-5010 under a license agreement with IPC. Under the BL-5010 license agreement, we are obligated to use commercially reasonable efforts to develop the licensed technology in accordance with a specified development plan, including meeting certain specified diligence goals.

Each of the foregoing in-licensing agreements, or the obligation to pay royalties thereunder, will generally remain in effect until the expiration, under the applicable agreement, of all the licensing, royalty and sublicense revenue obligations to the applicable licensors, determined on a product-by-product and country-by-country basis. We may terminate the BL-8040 in-licensing agreement upon 90 days' prior written notice to Biokine. Agalimmune may terminate each of the in-licensing agreements with University of Massachusetts and Kode Biotech relating to AGI-134, on 90 days' notice. We may terminate the BL-5010 in-licensing agreement upon 30 days' prior written notice to IPC.

Any party to any of the foregoing in-licensing agreements may terminate the respective agreement for material breach by the other party if the breaching party is unable to cure the breach within an agreed upon period, generally 30 days to 90 days, after receiving written notice of the breach from the non-breaching party.

Patent protection for our products is important and uncertain.

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

We try to protect our proprietary position by, among other things, filing U.S., European, Israeli and other patent applications related to our proprietary products, technologies, inventions and improvements that may be important to the continuing development of our therapeutic candidates. As of March 1, 2018, we owned or exclusively licensed for uses within our field of business 25 patent families that collectively contain over 58 issued patents, one allowed patent application and over 85 pending patent applications relating to our main therapeutic 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. 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 for our taxable year ending December 31, 2018 or in any subsequent year. There may be negative tax consequences for U.S. taxpayers that are holders of our ordinary shares or our ADSs if we are a PFIC.

We will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (i) at least 75% of our gross income is "passive income" or (ii) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account. We believe that we were a PFIC during certain prior taxable years and, although we have not determined whether we will be a PFIC for our taxable year ending December 31, 2018, or in any subsequent year, our operating results for any such years may cause us to be a PFIC. If we are a PFIC for our taxable year ending December 31, 2018, or any subsequent year, and a U.S. Investor (as defined below) does not make an election to treat us as a "qualified electing fund," or QEF, or make a "mark-to-market" election, then "excess distributions" to a U.S. Investor, and any gain realized on the sale or other disposition of our ordinary shares or ADSs will be subject to special rules. Under these rules: (i) the excess distribution or gain would be allocated ratably over the U.S. Investor's holding period for the ordinary shares (or ADSs, as the case may be); (ii) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (iii) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, if the U.S. Internal Revenue Service, or the IRS, determines that we are a PFIC for a year with respect to which we have determined that we were not a PFIC, it may be too late for a U.S. Investor to make a timely QEF or mark-to-market election. U.S. Investors who hold our ordinary shares or ADSs during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to exceptions for U.S. Investors who made a timely QEF or mark-to-market election. A U.S. Investor can make a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. A QEF election generally may not be revoked without the consent of the IRS. Upon request, we will annually furnish U.S. Investors with information needed in order to complete IRS Form 8621 (which form would be required to be filed with the IRS on an annual basis by the U.S. Investor) and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC.

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

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

announcements of technological innovations or new products by us or others;

announcements by us of significant acquisitions, strategic partnerships, in-licensing, out-licensing, joint ventures or capital commitments;

expiration or terminations of licenses, research contracts or other collaboration agreements;

public concern as to the safety of drugs we, our licensees or others develop;

general market conditions;

the volatility of market prices for shares of biotechnology companies generally;

success of research and development projects;

departure of key personnel;

developments concerning intellectual property rights or regulatory approvals;

variations in our and our competitors' results of operations;

changes in earnings estimates or recommendations by securities analysts, if our ordinary shares or ADSs are covered by analysts;

statements about the Company made in the financial media or by bloggers on the Internet;

statements made about drug pricing and other industry-related issues by government officials;

changes in government regulations or patent decisions;

developments by our licensees; and

general market conditions and other factors, including factors unrelated to our operating performance.

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

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

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

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

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

As a result of a previous financing, we have warrants outstanding (i) for the purchase of 2,973,451 ADSs at an exercise price of $2.00 per ADS and (ii) for the purchase of 2,973,451 ADSs at an exercise price of $4.00 per ADS. In addition, as of March 5, 2018, in the framework of our Share Incentive Plan, there are outstanding stock options, restricted stock units and performance stock units (granted to directors, employees and consultants) for the purchase of 10.9 million ordinary shares with a weighted average exercise price of $1.28 per ordinary share.

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

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

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

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

- the failure to obtain regulatory approval or achieve commercial success of our therapeutic candidates;
- our success in effecting out-licensing arrangements with third-parties;
- our 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 Listing Rules of the Nasdaq Stock Market for U.S. domestic issuers. For instance, we may follow home country practice in Israel with regard to, among other things, composition of the Board of Directors, director nomination procedure, composition of the compensation committee, approval of compensation of officers, and quorum at shareholders' meetings. In addition, we will follow our home country law, instead of the Listing Rules of the Nasdaq Stock Market, 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 Nasdaq may provide less protection than is accorded to investors under the Listing Rules of the Nasdaq Stock Market applicable to U.S. domestic issuers. See "Item 16G — Corporate Governance — Nasdaq Listing Rules and Home Country Practices."

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

If we are unable to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, as they apply to a foreign private issuer that is listed on a U.S. exchange, or our internal control over financial reporting are not effective, the reliability of our financial statements may be questioned and our share 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 control 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 control over financial reporting. In addition, in those years in which we are an accelerated filer, our independent registered public accounting firm is required to issue an opinion on our internal control over financial reporting.

The continuous process of strengthening our internal control and complying with Section 404 is complicated and time-consuming. Furthermore, as our business continues to grow both domestically and internationally, our internal control 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 control over financial reporting, or our independent registered public accounting firm identifies material weaknesses in our internal control, 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, most 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, and to a lesser extent since August 2016, Israel has been facing another escalation in violence with the Palestinian population. These conflicts involved missile strikes against civilian targets in various parts of Israel, as well as civil insurrection of Palestinians in the West Bank, on the border with the Gaza Strip and in Israeli cities, and negatively affected business conditions in Israel. In addition, Israel faces threats from more distant neighbors, in particular Iran. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah (a Lebanese Islamist Shiite militia group and political party), and various rebel militia groups in Syria. Recent political uprisings and social unrest in various countries in the Middle East and North Africa are affecting the political stability of those countries. The year 2014 saw the rise of an Islamic fundamentalist group known as ISIS. Following swift operations, ISIS gained control of large areas in the Middle East, including in Iraq and Syria, which have contributed to the turmoil experienced in these areas. As a result, the United States and Russian armed forces have engaged in limited operations in Syria, resulting in the defeat of ISIS and other rebel groups and their withdrawal in 2017 from most of the areas they had previously held in Syria, including places along the Israeli-Syrian border. While Iranian forces have supported operations of the Syrian army during the years of fighting in Syria, there are now reports of Iran setting up a permanent army base in relative proximity to the Israeli-Syrian border, a development that Israel has said it will not accept. 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. If the BDS Movement, the movement for boycotting, divesting and sanctioning Israel and Israeli institutions (including universities) and products become increasingly influential in the United States and Europe, this may also adversely affect our financial condition.

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 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.

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 certain research and development expenditures. The terms of these grants and loans may require us to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. We may be required to pay penalties in addition to repayment of the grants and loans.

Our research and development efforts were previously financed, in part, through grants and loans that we received from the Israel Innovation Authority, or the IIA (formerly the Office of the Chief Scientist of Israel's Ministry of Economy and Industry, or the OCS). In addition, before we in-licensed BL-8040, Biokine had received funding for the project from the IIA, and as a condition to IIA consent to our in-licensing of BL-8040, we were required to agree to abide by any obligations resulting from such funding. We therefore must comply with the requirements of the Israeli Law for the Encouragement of Industrial Research, Development and Technological Innovation, 1984, and related regulations, as amended, or the Research Law, with respect to these projects. Through December 31, 2017, we received approximately $22.0 million in funding from the IIA and paid the IIA approximately $7.0 million in royalties under our approved programs. As of December 31, 2017, we have no contingent obligation to the IIA other than for BL-8040 as agreed when we in-licensed the project. The contingent liability to the IIA assumed by us relating to this transaction (which liability has no relation to the funding actually received by us) amounts to $3.2 million as of December 31, 2017. We have a full right of offset for amounts payable to the IIA from payments that we may owe to Biokine in the future. Therefore, the likelihood of any payment obligation to the IIA with regard to the Biokine transaction is remote.

The transfer to third parties of know-how or technologies developed under the programs submitted to the IIA and as to which we or our licensors received grants, or manufacturing or rights to manufacture based on and/or incorporating such know-how to third parties, might require the consent of the IIA, and may require certain payments to the IIA. There is no assurance that we will be able to obtain such consent on terms that acceptable to us, or at all. Although such restrictions do not apply to the export from Israel of our products developed with such know-how, 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, leaves substantial discretion with the newly established IIA and includes only guidelines to some of the core issues of the Research Law. Since the coming into effect of the R&D Amendment, the IIA has published various incentive tracks and guidelines on its website, in large part reinstating the core provisions of the pre-R&D Amendment regime, including with respect to the requirement to obtain approvals prior to the transfer abroad of the rights to or the manufacturing of any IIA-supported product or technology. 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. We completed our initial public offering in Israel in February 2007 and our ordinary shares are traded on the TASE under the symbol "BLRX." In July 2011, we listed our ADSs on Nasdaq and they are traded under the symbol "BLRX."

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

Our capital expenditures for the year ended December 31, 2015 were $2.7 million and included the leasehold improvements on our new facility in Modi'in, as well as the purchase of laboratory equipment. For the year ended December 31, 2016, our capital expenditures were immaterial. For the year ended December 31, 2017, our capital expenditures were $4.2 million and included the acquisition of Agalimmune. Our current capital expenditures involve acquisitions of laboratory equipment, computers and communications equipment.

B. Business Overview

We are a clinical stage biopharmaceutical development company focused on oncology and immunology. Our current development and commercialization pipeline consists of a clinical-stage therapeutic candidate − BL-8040, a novel peptide for the treatment of multiple cancer and hematological indications; a near-clinical candidate – AGI-134, an immuno-oncology agent in development for solid tumors; and a product that is being commercialized − BL-5010, a customized, proprietary, pen-like applicator containing a novel, acidic, aqueous solution, which has been launched for sale 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 high probability of therapeutic and commercial success. To date, except for BL-5010, none of our therapeutic candidates have been approved for marketing or sold commercially. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies. 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 for the co-development of selected Israeli-sourced novel drug candidates. We are currently developing one preclinical project, BL-1230, in the framework of this collaboration, with the ongoing scientific support of Novartis. We are continually evaluating late preclinical and early clinical projects, with the goal of bringing additional projects into our pipeline during the next six to 12 months. Additionally, in January 2016, we entered into a collaboration with MSD (a tradename of Merck & Co., Inc.), in the field of cancer immunotherapy and, in September 2016, we entered into a collaboration with Genentech, Inc., or Genentech, a member of the Roche Group, in the field of cancer immunotherapy.

Although our focus is on the therapeutic areas of oncology and immunology, 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 opportunities may arise.

Main Therapeutic Candidates

BL-8040

Our clinical-stage, lead therapeutic candidate, BL-8040, is a novel, short peptide that functions as a high-affinity antagonist for CXCR4 and that we are developing for the treatment of solid tumors, AML and stem-cell mobilization for bone-marrow transplantation. 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, detaching them from the survival signals in the bone marrow microenvironment and sensitizing them to chemo- and bio-based anti-cancer therapy. In addition, in preclinical studies BL-8040 has demonstrated a direct anti-cancer effect by inducing apoptosis (cell death) and terminal differentiation. Clinical and preclinical studies have shown the safety and efficacy of BL-8040. Preclinical 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. Clinical data supporting BL-8040 as a robust mobilizer of hematopoietic stem cells ($CD34^+$ $CD38^-$ $CD45RA^-$ $CD90^+$ $CD49f^+$), or HSCs, associated with long-term engraftment was presented at the American Society of Hematology (ASH) Annual Meeting and Exhibition in December 2017.

In addition, preclinical and clinical data in the field of immuno-oncology suggest that BL-8040 is effective in inducing the migration of anti-tumor T cells into the tumor micro-environment, or TME. 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, such as pancreatic cancer. Clinical data supporting the ability of BL-8040 to promote T cell infiltration into pancreatic tumors were presented at the ASCO Gastrointestinal Cancers Symposium, or ASCO-GI, which took place in January 2018. In addition, preclinical data supporting the ability of BL-8040 to promote the migration of anti-tumor T cells into tumors were presented at the ASCO-SITC Clinical Immuno-Oncology Symposium, or ASCO-SITC, which also took place in January 2018.

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

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

Solid tumors

- In January 2016, we entered into a collaboration with MSD in the field of cancer immunotherapy. Based on this collaboration, in September 2016 we initiated a Phase 2a study focusing on evaluating the safety and efficacy of BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in up to 30 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. Partial results from the monotherapy portion of this study, showing that BL-8040 increases infiltration of T cells into the tumor in patients with metastatic pancreatic cancer, were announced at ASCO-GI. Top-line results from the trial are expected in the second half of 2018.

- In August 2016, in the framework of an agreement with MD Anderson Cancer Center, we entered into an additional collaboration for the investigation of BL-8040 in combination with KEYTRUDA in pancreatic cancer. The focus of this study, in addition to assessing clinical response, is the mechanism-of-action by which both drugs might synergize, as well as multiple assessments to evaluate the biological anti-tumor effects induced by the combination. We are supplying BL-8040 for this Phase 2b study, which commenced in January 2017.

- In September 2016, we entered into a collaboration with Genentech, in the framework of which both companies would carry out Phase 1b/2 studies investigating BL-8040 in combination with TECENTRIQ® (atezolizumab), Genentech's anti-PDL1 cancer immunotherapy, in various solid tumors and hematologic malignancies. Genentech commenced a Phase 1b/2 study for the treatment of pancreatic cancer in July 2017, as well as a Phase 1b/2 study in gastric cancer in October 2017. Genentech expects to commence an additional Phase 1b/2 study in lung cancer by early 2018. These studies will evaluate the clinical response, safety and tolerability of the combination of these therapies, as well as multiple pharmacodynamic parameters.

AML

- During 2016, we completed and reported on a Phase 2a proof-of-concept trial for the treatment of relapsed or refractory acute myeloid leukemia, or r/r AML, which was conducted on 42 patients at six world-leading cancer research centers in the U.S. and at five premier sites in Israel. The study included both a dose-escalation and a dose-expansion phase. At the annual meetings of the Society of Hematologic Oncology and ASH in September and December 2016, respectively, we presented detailed, positive safety and response rate data relating to the study. In December 2017, we announced positive overall survival data from the long-term follow-up part of this study. We continue to monitor long-term survival data for patients in the study.

- We are currently investigating BL-8040 as a consolidation treatment together with cytarabine (the current standard of care) for AML patients who have responded to standard induction treatment and are in complete remission and, in this regard, are conducting a significant Phase 2b trial in Germany, in collaboration with the German Study Alliance Leukemia Group. The Phase 2b trial is a double-blind, placebo-controlled, randomized, multi-center study aimed at assessing the efficacy of BL-8040 in addition to standard consolidation therapy in AML patients. Up to 194 patients will be enrolled in the trial. 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. We are considering conducting an interim analysis on this study in the second half of 2018, with top-line results expected in 2020.

- In September 2017, we initiated a Phase 1b/2 trial in AML under the collaboration with Genentech referred to above in " — Solid tumors." The trial will focus on the maintenance treatment of patients with intermediate- and high-risk AML who have achieved a complete response following induction and consolidation therapy. Up to 60 patients are planned to be enrolled in this single arm, open-label study, planned to take place at approximately 22 sites in the U.S., Europe and Israel.

Stem-cell mobilization

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

- Ø In March 2016, we initiated a Phase 2 trial for BL-8040 for allogeneic stem-cell transplantation, conducted in collaboration with the Washington University School of Medicine, Division of Oncology and Hematology. Initial results of this study announced in March 2017 show that a single injection of BL-8040 mobilized sufficient amounts of cells required for transplantation at a level of efficacy similar to that achieved by using 4-6 injections of G-CSF, the current standard of care. Top-line results of this study are now expected in mid-2018, as a result of certain delays in study recruitment in connection with the addition of two sites to the study and the regulatory filings associated therewith.

- Ø In December 2017, we commenced a randomized, controlled Phase 3 registrational trial of BL-8040 for the mobilization of HSCs for autologous transplantation in patients with multiple myeloma. The trial will commence with a lead-in period for dose confirmation, which will include 10-30 patients, and progress to the placebo-controlled main part, which is designed to include 177 patients in more than 15 centers. Top-line results of this study are expected in 2020.

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

AGI-134

In March 2017, we acquired substantially all the outstanding shares of Agalimmune. The acquisition expanded our pipeline to include Agalimmune's primary asset, AGI-134, a synthetic alpha-Gal glycolipid immunotherapy in development for the treatment of multiple solid tumors. At the near-clinical stage of development, AGI-134 has completed numerous proof-of-concept studies, demonstrating regression of established primary tumors after injection with AGI-134 and a robust protection against the development of secondary tumors in a model of melanoma. We expect to commence a first-in-man study using AGI-134 in patients with solid tumors in mid-2018.

BL-5010

Our commercialized therapeutic product, BL-5010, is a customized, proprietary pen-like applicator containing a novel, acidic, aqueous solution for the non-surgical removal of skin lesions. In December 2014, we entered into an exclusive out-licensing arrangement with Perrigo Company plc, or Perrigo, for the rights to BL-5010 for over-the-counter, or OTC, indications in Europe, Australia and additional selected countries. In March 2016, Perrigo received CE Mark approval for BL-5010 as a novel OTC treatment for the non-surgical removal of warts. The commercial launch of this first OTC indication (warts/verrucas) commenced in Europe in the second quarter of 2016 and sales are expected to slowly increase over the next 2-3 years.

Our Strategy

Our objective is to be a leader in developing innovative pharmaceutical and biopharmaceutical products in the fields of oncology and immunology. 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 six 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 most of our 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 Health Maintenance Organizations, manufacturing and/or marketing. If appropriate, we may also enter into co-development and similar arrangements with respect to any therapeutic candidate with third parties or commercialize a therapeutic candidate ourselves.

- **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.

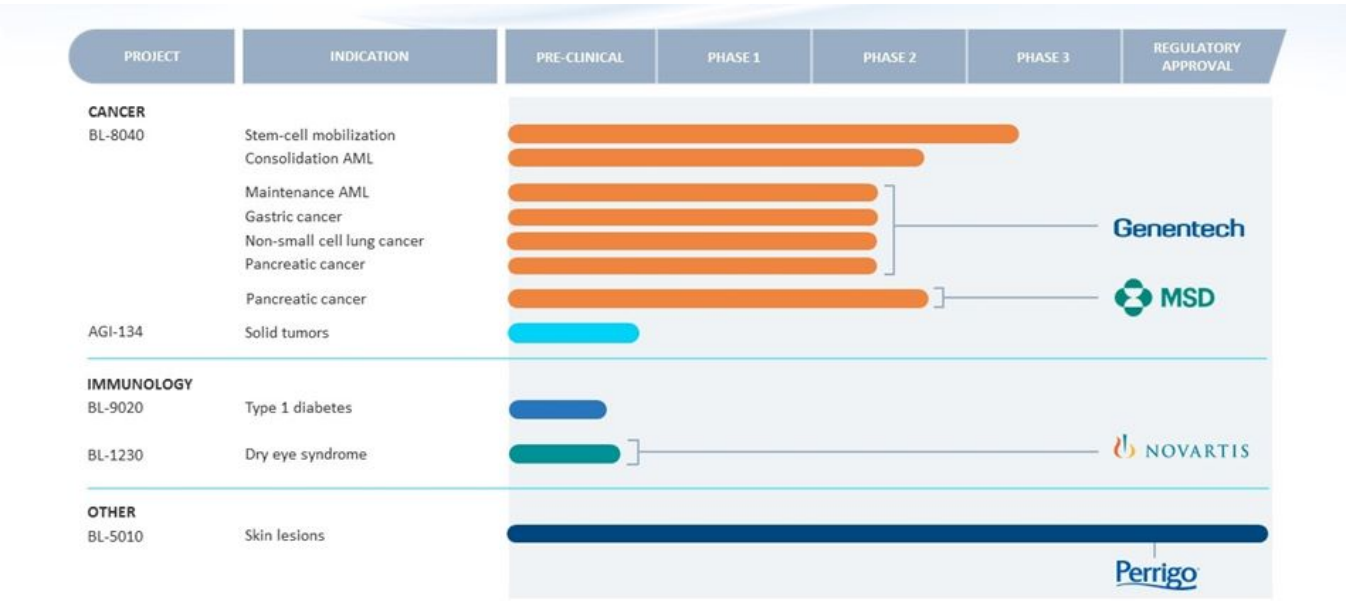
- **Use our expertise and proven screening methodology to evaluate in-licensing opportunities.** In order to review and select among various candidates efficiently and effectively, we developed and employ a rigorous screening system. In certain instances, disease-specific third-party advisors evaluate 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. In line with this strategy, in March 2017 we acquired Agalimmune, a privately-owned U.K. company. Agalimmune's primary asset, AGI-134, is a near-clinical immuno-oncology agent for various cancer indications.

- **Seek to co-develop certain preclinical 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 preclinical stage projects presented by us through 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 preclinical 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.

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

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

Solid malignancies (e.g., pancreatic, gastric and non-small cell lung cancer). According to the Journal of Oncology Practice, in 2020 approximately 1 of every 19 people worldwide will be either diagnosed with a solid tumor or be a cancer survivor. According to the American Cancer Society, lung cancers are the most common type of cancer worldwide, while pancreatic cancers of all types are the third most common cause of cancer-related deaths in the United States. Pancreatic, gastric and non-small cell lung malignancies have high mortality rates and poor five-years survival prognosis. Novel, emerging therapeutic approaches for targeting solid tumors are being developed and tested. Combinational therapies of immune checkpoint inhibitors with immuno-oncology supporting agents are among the most promising experimental treatments for solid malignancies.

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. The Surveillance, Epidemiology and End Results program, or SEER, of the National Cancer Institute estimates that approximately 21,000 new cases of AML were diagnosed in the United States in 2017. 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 G-CSF, harvested from the peripheral blood by apheresis, and infused to the patient after chemotherapy. G-CSF is approved only for autologous use, although it is also used to mobilize and collect stem cells in the allogeneic setting on an off-label basis. This type of treatment often replaces the use of traditional surgical bone marrow harvesting, because the stem cells are easier to collect and the treatment allows for a quicker recovery time and fewer complications.

Regulatory Approvals. In September 2013, the FDA granted an Orphan Drug Designation to BL-8040 as a therapeutic for the treatment of AML. In January 2014, the FDA granted an Orphan Drug Designation to BL-8040 for use, in combination with G-CSF, in mobilizing human stem cells from the bone marrow to the peripheral blood for collection for autologous or allogeneic (donor-based) transplantation. In January 2015, the FDA modified this Orphan Drug Designation for BL-8040 for use either as a single agent or in combination with G-CSF. 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 (1-10nM) and occupies it for prolonged periods of time (>48h). These studies have shown that BL-8040 mobilizes cancer cells from the bone marrow and may therefore detach these cells from survival signals in the bone marrow microenvironment as well as sensitize them to chemo- and bio-based anti-cancer therapies. In addition, BL-8040 directly induces apoptosis of cancer cells. BL-8040 was efficient, both alone and in combination with chemotherapy, in reducing malignant bone marrow cells and stimulating their cell death.

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

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

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

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

Clinical Trials.

Solid tumors

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

Partial results from the BL-8040 monotherapy portion of this trial were presented at ASCO-GI in January 2018. These results show that BL-8040 was safe and well-tolerated, and that it induced an increase in the number of total immune cells in the peripheral blood, while the frequency of peripheral blood regulatory T cells (Tregs), known to impede the anti-tumor immune response, was decreased. In addition, analysis of available biopsies (N = 7) showed infiltration of effector T cells, known to attack cancer cells, into the tumor periphery and tumor micro-environment (TME). In this regard, the results show up to a 15-fold increase in CD3+ T cells, and up to a 2-fold increase in CD8+ T cells, in the TME of 43% (3/7) of the patients, after five days of BL-8040 monotherapy.

Top-line results from the trial are expected in the second half of 2018.

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

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

In July 2017, Genentech commenced a Phase 1b/2 trial to evaluate the combination of TECENTRIQ and BL-8040 in metastatic pancreatic ductal adenocarcinoma. In September 2017, Genentech commenced an additional Phase 1b/2 trial to evaluate the combination of TECENTRIQ and BL-8040 in gastric cancer. Up to 40 patients are planned to be enrolled in each of these studies. Each study will be multicenter, randomized, controlled and open-label, intended to evaluate the clinical response, safety and tolerability, as well as multiple pharmacodynamic parameters, of the drug combination. Initially, patients will receive BL-8040 injections as priming monotherapy, after which they will receive both BL-8040 and TECENTRIQ, and continue with multiple treatment cycles for up to two years or until disease progression, clinical deterioration or unacceptable toxicity. A third Phase 1b/2 study in lung cancer is expected to commence under this collaboration in 2018.

AML

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

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

Results show that treatment with BL-8040 in combination with high-dose Ara-C, or HiDAC, was safe and well tolerated at all doses tested up to and including the highest dose level of 2.0 mg/kg. Response to treatment was associated with efficient CXCR4 inhibition, resulting in high mobilization of blasts and induction of their differentiation. The composite complete remission rate, including both CR and CRi, was 38% in subjects receiving up to two cycles of BL-8040 treatment at doses of 1 mg/kg and higher (n=39). In the 1.5 mg/kg dose selected for the expansion Phase of the study (n=22), the composite complete remission rate was 41%. These response rates are superior to the historical response rate of approximately 20% reported for high-risk AML patients treated with Ara-C alone. The ongoing follow-up of patients participating in the study's expansion Phase and responding to the combination treatment suggests long durability of the remissions achieved, with two-thirds of these patients still alive, based on a follow-up period to date of up to 12 months. Results further show that BL-8040 monotherapy had a substantial therapeutic effect. Treatment with BL-8040 as a single agent triggered robust mobilization of AML blasts from the bone marrow to the peripheral blood stream, and the extent of mobilization was correlated with a positive response to treatment. The preferential mobilization of AML blasts over normal cells (4.7-fold vs. 1.4-fold, respectively) was further confirmed by analysis using the fluorescence in situ hybridization, or FISH, technique in a subset of patients. In addition, BL-8040 monotherapy resulted in a 40% increase in AML blast apoptosis.

In December 2017, we announced positive overall survival data from the long-term follow-up part of the r/r AML study. The results demonstrate that the combination of BL-8040 with HiDAC in the tested patient population significantly improved overall survival, compared with historical data of HiDAC monotherapy. Median overall survival was 11.1 (1-28) months, the estimated one-year survival rate was 37.5% and the estimated two-year survival rate was 28.5%, compared to historical data for patients treated only with HiDAC showing overall survival of approximately 6.1 months. Furthermore, the subset of patients exhibiting a response showed prolonged overall survival, with estimated one-year and two-year survival rates of 60%.

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

The Phase 2b trial, which is being conducted in collaboration with the University of Halle as sponsor and with the participation of two large leukemia study groups in Germany, is a double-blind, placebo-controlled, randomized, multi-center study aimed at assessing the efficacy of BL-8040 in addition to standard consolidation therapy in AML patients. The primary endpoint of the study is to compare the RFS time in AML subjects in their first remission during a minimum follow-up time of 18 months after randomization. In addition, pharmacodynamic measurements will be conducted in order to assess the minimal residual disease, and biomarker analyses will be performed to identify predictors of BL-8040 response. The study will enroll up to 194 patients at up to 25 sites in Germany and five sites in the Czech Republic. 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. We are considering performing an interim analysis on this study in the second half of 2018, with top-line results expected in 2020.

In September 2017, we initiated a Phase 1b/2 trial in AML as part of the collaboration with Genentech referred to above in " — Solid tumors." The trial, known as the BATTLE study, will focus on the maintenance treatment of patients with intermediate- and high-risk AML who have achieved a complete response following induction and consolidation therapy. Up to 60 patients are planned to be enrolled in this multicenter, single arm, open-label study, to evaluate the relapse-free survival, minimal residual disease status, safety and tolerability of the combination of BL-8040 and TECENTRIQ for maintenance treatment in AML patients. The study's primary endpoint is to assess whether the combination of BL-8040 and TECENTRIQ prolongs relapse free survival. In addition, the effect of the combination therapy on minimal residual disease, multiple immunological parameters, and potential biomarkers will be evaluated. The trial is planned to take place at approximately 22 sites in the U.S., Europe and Israel. Top-line results from this study are expected in 2019.

Stem-cell mobilization

In a Phase 1/2a, open-label, dose escalation, safety and efficacy clinical trial in 18 multiple myeloma patients, BL-8040 demonstrated an excellent safety profile at all doses tested and was highly effective in combination with G-CSF, in the mobilization of hematopoietic stem cells 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 March 2015, we announced successful top-line results from a Phase 1 trial for BL-8040 as a novel treatment for the mobilization of stem cells from the bone marrow to the peripheral blood circulation, 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 x 10^6 cells per kg, which is more than two-fold higher than the target concentration, and five-fold higher than the minimum concentration, necessary for transplantation. In addition, the level of HPSCs in the peripheral blood circulation 24 hours after injection of BL-8040 enabled an additional apheresis on day 2, if needed. These data support the use of BL-8040 as a single-agent, single-injection, one-day regimen for the collection of stem cells.

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

In March 2017, we announced positive interim results from the first part of the study. This part initially enrolled 10 donor and recipient pairs, consisting of patients with advanced hematological malignancies and their sibling donors matched for human leukocyte antigen. Interim results show that a single injection of BL-8040 mobilized sufficient amounts of cells required for transplantation at a level of efficacy similar to that achieved by using 4-6 injections of G-CSF, the current standard of care. Furthermore, all recipients transplanted so far have experienced a successful neutrophil engraftment. The recipients will be followed for one year to assess acute and chronic GVHD events. As for the donors, BL-8040 treatment was safe and well tolerated. Top-line results for this study are expected in mid-2018.

In December 2017, we initiated a Phase 3 registration study for BL-8040 in autologous stem-cell mobilization. The trial, known as the GENESIS study, is a randomized, placebo-controlled, multicenter study, evaluating the safety, tolerability and efficacy of BL-8040 and G-CSF, compared to placebo and G-CSF, for the mobilization of HSCs for autologous transplantation in multiple myeloma patients. The study is expected to commence with a lead-in period for dose confirmation, which will include 10-30 patients, and progress to the placebo-controlled main part, which is designed to include 177 patients in more than 15 centers. Treatment will include 5-8 days of G-CSF, with a single dose of BL-8040 or placebo on day 4 and an optional additional dose of BL-8040 or placebo on day 6. Apheresis for stem cell collection will be performed on day 5. Further apheresis sessions may be conducted if needed in order to reach the benchmark of $\geq$ 6x106 mobilized $CD34^+$ cells. The primary objective of the study is to demonstrate that BL-8040 on top of G-CSF is superior to G-CSF alone in the ability of mobilize $\geq$ 6x106 $CD34^+$ cells in up to two apheresis sessions. Secondary objectives include time to engraftment of neutrophils and platelets and durability of engraftment, as well as other efficacy and safety parameters. Partial results from the lead-in, dose-confirmation part of the study are expected in mid-2018. Top-line results of this study are expected in 2020.

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

AGI-134

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

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

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

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

AGI-134 is now in near-clinical development, and we expect to commence a first-in-man study using AGI-134 in patients with solid tumors in mid-2018. Discussions about clinical trials have been held with both the FDA and the U.K. Medicines and Healthcare Products Regulatory Agency.

Commercialized Product

BL-5010

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

Development and 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 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 Perrigo 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 Perrigo for the rights to BL-5010 for OTC, indications in Europe, Australia and additional selected countries. We retain the OTC rights to BL-5010 in the United States and the rest of the world, as well as the non-OTC rights on a global basis. Under our out-licensing arrangement with Perrigo, Perrigo is obligated to use commercially reasonable best efforts to obtain regulatory approval in the licensed territory for at least two OTC indications and to commercialize BL-5010 for those two OTC indications. In addition, Perrigo will sponsor and manufacture BL-5010 in the relevant regions. Perrigo 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. In March 2016, Perrigo received CE Mark approval for BL-5010 as a novel OTC treatment for the non-surgical removal of warts. The commercial product launch of this first OTC indication (warts/verrucas) commenced in Europe in the second quarter of 2016.

As a result of our 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 Perrigo, primarily the U.S.

Other Therapeutic Candidates

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 was being developed as a medical device. We entered into an out-licensing arrangement for BL-1040 with the predecessor of Bellerophon Therapeutics, Inc., or Bellerophon, in 2009. 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. In July 2015, Bellerophon reported top-line results from PRESERVATION I, a CE mark registration clinical trial for BCM, showing no statistically significant difference between patients treated with BCM versus placebo for both the primary and the secondary endpoints of the study. Bellerophon is considering further exploratory work for the compound. We in-licensed BL-1040 from B.G. Negev Technologies and Applications Ltd., or B.G. Negev, in 2005.

BL-9020

BL-9020 is a novel monoclonal antibody treatment designed to prevent immune-mediated destruction of insulin-producing beta cells in the pancreas. The treatment was developed to treat Type 1 diabetes in early stage patients, during what is known as the "honeymoon period," where the pancreatic beta cells have not been completely destroyed and continue to secrete insulin. BL-9020 targets NKp46, a unique target that is involved in the innate response against the pancreas. Preclinical 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., or Yissum; B.G. Negev; and Hadasit Medical Research Services and Development Ltd., or Hadasit (the technology transfer company of Hadassah Medical Organization).

BL-1230

BL-1230 is a cannabinoid receptor type 2 (CB2R) intended as a novel anti-inflammatory treatment for Dry Eye Syndrome (DES). DES is one of the most prevalent ophthalmic medical conditions, but currently, treatment options are very limited, and include constant rehydration with artificial tears and local immunosuppressants. The involvement of CB2R in immune modulation is well established, and preclinical studies in three ocular inflammatory models have demonstrated that BL-1230 eye drops have significant anti-inflammatory activity, which attenuates the pathology and improves histological outcomes. In addition to DES, we intend to explore the potential use of this compound in systemic inflammatory conditions. We in-licensed BL-1230 in 2016 from Yissum.

BL-1230 was in-licensed under the framework of our strategic collaboration with Novartis for the screening and development of novel drug candidates.

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 2017 and the period subsequent thereto through the date of this report, we terminated one clinical stage and two preclinical stage therapeutic candidates.

BL-7010 was a novel, non-absorbable, orally available, high-molecular-weight co-polymer intended for the treatment of celiac disease and gluten sensitivity. Over the last two years, we invested significant 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. At the same time, we continued to evaluate the pathway for celiac disease in Europe. However, it became apparent that in light of the scientific and regulatory challenges attending the development of a drug for gluten sensitivity in general and celiac disease in particular, the probability of success for BL-7010 in any pathway was low. In view of our decision to focus on immuno-oncology, we concluded that it would be preferable not continue to invest in research and development efforts related to BL-7010 and to allocate resources and management attention to projects that have a higher probability of succeeding. Therefore, we terminated the project in early 2017.

BL-1210 was a mechanism intended for the treatment of liver fibrosis, and in particular, non-alcoholic steatohepatitis, or NASH. BL-1220 was an orally administered, novel composition of sodium alginate, intended as a treatment for various liver failure conditions such as end-stage liver disease and for conditions potentially leading to liver failure such as NASH. These two preclinical projects were terminated due to lack of efficacy and other scientific considerations as well as market considerations.

Product Development Approach

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

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 our development activities in our 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 usually 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. We intend to co-develop a number of preclinical and early clinical therapeutic projects through clinical proof-of-concept. We currently have one preclinical project, BL-1230, that we are developing in the framework of this collaboration. As part of the collaboration agreement, Novartis made an initial equity investment in BioLineRx of $10 million, and as of year-end, holds approximately 5% of our outstanding share capital.

Collaboration Agreements with MSD and Genentech

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

Out-Licensing Agreement with Perrigo

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

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

Perrigo 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 Perrigo, within our standard range of sublicense receipt consideration, to IPC, the company from which we initially in-licensed the development rights to BL-5010. See "— In-Licensing Agreements — BL-5010."

We have the right to prosecute and maintain the patents for BL-5010 in the Territory, and Perrigo will bear the cost of all renewal fees 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 Perrigo will continue in effect until the cessation of all commercialization in the Territory. After the fifth anniversary of the first commercial sale of a licensed product, either party may terminate the agreement by giving at least 18 months' prior written notice to the other party. Either party may terminate the agreement (a) by providing 60 days' written notice of a material breach of the agreement by the other party if the breaching party does not cure the breach during that time or (b) with immediate effect on written notice to the other party if there is a change of control of the other party. The parties have agreed that the announced acquisition of Perrigo by Perrigo Company Plc is a change of control event that will not give rise to a right on our part to terminate the license agreement. In addition, we have the right to terminate the agreement if Perrigo does not fulfill any of its obligations of diligence with respect to launching a licensed product or obtaining regulatory approval for, and commercializing, licensed products as described above.

Other Out-licensing/Collaboration Agreements

iPharma

In 2016, we established a joint venture with I-Bridge Capital, a Chinese venture capital fund focused on developing innovative therapies in China. The joint venture, named iPharma, is focusing on the development of innovative clinical and preclinical therapeutic candidates to serve the Chinese and global healthcare markets. In accordance with the terms of the joint venture agreement, each partner has provided seed capital of $1 million to the venture. As of the date of this report, iPharma has licensed exclusive worldwide rights to one clinical-stage asset and one preclinical stage asset. The clinical-stage asset, licensed from Boehringer Ingelheim, is a focal adhesion kinase inhibitor (FAKi), being developed for multiple solid tumors. Additional therapeutic candidates for indications that are of special interest for the Chinese population are being screened and, if found suitable, will be in-licensed by iPharma for further development and commercialization in China and possibly in other countries as well. iPharma expects to raise the funds needed to develop its pipeline primarily from third-party investors. In this regard, we do not expect to invest material additional capital in iPharma.

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 preclinical and clinical development stages, and we will be responsible for all preclinical 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 and Hadasit, 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.

MaRS Innovation

In May 2016, we entered into a collaboration with MaRS Innovation, the commercialization agent for 15 of Toronto's top academic institutions. Under the terms of the agreement, we intend to review innovative projects and assets of startup companies originating from MaRS Innovation's members, to identify in-licensing, co-development or other partnering opportunities.

In-Licensing Agreements

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

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

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

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

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

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

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

The royalty and revenue sharing rates we agree to pay in our in-licensing agreements vary from case to case but in most cases range from 20% to 29.5% of the consideration we receive from sublicensing the applicable therapeutic candidate. We are required to pay a substantially lower percentage, generally less than 5%, if we elect to commercialize the subject therapeutic candidate independently. Due to the relatively advanced stage of development of the compound licensed from Biokine, our license agreement with Biokine provides for royalty payments of 40% of the consideration we receive from sublicensing and 10% of net sales, subject to certain limitations, should we independently sell products. 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 main therapeutic candidates. In addition to the in-licensing agreements discussed herein, we have entered into other in-licensing arrangements in connection with our therapeutic candidates in clinical, advanced preclinical and feasibility stages.

BL-8040

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

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

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

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

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

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

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

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

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

AGI-134

Acquisition Agreements with Agalimmune

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

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

License from the University of Massachusetts

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

License from Kode Biotech

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

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

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

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. 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.

Under the license agreement, we 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.

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, 2018, we owned or exclusively licensed for uses within our field of business 25 patent families that collectively contain over 58 issued patents, one allowed patent application and over 85 pending patent applications relating to the three candidates listed below. We are also pursuing patent protection for other drug candidates in our pipeline. Patents related to our therapeutic candidates may provide future competitive advantages by providing exclusivity related to the composition of matter, formulation, and method of administration of the applicable compounds and could materially improve the value of our therapeutic candidates. The patent positions for our three 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 U.S., Europe, Japan and Canada. The patents and any patents to issue in the future based on pending patent applications in these families will expire in 2023 (in the U.S.) and 2021 (in other countries), 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 AGI-134, Agalimmune owns or has an exclusive license to three patent families that cover a genus of compounds including AGI-134, methods of using compounds, including AGI-134, and for a pharmaceutical composition that contains AGI-134. Patents have been granted in the families that cover a genus of compounds including AGI-134 and methods of using compounds including AGI-134, in the United States and Japan and will expire in 2025 and 2026. Applications in these families are pending in China, Europe, and other countries that would have the same expiration, if granted. Patent applications are pending in the third family in the U.S., China, Europe, Japan, and other countries that, if granted, would cover a pharmaceutical composition that contains AGI-134 and expire in 2035. In addition, the future drug product could be eligible for obtaining regulatory NCE exclusivity (five years data exclusivity in the U.S., 10-11 years marketing exclusivity in Europe, eight years marketing exclusivity in Japan).

- 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 U.S., 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.

Manufacturing

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

There can be no assurance that our therapeutic candidates, if approved, can be manufactured in sufficient commercial quantities, in compliance with regulatory requirements and at an acceptable cost. Our contract manufacturers are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products or medical devices. Our contract manufacturers must ensure that all of the processes, methods and equipment are compliant with cGMP, for drugs or QSR for devices on an ongoing basis, mandated by the FDA and other regulatory authorities, and conduct extensive audits of vendors, contract laboratories and suppliers.

Contract Research Organizations

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

Competition

The pharmaceutical, medical device and biotechnology industries are intensely competitive. 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

There are a number of potentially competitive compounds under development that act as CXCR4 inhibitors, including, among others, Mozobil® (plerixafor), which is being marketed by Sanofi Genzyme as a stem cell mobilizer for autologous stem-cell transplantation; LY-2510924, which is being developed by Eli Lilly & Co; BMS-936564 (MDX-1338; ulocuplumab) developed by Bristol-Myers Squibb; TG-0054 (burixafor) developed by TaiGen Biotechnology Co; POL-6326 (balixafortide) developed by Polyphor Ltd.; X4P-001 developed by X4 Pharmaceuticals Inc.; GMI-1271 developed by Glyco-Mimetics Inc. and USL-311developed by Proximagen Group.

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

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, Eisai and Johnson & Johnson) and Vidaza® (azacitidine, Celgene). Other approved drugs for AML are Vyxeos® (liposomal cytarabine and daunorubicin, Jazz Pharmaceuticals); Idhifa® (enasidenib, Agios Pharmaceuticals Inc. and Celgene Corp); and Venclexta® (venetoclax, AbbVie Inc.).

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

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

AGI-134

The field of cancer immunotherapy is still in the early stages of development, and only a few checkpoint inhibitors have been approved since 2011, targeting either CTLA-4, PD1 or PDL1 via antibody blockade. Most of these agents have been approved for melanoma and non-small cell lung cancer. However, in recent years approval has been granted for use of these agents in renal cell carcinoma and head and neck and bladder cancer. As noted above, there are currently hundreds of immuno-oncology combinations being tested in clinical trials. Many of these combinations could be competitive with AGI-134.

In general, the competitive landscape is comprised of compounds that target tumor specific neoantigens and create adaptive, anti-tumor immune response. Examples of such therapeutic approaches include oncolytic viruses, dendritic cell vaccines, personalized neoantigen-based cancer vaccines and Pathogen-Associated Molecular Patterns (PAMPs) as cancer vaccines.

If approved, AGI-134 will compete with currently approved treatments such as the oncolytic viruses (Imlygic®, T-VEC; Amgen) and dendritic cell cancer vaccine (Provenge®, sipuleucel-T; Valeant). In addition, there are several potentially-competitive compounds that are currently under development, including, among others, IVAC mutanome (BioNTech AG), NeoVax (Neon Therapeutics); TLR9 agonists such as lefitolimod (MGN-1703, Mologen Ag), IMO-2125 (Idera Pharmaceuticals Inc.), SD-101 (Dynavax Technologies Corp) and CMP-001 (Checkmate Pharmaceuticals); ADU-S100 (Novartis); imprime PGG® (Biothera Pharmaceuticals Inc), dorgenmeltucel-L (NewLink Genetics Corp), inCVAX (Immunophotonics Inc.), MG1MA3 (Turnstone Biologics Inc) and LTX-315 (Lytix Biopharma AS). Most of these competitors have ongoing combination trials with the approved checkpoint inhibitors.

BL-5010

BL-5010 will compete with a variety of approved destructive and non-destructive treatments for skin lesions. 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® (ingenol mebutate, Leo Pharma) and Metvixia® (methyl aminolevulinate, Galderma Pharma) are cream-based treatments marketed for skin lesions. Endwarts® (Meda Health) is a medical device-based treatment marketed for removal of warts.

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 $30.0 million per occurrence and product liability and clinical trials coverage with an annual coverage amount of $30.0 million each claim and in the aggregate. The maximum indemnity for a single occurrence, claim or circumstances under this insurance is $30.0 million. In addition, we maintain the following insurance: employer's liability with coverage of approximately $10.0 million for each occurrence and in the aggregate; third party liability with coverage of approximately $5.0 million for each occurrence and in the aggregate; all risk coverage of approximately $2.0 million for electronic and mechanical equipment; directors' and officers' liability with coverage of $20.0 million for each occurrence and in the aggregate; and a global travel insurance policy.

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

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

Environmental Matters

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

Government Regulation and Funding

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

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

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

Historically, different requirements by different countries' regulatory authorities have influenced the submission of applications. However, a trend toward harmonization of drug and medical device approval standards, starting in individual countries in Europe and then in the EU as a whole, in Japan, and in the United States under the aegis of what is now known as the International Council on Harmonisation, or ICH (created as the International Conference on Harmonisation in 1990), is gradually narrowing these differences. In many cases, compliance with ICH standards can help avoid duplication of non-clinical and clinical trials and enable companies to use the same basis for submissions to each of the respective regulatory authorities. The adoption of the Common Technical Document format by the ICH has greatly facilitated use of a single regulatory submission for seeking approval in the ICH regions and certain other countries including Canada, Hong Kong, Japan, Saudi Arabia, Singapore, South Africa, South Korea, Switzerland, Taiwan, Turkey and Australia.

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

United States

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

Unless a drug is exempt from the NDA process or subject to another regulatory procedure, the steps required before a drug may be marketed in the United States include:

- preclinical laboratory tests, animal studies and formulation development;
- submission to the FDA of a request for an IND to conduct human clinical testing;
- adequate and well controlled clinical trials to determine the safety and efficacy of the drug for each indication as well as to establish the exposure levels;
- submission to the FDA of an application for marketing approval;
- a potential public hearing of an outside advisory committee to discuss the application;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is manufactured; and
- FDA review and approval of the drug for marketing.

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

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

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

Clinical Trials

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

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

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 of reference. Such an application, known as a 505(b)(2) NDA, is permitted for new drug products that incorporate previously approved active ingredients, even if the proposed new drug incorporates an approved active ingredient in a novel formulation or for a new indication. Although 505(b)(2) is a type of NDA, it has been used in the U.S. 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 GMP. If the FDA determines that the NDA or BLA is supported by adequate data and information, the FDA may issue an approval letter. During review, the FDA may request additional information via an information request, or IR letter, or state deficiencies via a deficiency letter, or DR letter. Upon compliance with the conditions stated, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of approval, the FDA may require additional trials or post-approval testing and surveillance to monitor the drug's safety or efficacy, the adoption of risk evaluation and mitigation strategies, and may impose other conditions, including labeling and marketing restrictions on the use of the drug, which can materially affect its potential market and profitability. Once granted, product approvals may be withdrawn if compliance with regulatory standards for manufacturing and quality control are not maintained or if additional safety problems are identified following initial marketing.

If the FDA's evaluation of the NDA or BLA submission or manufacturing processes and facilities is not favorable, the FDA may refuse to approve the NDA or BLA and may issue a complete response letter. The complete response letter indicates that the review cycle for an application is complete and that the application is not ready for approval. The complete response letter will describe specific deficiencies and, when possible, will outline recommended actions the applicant might take in order to place the application in condition for approval. Following receipt of a complete response letter, the company may submit additional information and start a new review cycle, withdraw the application or request a hearing. Failure to take any of the above actions may result in the FDA considering the application withdrawn following 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 and BLAs (or supplements) for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to contain results assessing the safety and efficacy for the claimed indication in all relevant pediatric subpopulations. Data to support dosing and administration also must be provided for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for the submission of results or full or partial waivers from the PREA requirements (for example, if the product is ready for approval in adults before pediatric studies are complete, if additional safety data is needed, among others). In addition, under the Best Pharmaceuticals for Children Act, or BPCA, the FDA may issue a written request to the company to conduct clinical trials in the pediatric population that are related to the moiety and expand on the claimed indication. The studies are voluntary, but may award the company with 6 months of marketing exclusivity if conducted according to good scientific principles and address the written request. Finally, a sponsor can request that a product that must be studied under PREA to be studied also under the BPCA to allow the sponsor to be eligible for six-months of pediatric exclusivity. The pediatric studies requested under BPCA are usually more extensive and would generally also fulfill the PREA requirement; however, even if the sponsor does not complete the studies outlined in the BPCA written request, it is still required to complete any studies required under PREA.

Post-Marketing Requirements

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

Generic Competition

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

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

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

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

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

The BPCIA provides the manufacturer of the innovator product with economic protection by granting a period of "exclusivity" during which follow-on products may not be approved. A BLA for approval of a follow-on biological product may not be submitted for 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 biosimilar and innovator products is ongoing, this period of exclusivity may be extended for up to 42 months.

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

FDA Approval or Clearance of Medical Devices

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

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

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

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

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

European Economic Area

Clinical Trials

The European Medicines Agency, or the Agency, relies on the results of clinical trials carried out by pharmaceutical companies to reach its opinions on the authorization of medicines. Although the authorization of clinical trials occurs at member state level, the Agency plays a key role in ensuring that the standards of good clinical practice (GCP) are applied across the European Economic Area (EEA) in cooperation with the member states. It also manages a database of clinical trials carried out in the EU. Clinical trials are currently regulated under Directive 2001/20/EC. However, in April 2014 a new regulation on clinical trials on medicinal products for human use was adopted. Regulation 536/2014, or the Regulation, entered into force on in June 2014 and is scheduled to become effective in October 2018. 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 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 EMA. That authorization is valid throughout the entire EEA and directly or (as to Norway, Iceland and Liechtenstein) indirectly allows the applicant to place the product on the market in all member states of the EEA. The EMA is the administrative body responsible for coordinating the existing scientific resources available in the member states for evaluation, supervision and pharmacovigilance of medicinal products. Certain medicinal products, as described in the Annex to Regulation 726/2004, must be authorized centrally. These are products that are developed by means of a biotechnological process in accordance with Paragraph 1 to the Annex to the Regulation or veterinary products designed to promote animal growth or increase yield in accordance with Paragraph 2. The mandatory centralized procedure is applicable to: (a) medicinal products for human use containing an active substance authorized in the EU after May 20, 2004 for which the therapeutic indication is the treatment of acquired immune deficiency syndrome, or AIDS, cancer, neurodegenerative disorder or diabetes; (b) autoimmune diseases and other immune dysfunctions and viral diseases; (c) all medicinal products that are designated as orphan medicinal products pursuant to Regulation 141/2000; and (d) medicines derived from biotechnology processes or advanced therapy medicinal products, such as gene therapy, tissue engineered and somatic cell therapy products. An applicant may also opt for assessment through the centralized procedure if it can show that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization centrally is in the interests of patients at the EU level. For each application submitted to the EMA for scientific assessment, the EMA is required to ensure that the opinion of the Committee for Medicinal Products for Human Use, or CHMP, is given within 210 days after receipt of a valid application or within 150 days by means of an accelerated procedure. If the opinion is positive, the EMA is required to send the opinion to the European Commission, which is responsible for preparing the decision granting a marketing authorization, within 67 days. If the initial opinion of the CHMP is negative, the applicant is afforded an opportunity to seek a re-examination of the opinion. The CHMP is required to re-examine its opinion within 60 days following receipt of the request by the applicant. A refusal of a centralized marketing authorization constitutes a prohibition on placing the given medicinal product on the market in the EU.

Mutual Recognition and Decentralized Procedures.

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

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

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

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

National Procedure

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

When a member state avails itself of this possibility, it must adopt the necessary measures in order to ensure that the requirements for the labelling and package leaflet, classification of the medicinal product, advertising, pharmacovigilance and supervision and sanctions are complied with. For the specific mechanisms chosen by the member states to implement this provision, the relevant national legislation is referred to. The register of the medicinal products authorized under Article 126a is available at the European Commission 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) of Directive 2001/83/EC refers to a biological medicinal product which is similar to a reference biological product and does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product. For such products, the results of appropriate preclinical tests or clinical trials relating to these conditions must be provided in accordance with the criteria stated in the annex and related guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

(2) Well-established Medicinal Use

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

(3) Fixed Combination Application

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

(4) Informed Consent

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

C. Mixed Marketing Authorization Applications

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

Law Relating to Pediatric Research

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

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

Post-authorization Obligations

An authorization to market a medicinal product in the EU carries with it an obligation to comply with many post-authorization regulations relating to the marketing and other activities of authorization holders. These include requirements relating to provision of a risk management plan and provision of annual periodic safety update reports, carrying out of post-authorization efficacy studies and/or post-authorization safety studies, maintenance of a pharmacovigilance system master file, adverse event reporting, signal detection and management and other pharmacovigilance activities conducted under an established quality system, advertising, packaging and labeling, patient package leaflets, distribution and wholesale dealing. The regulations frequently operate within a criminal law framework, and failure to comply with the requirements may not only affect the authorization, but also can lead to financial and other sanctions levied on the company in question and responsible officers.

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

Approval of Medical Devices

In the EEA there is a consolidated system for the authorization of medical devices. Currently applicable regulations are: Regulation 2017/745 on Medical Devices (amending Directive 2001/83/EC, Regulation 178/2002 and 1223/2009 and repealing Directives 93/42/EEC and Directive 90/385/EEC regarding active implantable medical devices), and Regulation 2017/746 regarding in vitro diagnostic medical devices (repealing Directive 98/79/EC and commission decision 2010/227/EU). The new regulations will apply after a 3-year transitional period (in May 2020) for the regulation of medical devices and a 5-year transitional period (May 2022) for the regulation of in-vitro diagnostic medical devices. The EU requires that manufacturers of medical devices obtain the right to affix the CE mark to their products, which shows that the device has a Declaration of Conformity, before selling them in EU member countries. The CE mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain the right to affix the CE mark to products, a manufacturer must obtain certification that its processes meet certain European quality standards, which vary according to the nature of the device. Compliance with the Medical Device Directive, as certified by a recognized European Notified Body, permits the manufacturer to affix the CE mark on its products and commercially distribute those products throughout the EU without further conformance tests being required in other member states.

Israel

Israel Ministry of the Environment — Toxin Permit

In accordance with the Israeli Dangerous Substances Law - 1993, the Israeli Ministry of the Environment is required to grant a permit in order to use toxic materials. Because we utilize toxic materials in the course of operation of our laboratories, we were required to apply for a permit to use these materials. Our current toxin permit will remain in effect until December 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 Israeli Ministry of Health's overseeing ethics committee. The institutional ethics committee must, among other things, evaluate the anticipated benefits that are likely to be derived from the project to determine if it justifies the risks and inconvenience to be inflicted on the human subjects, and the committee must ensure that adequate protection exists for the rights and safety of the participants as well as the accuracy of the information gathered in the course of the clinical testing. Since we intend to perform a portion of the clinical studies on certain of our therapeutic candidates in Israel, we will be required to obtain authorization from the ethics committee and general manager of each institution in which we intend to conduct our clinical trials, and in most cases, from the Israeli Ministry of Health.

Other Countries

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

Related Matters

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

Israeli Government Programs

Israel Innovation Authority

Research and Development Grants. A number of our therapeutic products have been financed, in part, through funding from the IIA in accordance with Research Law. Through December 31, 2017 we have received approximately $22.0 million in aggregate funding from the IIA and have paid the IIA approximately $6.3 million in royalties under our approved programs. As of December 31, 2017, we have no contingent obligation to the IIA other than for BL-8040. In connection with the in-licensing of BL-8040 from Biokine, and as a condition to IIA consent to the transaction, we agreed to abide by any obligations resulting from funds previously received by Biokine from the IIA. The contingent liability to the IIA assumed by us relating to this transaction (which liability has no relation to the funding actually received by us) amounts to $3.2 million as of December 31, 2017. We have a full right of offset for amounts payable to the IIA from payments that we may owe to Biokine in the future. Therefore, the likelihood of any payment obligation to the IIA with regard to the Biokine transaction is remote. Under the Research Law 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 IIA were payable to the Israeli government, generally at the rate of 3% -3.5% with the current rates generally at 3%, although these terms would be different if we were to receive IIA approval to manufacture or to transfer the rights to manufacture our products developed with IIA grants outside of Israel. The obligation to make these payments terminates upon repayment of the amount of the received grants as adjusted for fluctuation in the dollar/shekel exchange rate, plus interest and any additional amounts as described below. However, we could be required to pay an increased total amount of royalties (possibly up to 300% of the grant amounts plus interest) if we receive approval to manufacture or to transfer the rights to manufacture our products developed with IIA grants outside of Israel, depending on the portion of total manufacturing that was performed outside of Israel, as further described below, and we could be required to pay additional amounts in respect of the technology developed under these projects that was otherwise transferred outside of Israel, as further described below. The amounts received bear interest equal to the 12-month London Interbank Offered Rate applicable to dollar deposits that was published on the first business day of each calendar year.

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

Under the Research Law, as in effect prior to the R&D Amendment, and the tracks published by the IIA, we are prohibited from transferring our IIA-financed technologies, technologies derived therefrom and related intellectual property rights outside of Israel except under limited circumstances and only with the approval of the IIA and generally upon making a payment to the IIA. The required approvals may not be received for any proposed transfer and, if received, we could be required to pay the IIA an amount calculated in accordance with the applicable formula set out in the tracks published by the IIA. The scope of the support received, the royalties that we already paid to the IIA, the amount of time that elapsed between the date on which the technology was transferred and the date on which the applicable project performance period for the IIA grants was completed, and the sale price and the form of transaction are to be taken into account in order to calculate the amount of the payment to the IIA. The repayment amount is subject to a maximum limit calculated in accordance with a formula set forth in 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 IIA with respect to the product or technology, could require us to notify, or to obtain the approval of, the IIA, and could result in increased royalty payments to the IIA of up to 300% of the total grant amounts received in connection with the product or technology, plus interest, depending on the portion of total manufacturing that was performed outside of Israel.

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

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 IIA, which is comprised of the Council, a Director General and the Research Committees. The chief scientist of the OCS became the head of the IIA. 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 know-how 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 are now 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 IIA-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. Since the coming into effect of the R&D Amendment, the IIA has published various tracks and guidelines on its website, in large part reinstating the core provisions of the pre-R&D Amendment regime.

The State of Israel does not own intellectual property rights in technology developed with IIA funding and there is no restriction on the export of products manufactured using technology developed with IIA 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 EMA, making it comparatively straightforward for studies conducted in Israel to satisfy FDA and the EMA requirements, thereby enabling medical technologies subjected to clinical trials in Israel to reach U.S. and EU commercial markets in an expedited fashion. Many members of Israel's medical community have earned international prestige in their chosen fields of expertise and routinely collaborate, teach and lecture at leading medical centers throughout the world. Israel also has free trade agreements with the United States and the EU.

C. Organizational Structure

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

D. Property, Plant and Equipment

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

Agalimmune leases laboratory space for its employees in Discovery Park located in Sandwich, Kent County in the United Kingdom.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this Annual Report on Form 20-F. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report on Form 20-F, particularly those in "Item 3. Key Information — Risk Factors."

We are a clinical stage biopharmaceutical development company focused on oncology and immunology. Our current development and commercialization pipeline consists of a clinical-stage therapeutic candidate, BL-8040; a near-clinical therapeutic candidate, AGI-134; and one commercialized product, BL-5010. In addition, we have three other therapeutic candidates in clinical and preclinical development. We generate our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a high probability of therapeutic and commercial success. 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 opportunities may arise.

A. Operating Results

History of Losses

Since inception in 2003, we have generated significant losses in connection with our research and development. As of December 31, 2017, we had an accumulated deficit of $199.6 million. We may continue to generate losses in connection with the research and development activities relating to our pipeline of therapeutic candidates. Such research and development activities are budgeted to expand over time and will require further resources if we are to be successful. As a result, we expect to continue to incur operating losses, which may be substantial over the next several years, and we expect to need to obtain additional funds to further pursue our research and development programs.

We have funded our operations primarily through the sale of equity securities (both in public and private offerings), payments received under our strategic licensing and collaboration arrangements, interest earned on investments and funding received from the IIA. We expect to continue to fund our operations over the next several years through our existing cash resources, potential future upfront, milestone, royalty or other payments that we may receive from Perrigo, 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, 2017, we held $49.5 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 Perrigo, 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 pipeline projects:

Project	**Status**	**Expected Near Term Milestones**
BL-8040	1. Phase 2a study for relapsed or refractory AML completed	1. Follow-up for overall survival is ongoing
	2. Phase 2b consolidation treatment for AML ongoing	2. Completion of enrollment and possible interim results expected in H2 2018; top-line results expected in 2020
	3. Phase 2 study in stem-cell mobilization ongoing	3. Top-line results expected in mid-2018
	4. Phase 2a study in pancreatic cancer, in collaboration with Merck (COMBAT), ongoing; partial results presented at ASCO-GI in January 2018	4. Top-line results expected in H2 2018
	5. Phase 2b study in pancreatic cancer, in collaboration with MD Anderson Cancer Center, ongoing	5. Top-line results expected in H2 2018
	6. Phase 1b/2 study in AML, in collaboration with Genentech (BATTLE), commenced	6. Top-line results expected in 2019
	7. Phase 1b/2 studies in pancreatic and gastric cancer, under collaboration with Genentech (MORPHEUS) commenced	7. Top-line results expected in 2019; commencement of additional study in lung cancer expected in 2018
	8. Phase 3 registration study in autologous stem-cell mobilization commenced (GENESIS)	8. Partial results from initial lead-in, dose-confirmation part of the study expected mid-2018; top-line results from full study expected in 2020
AGI-134	Near-clinical development studies	Commencement of first-in-man study expected in mid-2018
BL-5010	Out-licensed to Perrigo; CE mark approval obtained; commercial launch of first OTC indication in Europe commenced	Gradual full roll-out of commercial launch over next 2-3 years; 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 preclinical stages of development (BL-9020, BL-1230 and BL-1040) that are significantly less material to our ongoing research and development expenditures. See “Item 4. Information on the Company — Business Overview — Other Therapeutic Candidates.”

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, 2015, 2016 and 2017, and on an aggregate basis since project inception.

	Year Ended December 31,			Total Costs Since Project Inception
	2015	2016	2017	
	(U.S. $ in thousands)			
BL-8040	7,045	8,281	12,369	37,026
AGI-134	-	-	3,730	3,730
BL-5010	400	75	32	4,176
Other projects	3,573	2,647	2,628	116,759
Total project costs	11,018	11,003	18,759	161,691

From our inception through December 31, 2017, we have incurred research and development expense of $196.5 million. We expect that a large percentage of our research and development expense in the future will be incurred in support of our current and future preclinical and clinical development projects. Due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage of our preclinical product development projects, we are unable to estimate with any certainty the costs we will incur in the continued development of the therapeutic candidates in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test our product candidates in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for each product candidate. If we are not able to enter into an out-licensing arrangement with respect to any therapeutic candidate prior to the commencement of later stage clinical trials, we may fund the trials for the therapeutic candidate ourselves.

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

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

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

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

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

Sales and Marketing Expenses

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

General and Administrative Expenses

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

Non-Operating Expense and Income

Non-operating expense and income includes fair-value adjustments of derivative liabilities on account of the warrants issued in direct placements which we conducted in 2013 and 2017. 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.

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. In addition, it may also include gains/losses on foreign exchange hedging transactions, which we carry out from time to time to protect against a portion of our NIS-denominated expenses (primarily compensation) in relation to the dollar.

Critical Accounting Policies and Estimates

We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the year ended December 31, 2017. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

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

Revenue Recognition

We recognize revenues in accordance with International Financial Reporting Standards No. 15, or IFRS 15. IFRS 15, "Revenue from Contracts with Customers," which was issued in May 2014, amends revenue recognition requirements and establishes principles for reporting information about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The standard replaces International Auditing Standard, or IAS, 18, "Revenue" and IAS 11, "Construction Contracts" and related interpretations. The standard is effective for annual periods beginning on or after January 1, 2018. The Company currently does not have any revenues; however, revenues incurred in connection with out-licensing of the Company's patents and other intellectual property will be recognized when all of the following criteria have been met as of the balance sheet date:

- The Company has transferred to the licensee 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.

Revenue from reaching additional milestones is recognized upon achievement of the specific milestone, in accordance with the relevant agreement.

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 accrual basis 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.

Stock-based Compensation

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

Warrants

In connection with the 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 were exercisable for a period of five years from the date of issuance. Since the exercise price was not deemed to be fixed, the warrants did not qualify for classification as an equity instrument and were therefore classified as a non-current financial liability. The warrants expired in February 2017 without having been exercised.

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

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

Recent Accounting Changes and Pronouncements

There were no changes in the accounting policies applied by the Company during 2017.

For information concerning new standards and interpretations not yet adopted, see Note 2q to our consolidated financial statements for the year ended December 31, 2017 included elsewhere in this report. As of the date of this report, we are not able to estimate the impact of the new standards on the Company's financial statements, and continue to assess the possible impact. We will make more detailed assessments over the next 12 months.

Results of Operations -- Overview

Revenues

We did not record any revenues for the years ended December 31, 2015, 2016 and 2017.

Cost of revenues

We did not record any cost of revenues for the years ended December 31, 2015, 2016 and 2017.

Research and development expenses

At December 31, 2014, our drug development pipeline consisted of nine 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 eight therapeutic candidates. During 2016, we added three compounds to our pipeline and discontinued the development of three compounds in our pipeline, so that our drug development pipeline as of December 31, 2016 consisted of eight therapeutic candidates. During 2017, we terminated two therapeutic candidates in our pipeline, and added one therapeutic candidate to the pipeline, so that our drug development pipeline as of December 31, 2017 consisted of seven therapeutic candidates. Subsequent to December 31, 2017, we terminated one therapeutic candidate in our pipeline, so that our drug development pipeline as of the date of this report consists of six therapeutic candidates.

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

Research and development expenses

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

Sales and marketing expenses

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

General and administrative expenses

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

Non-operating income (expense), net

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

Financial income (expense), net

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

Comparison of the Year Ended December 31, 2016 to the Year Ended December 31, 2015

Research and development expenses

Research and development expenses for the year ended December 31, 2016 were $11.2 million, a decrease of $0.3 million, or 2.6%, compared to $11.5 million for the year ended December 31, 2015. The decrease results primarily from a decrease in spending on BL-7010, partially offset by increased spending on new projects.

Sales and marketing expenses

Sales and marketing expenses for the year ended December 31, 2016 were $1.4 million, an increase of $0.4 million, or 40.0%, compared to $1.0 million for the year ended December 31, 2015. The increase results primarily from consultancy services related to BL-8040 and new projects.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2016 were $4.0 million, an increase of $0.3 million or 8.1%, compared to $3.7 million for the year ended December 31, 2015. The increase results primarily from one-time salary-related payments and an increase in professional fees.

Non-operating income (expense), net

We recognized net non-operating income of $0.2 million for the year ended December 31, 2016, a decrease of $1.2 million compared to net non-operating income of $1.4 million for the year ended December 31, 2015. Non-operating expenses and income for both periods primarily relate to fair-value adjustments of liabilities on account of warrants. These fair-value adjustments were highly influenced by our share price at each period end.

Financial income (expense), net

We recognized net financial income of $0.5 million for the year ended December 31, 2016 compared to net financial income of $0.4 million for the year ended December 31, 2015. Net financial income for the two periods primarily relates to investment income earned on our bank deposits, as well as banking fees.

Quarterly Results of Operations

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

	Three Months Ended							
	March 31	**June 30**	**Sept. 30**	**Dec. 31**	**March 31**	**June 30**	**Sept. 30**	**Dec. 31**
	2016				**2017**			
	(in thousands of U.S. dollars)							
Consolidated Statements of Operations								
Revenues	–	–	–	–	–	–	–	–
Cost of revenues	–	–	–	–	–	–	–	–
Research and development expenses, net	(2,539)	(2,740)	(2,954)	(2,944)	(3,590)	(4,062)	(5,654)	(6,204)
Sales and marketing expenses	(248)	(272)	(409)	(423)	(681)	(288)	(249)	(475)
General and administrative expenses	(989)	(854)	(1,125)	(1,016)	(1,030)	(844)	(1,154)	(1,009)
Operating loss	(3,776)	(3,866)	(4,488)	(4,383)	(5,301)	(5,194)	(7,057)	(7,688)
Non-operating income (expenses), net	148	48	(14)	32	(5)	(4)	(333)	82
Financial income	143	88	172	77	457	304	153	255
Financial expenses	(4)	(5)	(4)	(9)	(6)	(3)	(6)	(6)
Net loss	(3,489)	(3,735)	(4,334)	(4,283)	(4,855)	(4,897)	(7,243)	(7,357)

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

B. Liquidity and Capital Resources

Since inception, we have funded our operations primarily through public and private offerings of our equity securities, payments received under our strategic licensing and collaboration arrangements, interest earned on investments and funding from the IIA. At December 31, 2017, we held $49.5 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 ATM program we executed with BTIG in October 2017, we may, in our discretion and from time to time, offer and sell through BTIG, acting as sales agent, our ADSs having an aggregate offering price of up to $30 million. From the effective date of the agreement through December 31, 2017, we sold 944,966 of our ADSs under the program for total net proceeds of approximately $1.0 million, leaving an available balance under the facility of approximately $29.0 million.

Net cash used in operating activities for the year ended December 31, 2017 was $20.5 million, compared to $14.5 million for the year ended December 31, 2016 and $14.2 million for the year ended December 31, 2015. The $6.0 million increase in net cash used in operating activities in 2017 was primarily the result of increased research and development expenses. The change in net cash used in operating activities from 2015 to 2016 was not material.

Net cash used in investing activities for the year ended December 31, 2017 was $15.9 million, compared to net cash provided by investing activities of $9.3 million for the year ended December 31, 2016 and $15.6 million net cash used in investing activities for the year ended December 31, 2015. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits during the respective periods, as well as the acquisition of Agalimmune and the investment in iPharma during 2017.

Net cash provided by financing activities for the year ended December 31, 2017 was $38.7 million, compared to $2.1 million for the year ended December 31, 2016 and $29.5 million for the year ended December 31, 2015. The cash flows in 2017 primarily reflect the underwritten public offering of our ADSs in March 2017 and the direct placement of ADSs and warrants to BVF Partners in July 2017. The cash flows in 2016 primarily reflect the funding under a share purchase agreement with Lincoln Park Capital Fund, LLC. The cash flows in 2015 primarily reflect the underwritten public offering of our ADSs in March 2015.

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 2020, 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 IIA.

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

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

C. Research and Development, Patents and Licenses

For our research and development policies, see "Item 4 — Information on the Company — Business Overview —Our Strategy." For information regarding the amounts spent during each of the last three financial years on our research and development activities, see the table in this Item 5 summarizing the costs allocated to our projects. For information regarding patents, see Item 4 — Information on the Company — Intellectual Property." For information regarding licenses, see "Item 4 — Information on the Company — Collaboration and Out-Licensing Arrangements" and Item 4 — Information on the Company — In-Licensing Agreements."

D. Trend Information

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

E. Off-Balance Sheet Arrangements

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

F. Contractual Obligations

The following table summarizes our significant contractual obligations at December 31, 2017:

	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
	(in thousands of U.S. dollars)				
Car leasing obligations	596	266	330	–	–
Premises leasing obligations	927	366	561	–	–
Purchase commitments	6,128	4,074	2,027	27	–
Total	7,364	4,593	2,744	27	–

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

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

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth information for our executive officers and directors as of March 5, 2018. 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)
Philip A. Serlin, CPA, MBA	57	Chief Executive Officer
Mali Zeevi, CPA	42	Chief Financial Officer
David Malek, MBA[(1)]	40	Chief Business Officer
Ella Sorani, Ph.D.	50	Vice President Development
Abi Vainstein-Haras, M.D.	43	Vice President Clinical and Medical Affairs
Aharon Schwartz, Ph.D.	75	Chairman of the Board
Michael J. Anghel, Ph.D.	78	Director
Nurit Benjamini, MBA	51	External Director
B.J. Bormann, Ph.D.	59	Director
Raphael Hofstein, Ph.D.	68	Director
Avraham Molcho, M.D.	60	External Director
Sandra Panem, Ph.D.	71	Director

(1) As of March 31, 2018, Mr. Malek will be departing the Company. Effective April 1, 2018, Hillit Mannor Shachar, M.D., MBA, M.S.F.S., will become our Vice President Business Development. Dr. Shachar will be responsible for our business development, commercialization of assets and pipeline strategy. Dr. Shachar joins the Company with over 15 years of experience in senior business development, corporate development and venture capital positions in the life sciences field. Her recent experience has included service as Vice President Business Development of Pluristem Therapeutics (NASDAQ:PSTI), a leading developer of placenta-based cell therapy products, and Director of New Business Development at West Pharmaceutical Services. In addition, Dr. Shachar has served at several life science companies and venture capital funds, including Apax Partners, Nektar Therapeutics, Orex Computed Radiography, Kodak and Transpharma Medical. Dr. Shachar received her B.A. and M.D. from Northwestern University, her M.S.F.S. (Healthcare focus) from Georgetown University School of Foreign Service and her MBA from the Kellogg Recanati School of Management at Tel Aviv University.

Philip A. Serlin, CPA, MBA, has served as our Chief Executive Officer since October 2016. From May 2009 to October 2016, Mr. Serlin served as our Chief Financial and Operating Officer. From January 2008 to August 2008, Mr. Serlin served as the Chief Financial Officer and Chief Operating Officer of Kayote Networks Inc. From January 2006 to December 2007, he served as the Chief Financial Officer of Tescom Software Systems Testing Ltd., an IT services company publicly traded in both Tel Aviv and London. His background also includes senior positions at Chiaro Networks Ltd. and at Deloitte, where he was head of the SEC and U.S. Accounting Department at the National Office in Tel Aviv, as well as seven years at the SEC at its Washington, D.C., headquarters. Mr. Serlin 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.

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

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.

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

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

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

Michael J. Anghel, Ph.D., has served on our Board of Directors since 2010 and on our Investment Monitoring Committee since 2010. From 1977 to 1999, he led the Discount Investment Corporation Ltd. (of the IDB Group) activities in the fields of technology and communications. Dr. Anghel was instrumental in founding Tevel, one of the first Israeli cable television operators and later in founding Cellcom Israel Ltd. (NYSE:CEL), the second Israeli cellular operator. In 1999, he founded CAP Ventures, an advanced technology investment company. From 2004 to 2005, Dr. Anghel served as CEO of DCM, the investment banking arm of the Israel Discount Bank (TASE:DSCT). 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. From 2011 to 2013, Ms. Benjamini served as the Chief Financial Officer of Wix.com Ltd. (Nasdaq:WIX); from 2007 through 2011, she served as the Chief Financial Officer of CopperGate Communications Ltd. (now Sigma Designs Israel Ltd., a subsidiary of Sigma Designs Inc. (Nasdaq:SIGM)); and from 2000 through 2007, she served as the Chief Financial Officer of Compugen Ltd. (Nasdaq: CGEN). Prior to that, from 1993 through 1998, Ms. Benjamini served as the Chief Financial Officer of Aladdin Knowledge Systems Ltd. (formerly Nasdaq: ALDN, TASE:ALDN), 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 Vice President of Translational Science and Network Alliances at The Jackson Laboratory, a non-profit organization focused on the genetic basis of disease. Dr. Bormann was previously the Chief Executive Officer of Supportive Therapeutics, LLC, a Boston based company that is developing two molecules for use in the supportive care of oncology patients. In the past several years Dr. Bormann has held executive positions in several biotechnology companies including NanoMedical Systems (Austin, Texas), Harbour Antibodies (Rotterdam, The Netherlands) and Pivot Pharmaceuticals (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 for 15 of Toronto's universities, institutions and research institutes plus the MaRS Discovery District) since June 2009. From 2000 through June 2009, Dr. Hofstein was the President and Chief Executive Officer of Hadasit Medical Research Services and Development Ltd., or Hadasit, the technology transfer company of Hadassah University Hospitals. He has served as chairman of the board of directors of Hadasit since 2006. Prior to joining Hadasit, Dr. Hofstein was the President of Mindsense Biosystems Ltd. and the Business Unit Director of Ecogen Inc. and has held a variety of other positions, including manager of R&D and chief of immunochemistry at the International Genetic Science Partnership. Dr. Hofstein serves on the board of directors of numerous companies. Dr. Hofstein received his Ph.D. and M.Sc. from the Weizmann Institute of Science, and his B.Sc. in chemistry and physics from the Hebrew University in Jerusalem. Dr. Hofstein completed postdoctoral training at Harvard Medical School in both the departments of biological chemistry and neurobiology.

Avraham Molcho, M.D., has served as an external director on our Board of Directors and on our Audit Committee since 2010. In addition, Dr. Molcho has served on our Compensation Committee since 2012. Dr. Molcho is the founder Biolojic Design Ltd., a technology platform that encourages human antibody discoveries, and is a venture partner at Forbion Capital Partners, a Dutch life sciences venture capital firm. In 2012, he became the co-founder, Chief Executive Officer and director of Ayana Pharma Ltd. (formerly DoxoCure), a privately-held company engaged in the manufacturing of liposome-based therapeutics. 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 served on our Board of Directors since February 2014. She is currently a managing partner at Cross Atlantic Partners, which she joined in 2000. She is also co-founder and President of NeuroNetworks Fund, a not-for-profit venture capital fund focusing on epilepsy, schizophrenia and autism. From 1994 to 1999, Dr. Panem was President of Vector Fund Management, the then asset management affiliate of Vector Securities International. Prior thereto, Dr. Panem served as Vice President and Portfolio Manager for the Oppenheimer Global BioTech Fund, a mutual fund that invested in public and private biotechnology companies. Previously, she was Vice President at Salomon Brothers Venture Capital, a fund focused on early and later-stage life sciences and technology investments. Dr. Panem was also a Science and Public Policy Fellow in economic studies at the Brookings Institution, and an Assistant Professor of Pathology at the University of Chicago. Dr. Panem currently serves on the boards of directors of Acorda Therapeutics, Inc. (NASDAQ:ACOR) and Labcyte, 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 our Compensation Policy for Executives and Directors, or Compensation Policy, which was approved by our shareholders in July 2016. All of these agreements contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable law.

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

Compensation of Directors and Senior Management

The following table presents in the aggregate all compensation we paid to all of our directors and senior management as a group for the year ended December 31, 2017. 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	**Pension, retirement, options and other similar benefits**
	(in thousands of U.S. dollars)	
All directors and senior management as a group, consisting of 13 persons	1,666	873

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, 2017.

Name and Position	Salary	Social Benefits[1]	Bonuses	Value of Options Granted[2]	All Other Compensation[3]	Total
	(in thousands of U.S. dollars)					
Philip A. Serlin Chief Executive Officer	240	54	171	123	24	612
David Malek Chief Business Officer	167	43	86	97	16	409
Mali Zeevi Chief Financial Officer	140	36	90	88	18	372
Abi Vainstein-Haras Vice President Clinical and Medical Affairs	150	35	100	88	17	390
Ella Sorani Vice President Development	147	40	75	59	18	339

(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, 2017.

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

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

C. Board Practices

Board of Directors

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

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

According to our Articles of Association, our Board of Directors must consist of at least five and not more than 10 directors, including external directors. Currently, our Board of Directors consists of seven directors, including two external directors as required by the Companies Law. Pursuant to our Articles of Association, other than the external directors, for whom special election requirements apply under the Companies Law (unless the company is an Eligible Company and opted to follow the exemption provided under the Amendment to the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees) as detailed below, our directors are elected at a general or special meeting of our shareholders and serve on the Board of Directors until they are removed by the majority of our shareholders at a general or special meeting of our shareholders or upon the occurrence of certain events, in accordance with the Companies Law and our Articles of Association. In addition, our Articles of Association allow our Board of Directors to appoint directors, other than external directors, to fill vacancies on the Board of Directors to serve until the next general meeting or special meeting, or earlier if required by our Articles of Association or applicable law. We have held elections for each of our non-external directors at each annual meeting of our shareholders since our initial public offering in Israel. External directors are elected for an initial term of three years and may be elected, under certain conditions, to two additional terms, although the term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including the Nasdaq, may be further extended under certain conditions. External directors may be removed from office only pursuant to the terms of the Companies Law. Our last annual meeting of shareholders was held in July 2017. For additional information concerning external directors, see "— External Directors."

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

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

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

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

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

External Directors

Under Israeli law, the boards of directors of companies whose shares are publicly traded are required to include at least two members who qualify as external directors. Each of our current external directors, Dr. Avraham Molcho and Ms. Nurit Benjamini, was elected as an external director by our shareholders in July 2010. Their second terms expired in July 2016, at which time they were each re-elected by the shareholders of the Company for a third three-year term as external directors.

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

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

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

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

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

The term "affiliation" includes:

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

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

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

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

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

The Companies Law provides that an external director must meet certain professional qualifications or have financial and accounting expertise and that at least one external director must have financial and accounting expertise. However, if at least one of our other directors (1) meets the independence requirements of the Exchange Act, (2) meets the standards of the Nasdaq 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, or the Israeli Securities Law. The regulations define a director with the requisite professional qualifications as a director who satisfies one of the following requirements: (1) the director holds an academic degree in either economics, business administration, accounting, law or public administration; (2) the director either holds an academic degree in any other field or has completed another form of higher education in the company's primary field of business or in an area which is relevant to the office of an external director; or (3) the director has at least five years of experience serving in any one of the following, or at least five years of cumulative experience serving in two or more of the following capacities: (1) a senior business management position in a corporation with a substantial scope of business; (2) a senior position in the company's primary field of business; or (3) a senior position in public administration. Our Board of Directors has determined that Ms. Nurit Benjamini possesses "accounting and financial" expertise, and that both of our external directors possess the requisite professional qualifications.

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

Audit Committee

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

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

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

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

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

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

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

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

In November 2012, our Board of Directors adopted an audit committee charter that added to the responsibilities of our Audit Committee under the Companies Law, setting forth the responsibilities of the audit committee consistent with the rules of the SEC and the 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 our independent registered public accounting firm to our Board of Directors in accordance with Israeli law;
- recommending the engagement or termination of the office of our internal auditor; and
- reviewing and pre-approving the terms of audit and non-audit services provided by our independent auditors.

Our Audit Committee provides assistance to our Board of Directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our Audit Committee also oversees the audit efforts of our independent accountants and takes those actions it deems necessary to satisfy itself that the accountants are independent of management. Pursuant to the Companies Law, the audit committee of a company shall be responsible for: (i) determining whether there are delinquencies in the business management practices of a company, including in consultation with an internal auditor or independent auditor, and making recommendations to the company's board of directors to improve such practices; (ii) determining whether to approve certain related party transactions (including compensation of office holders or transactions in which an office holder has a personal interest and whether such transaction is material or otherwise an extraordinary transaction); (iii) where the company's board of directors approves the working plan of the internal auditor, examining such working plan before its submission to the board and proposing amendments thereto; (iv) examining internal control and the internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of his responsibilities (taking into consideration the special needs and size of a company); (v) examining the scope of the auditor's work and compensation and submitting its recommendation with respect thereto to the corporate body considering the appointment thereof (either the board or the general meeting of shareholders); and (vi) establishing procedures for the handling of employees' complaints as to the management of the business and the protection to be provided to such employees. 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."

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

Compensation Committee

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.

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

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

The responsibilities of the compensation committee include the following:

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

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

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

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

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

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

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

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

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

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

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

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

Nominating Committee

Our Board of Directors does not currently have a nominating committee, having availed BioLineRx of the exemption available to foreign private issuers under the 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 which consists of the following four members: Directors Dr. Michael Anghel (Chairperson) and Ms. Nurit Benjamini; Ms. Mali Zeevi, our Chief Financial Officer; and Mr. Raziel Fried, our Budget Control Manager and Treasurer. The function of the Investment Monitoring Committee includes providing recommendations to our Board of Directors regarding investment guidelines and performing an on-going review of the fulfillment of established investment guidelines. The Investment Monitoring Committee convenes for a meeting in accordance with our needs, but in any event at least twice per year. The Investment Monitoring Committee reports to our Board of Directors on a semi-annual basis.

Internal Auditor

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

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

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

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, or 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 2% of the voting rights in the company.

A transaction with the chief executive officer in a public company regarding his or her terms of office and employment requires approval by the (i) compensation committee; (ii) the board of directors; and (iii) the shareholders of the company by the Special Majority Requirements. Approval of terms of office and employment for the chief executive officer which do not comply with the compensation policy may nonetheless be approved subject to two cumulative conditions: (i) the compensation committee and thereafter the board of directors, approved the terms after having taken into account the various considerations and mandatory requirements set forth in 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 chief executive officer) who is not a director regarding his or her terms of office and employment may be approved despite shareholder rejection, provided that a company's compensation committee and thereafter the board of directors have determined to approve the proposal, based on detailed reasoning, after having re-examined the terms of office and employment, and taken the shareholder rejection into consideration. In addition, the compensation committee may exempt the transaction regarding terms of office and employment with a chief executive officer who has no relationship with the controlling shareholder or the company from shareholder approval if it has found, based on detailed reasons, that bringing the transaction to the approval of the shareholders meeting shall prevent the employment of such candidate by the company. Such approval may be given only in respect of terms of office and employment which are in accordance with the company's compensation policy.

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

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

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

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

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

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

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

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

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

D. Employees

As of December 31, 2017, we had 51 employees, all of whom are employed in Israel, except the three employees of Agalimmune who are employed in the U.K. Of our employees, 19 hold M.D. or Ph.D. degrees.

	December 31,		
	2015	**2016**	**2017**
Management and administration	12	11	11
Research and development	32	28	36
Sales and marketing	4	4	4
Total	48	43	51

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. Share Ownership

The following table sets forth information regarding the beneficial ownership of our outstanding ordinary shares as of March 5, 2018 of each of our directors and executive officers individually and as a group.

	Number of Ordinary Shares Beneficially Held	Percent of Class
Directors		
Aharon Schwartz[1]		*
Michael J. Anghel[2]		*
Nurit Benjamini[3]		*
B.J. Bormann[4]		*
Raphael Hofstein[5]		*
Avraham Molcho[6]		*
Sandra Panem[7]		*
Executive officers		
Philip A. Serlin[8]		*
Mali Zeevi[9]		*
David Malek[10]		*
Ella Sorani[11]		*
Abi Vainstein-Haras[12]		*
All directors and executive officers as a group (12 persons)[13]		1.0%

* Less than 1.0%.

(1) Includes 71,669 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2018. Does not include 33,331 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2018.

(2) Includes 71,669 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2018. Does not include 33,331 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2018.

(3) Includes 51,669 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2018. Does not include 33,331 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2018.

(4) Includes 71,669 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2018. Does not include 33,331 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2018.

(5) Includes 71,669 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2018. Does not include 33,331 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2018.

(6) Includes 51,669 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2018. Does not include 33,331 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2018.

(7) Includes 69,169 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2018. Does not include 33,331 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2018.

(8) Includes 301,631 issued ordinary shares upon exercise of outstanding options within 60 days of March 5, 2018. Does not include 666,773 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 5, 2018.

(9) Includes 174,343 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2018. Does not include 680,627 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 5, 2018.

(10) Includes 274,545 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2018. Does not include 685,255 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 5, 2018.

(11) Includes 42,125 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2018. Does not include 580,675 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 5, 2018.

(12) Includes 101,682 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2018. Does not include 736,318 ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 5, 2018.

(13) Includes 1,351,509 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2018. Does not include 3,044,415ordinary shares issuable upon exercise of outstanding equity instruments that are not exercisable within 60 days of March 5, 2018.

Equity Compensation Plan

2003 Share Incentive Plan

In 2003, we adopted the BioLineRx Ltd. 2003 Share Incentive Plan, or the Plan. The Plan provides for the granting of options, ordinary shares, restricted stock units and performance stock units to our directors, employees, consultants and service providers, and to the directors, employees, consultants and service providers of our subsidiaries and affiliates. The Plan provides for equity grants to be made at the determination of our Board of Directors in accordance with applicable law. As of March 5, 2018, there were 10.9 million ordinary shares issuable upon the exercise of outstanding equity grants under the Plan.

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

From time to time, our Board of Directors has approved an increase in the number of shares reserved for the purpose of equity grants pursuant to the Plan. As of March 5, 2018, the number of shares so reserved was 3.1 million.

Administration of Our Plan

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

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

In the event of a merger, consolidation, reorganization or similar transaction or our voluntary liquidation or dissolution, all of our unexercised vested equity grants and any unvested equity grants will be automatically terminated. However, in the event of a change of control, or merger, consolidation, reorganization or similar transaction resulting in the acquisition of at least 50% of our voting power, or the sale or transfer of all or substantially all of our outstanding shares assets, the equity grants then outstanding may be assumed or substituted for an appropriate number of shares of each class of shares or other securities and/or assets of the successor company in such transaction (or a parent or subsidiary or another affiliate of such successor company) as were distributed to our shareholders in respect of the transaction. In addition to the foregoing, our Board of Directors has approved the inclusion in the option agreements of the Company's officers of a provision for accelerated vesting of options if both a change of control of the Company occurs and, following such change of control, the officer's employment is terminated or there is a significant demotion in the officer's new job or position.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth certain information regarding the beneficial ownership of our outstanding ordinary shares as of March 5, 2018 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 106,268,860 ordinary shares outstanding as of March 5, 2018 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 5, 2018, to be outstanding and to be beneficially owned by the person holding the options or warrants for the purposes of computing the percentage ownership of that person but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. To our knowledge, none of our shareholders of record are U.S. holders. Our principal shareholders do not have different or special voting rights.

	Number of Ordinary Shares Beneficially Held	Percent of Class
BVF Partners L.P. [(1)]	26,556,588	24.99
Senvest Management, LLC [(2)]	7,781,641	7.32

(1) Based upon information provided by the shareholder, or the BVF Group, in its Schedule 13D filed with the SEC on August 8, 2017. BVF Partners L.P., or Partners, as the general partner of Biotechnology Value Fund, L.P., or BVF, and Biotechnology Value Fund II, L.P., or BVF2, the sole member of BVF Partners OS Ltd., or Partners OS, and the investment manager of Biotechnology Value Trading Fund OS LP, or Trading Fund OS, and certain Partners managed accounts, or the Partners Managed Accounts, may be deemed to beneficially own the 26,556,588 ordinary shares beneficially owned in the aggregate by BVF, BVF2, Trading Fund OS and the Partners Managed Accounts. BVF Inc., as the general partner of Partners, may be deemed to beneficially own the 26,556,588 ordinary shares beneficially owned by Partners. Mark N. Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the 26,556,588 ordinary shares beneficially owned by BVF Inc. In addition to ADSs, the BVF Group is the beneficial owner of Series A warrants and Series B warrants issued by us in July 2017. All the warrants held by the BVF Group are subject to a blocker provision that precludes the holders from exercising the warrants to the extent that the holder and its affiliates would beneficially own in excess of 24.99% of our ordinary shares outstanding immediately after giving effect to such exercise. Accordingly, excluded from the number of ordinary shares beneficially held by the BVF Group are an aggregate of 2,412,438 ordinary shares underlying Series A warrants and 2,973,451 ordinary shares underlying Series B warrants. The address of the principal business office of BVF Partners L.P. is 1 Sansome Street, 30th Floor, San Francisco, California 94104.

(2) Based upon information provided by the shareholder in its Schedule 13G filed with the SEC on February 12, 2018. The securities indicated above are held in the accounts of Senvest Master Fund, LP, Senvest Israel Partners Master Fund, LP and Senvest Global (KY), LP or collectively, the Investment Vehicles. Senvest Management, LLC may be deemed to beneficially own the securities held by the Investment Vehicles by virtue of Senvest Management, LLC's position as investment manager of the Investment Vehicles. Richard Mashaal may be deemed to beneficially own the securities held by the Investment Vehicles by virtue of Mr. Mashaal's status as the managing member of Senvest Management, LLC. None of the foregoing should be construed in and of itself as an admission by either Senvest Management, LLC or Mr. Mashaal as to beneficial ownership of the securities indicated above. The address of the principal business office of Senvest Management, LLC is 540 Madison Avenue, 32nd Floor, New York, New York 10022.

B. Related Party Transactions

Agreements with Directors and Officers

Employment Agreements

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

Indemnification Agreements

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

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and other Financial Information

See "Item 18. Financial Statements."

Legal Proceedings

We are not involved in any material legal proceedings.

Dividend Distributions

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

B. Significant Changes

None.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Price Range of our ADSs

Our ADSs have been trading on Nasdaq 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 Nasdaq in dollars.

	U.S.$ Price Per ADS	
	High	**Low**
Annual:		
2017	1.31	0.81
2016	1.30	0.75
2015	2.84	1.23
2014	3.07	1.23
2013	4.75	1.58
Quarterly:		
First Quarter (through March 5, 2018)	1.20	0.94
Fourth Quarter 2017	1.31	0.94
Third Quarter 2017	1.18	0.81
Second Quarter 2017	0.92	0.82
First Quarter 2017	1.30	0.88
Fourth Quarter 2016	1.16	0.92
Third Quarter 2016	1.28	0.75
Second Quarter 2016	1.02	0.79
First Quarter 2016	1.30	0.90
Most Recent Six Months:		
March 2018 (through March 5, 2018)	1.01	0.97
February 2018	1.07	0.94
January 2018	1.20	1.06
December 2017	1.14	1.05
November 2017	1.14	0.94
October 2017	1.31	1.03
September 2017	1.16	1.03

On March 5, 2018, the last reported sales price of our ADSs on Nasdaq was $1.01 per ADS. As of March 5, 2018, 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:				
2017	4.67	2.90	1.26	0.82
2016	5.21	3.07	1.34	0.79
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
Quarterly:				
First Quarter (through March 5, 2018)	4.03	3.41	1.18	0.98
Fourth Quarter 2017	4.36	3.35	1.24	0.95
Third Quarter 2017	4.19	2.90	1.16	0.82
Second Quarter 2017	3.65	2.92	1.01	0.82
First Quarter 2017	4.67	3.52	1.26	0.92
Fourth Quarter 2016	4.31	3.48	1.12	0.91
Third Quarter 2016	4.60	3.07	1.22	0.80
Second Quarter 2016	3.92	3.07	1.04	0.79
First Quarter 2016	5.21	3.67	1.34	0.94
Most Recent Six Months:				
March 2018 (through March 5, 2018)	3.50	3.49	1.01	1.00
February 2018	3.62	3.41	1.03	0.98
January 2018	4.03	3.65	1.18	1.07
December 2017	4.05	3.73	1.14	1.06
November 2017	3.93	3.35	1.12	0.95
October 2017	4.36	3.64	1.24	1.03
September 2017	4.02	3.45	1.14	0.98

On March 5, 2018, the last reported sales price of our ordinary shares on the TASE was NIS 3.50 per share, or $1.01 per share (based on the exchange rate reported by the Bank of Israel for such date). On March 5, 2018, the exchange rate of the NIS to the dollar was $1.00 = NIS 3.456, as reported by the Bank of Israel. As of March 5, 2018, 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. Markets

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

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Articles of Association

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

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

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

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

Dividends

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

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

Election of Directors

Our ordinary shares do not have cumulative voting rights in the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors, other than with respect to the special approval requirements for the election of external directors (unless we qualify as an Eligible Company and opt to follow the exemption provided under the Amendment to the Relief Regulations regarding appointment of external directors and composition of the Audit and Compensation Committees) described under "Item 6. Directors, Senior Management and Employees — Board Practices — External Directors."

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

Shareholder Meetings

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

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

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

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

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

Quorum

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

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

Resolutions

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

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

- an appointment or removal of directors;
- an approval of transactions with office holders or interested or related parties;
- an approval of a merger or any other matter in respect of which there is a provision in the articles of association providing that decisions of the general meeting may also be passed by written ballot;
- authorizing the chairman of the board of directors or his relative to act as the company's chief executive officer or act with such authority; or authorize the company's chief executive officer or his relative to act as the chairman of the board of directors or act with such authority; and
- other matters which may be prescribed by Israel's Minister of Justice.

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

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

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

Under 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 (unless the company qualifies as an Eligible Company and opt to follow the exemption provided under the Amendment to the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees). The final adoption of such compensation policy is subject to the approval of the shareholders, which approval is subject to certain special majority requirements, as set forth in the Companies Law, pursuant to which one of the following must be met:

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

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

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

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

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

Access to Corporate Records

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

Acquisitions under Israeli Law

Full Tender Offer

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

Special Tender Offer

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

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

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

Merger

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

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

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

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

Antitakeover Measures

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

C. Material Contracts

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

Clinical Trial Collaboration and Supply Agreement with MSD

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

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.

Combination Study Agreement with Genentech

In September 2016, we entered into a collaboration with Genentech to support several Phase 1b studies investigating BL-8040 in combination with TECENTRIQ® (atezolizumab), Genentech's anti-PDL1 cancer immunotherapy, in multiple cancer indications. Under the collaboration agreement, Genentech will sponsor and conduct several trials in multiple solid cancer indications. In addition, we will sponsor and conduct a study in AML patients. The Phase 1b studies, which are all expected to commence in the second half of 2017, will evaluate the clinical response, safety and tolerability of the combination of these therapies, as well as multiple pharmacodynamic parameters, in hematologic malignancies and solid tumors.

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

D. Exchange Controls

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

E. Taxation

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

Israeli Tax Considerations

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

General Corporate Tax Structure in Israel

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

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

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

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

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

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

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

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

Taxation of Non-Israeli Shareholders on Receipt of Dividends. Non-residents of Israel are generally subject to Israeli income tax on the receipt of dividends paid on our ordinary shares at the rate of 25% (or 30% if such person is a "substantial shareholder" at the time receiving the dividend or on any date in the 12 months preceding such date), which tax will be withheld at the source, unless a lower rate is provided in a tax treaty between Israel and the shareholder's country of residence. If the income out of which the dividend is being paid is sourced from profits attributable to a Benefited Enterprise under the Investments Law, the rate is generally not more than 20%.

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

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

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

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

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

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

Capital Gains Taxes Applicable to Non-Israeli Resident Shareholders. Shareholders that are not Israeli residents are generally exempt from Israeli capital gains tax on any gains derived from the sale, exchange or disposition of our ordinary shares, provided that such shareholders did not acquire their ordinary shares prior to our initial public offering on the TASE and such gains were not derived from a permanent establishment or business activity of such shareholders in Israel. However, non-Israeli corporations will not be entitled to the foregoing exemptions if one or more Israeli residents (a) have a controlling interest of 25% or more in such non-Israeli corporation or (b) are the beneficiaries of or are entitled to 25% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly.

In addition, under the U.S.-Israel Tax Treaty, the sale, exchange or disposition of our ordinary shares by a shareholder who is a U.S. resident (for purposes of the U.S.-Israel Tax Treaty) holding the ordinary shares as a capital asset is exempt from Israeli capital gains tax unless (1) the shareholder holds, directly or indirectly, shares representing 10% or more of our voting capital during any part of the 12-month period preceding such sale, exchange or disposition; (2) the capital gains arising from such sale are attributable to a permanent establishment of the shareholder located in Israel; (3) a shareholder who is an individual is present in Israel for a period or periods aggregating 183 days or more during a taxable year. In either case, the sale, exchange or disposition of ordinary shares would be subject to Israeli tax, to the extent applicable; however, under the U.S.-Israel Tax Treaty, the U.S. resident would be permitted to claim a credit for the tax against the U.S. federal income tax imposed with respect to the sale, exchange or disposition, subject to the limitations in U.S. laws applicable to foreign tax credits. The U.S.-Israel Tax Treaty does not relate to U.S. state or local taxes.

Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale.

Excess Tax. Individuals who are subject to tax in Israel are also subject to an additional tax at a rate of 3% in 2017 and thereafter on annual income exceeding a certain threshold (NIS 640,000 for 2017 and thereafter, which amount is linked to the annual change in the Israeli consumer price index), including, but not limited to, dividends, interest and capital gains.

U.S. Federal Income Tax Considerations

The following is a general summary of the material U.S. federal income tax considerations relating to the purchase, ownership and disposition of our ordinary shares and ADSs by U.S. Investors (as defined below) that are initial purchasers of such ordinary shares or ADSs and that hold such ordinary shares or ADSs as capital assets. This summary is based on the Internal Revenue Code of 1986, as amended, or the Code, the regulations of the U.S. Department of the Treasury issued pursuant to the Code, or the Treasury Regulations, and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect, or to different interpretation. This summary is for general information only and does not address all of the tax considerations that may be relevant to specific U.S. Investors in light of their particular circumstances or to U.S. Investors subject to special treatment under U.S. federal income tax law (such as banks, insurance companies, tax-exempt entities, retirement plans, regulated investment companies, partnerships, dealers in securities, brokers, real estate investment trusts, certain former citizens or residents of the United States, persons who acquire our ordinary shares or ADSs as part of a straddle, hedge, conversion transaction or other integrated investment, persons that have a "functional currency" other than the Dollar, persons that own (or are deemed to own, indirectly or by attribution) 10% or more of our ordinary shares or ADSs, persons subject to special tax accounting rules under section 451(b), or persons that generally mark their securities to market for U.S. federal income tax purposes). This summary does not address any U.S. state or local or non-U.S. tax considerations or any U.S. federal estate, gift or alternative minimum tax considerations.

As used in this summary, the term "U.S. Investor" means a beneficial owner of our ordinary shares or ADSs that is, for U.S. federal income tax purposes, (i) an individual citizen or resident of the United States, (ii) a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income tax regardless of its source or (iv) a trust with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions, or a trust that has validly elected to be treated as a U.S. person for U.S. federal income tax purposes, whose status as a U.S. person is not overwritten by an applicable tax treaty.

If an entity treated as a partnership for U.S. federal income tax purposes holds our ordinary shares or ADSs, the tax treatment of such partnership and each partner thereof will generally depend upon the status and activities of the partnership and such partner. A holder that is treated as a partnership for U.S. federal income tax purposes should consult its own tax advisor regarding the U.S. federal income tax considerations applicable to it and its partners of the purchase, ownership and disposition of its ordinary shares or ADSs.

Prospective investors should be aware that this summary does not address the tax consequences to investors who are not U.S. Investors. Prospective investors should consult their own tax advisors as to the particular tax considerations applicable to them relating to the purchase, ownership and disposition of their ordinary shares or ADSs, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Taxation of U.S. Investors

The discussions under "— Distributions," and under "— Sale, Exchange or Other Disposition of Ordinary Shares or ADSs" below assumes that we will not be treated as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. However, we have not determined whether we will be a PFIC for the taxable year ending December 31, 2018, and it is possible that we will be a PFIC for the taxable year ending December 31, 2018 or in any subsequent year. For a discussion of the rules that would apply if we are treated as a PFIC, see the discussion under "— Passive Foreign Investment Company."

Distributions. We have no current plans to pay dividends. To the extent we pay any dividends, a U.S. Investor will be required to include in gross income as a taxable dividend the amount of any distributions made on the ordinary shares or ADSs, including the amount of any Israeli taxes withheld, to the extent that those distributions are paid out of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes. Any distributions in excess of our earnings and profits will be applied against and will reduce the U.S. Investor's tax basis in its ordinary shares or ADSs and to the extent they exceed that tax basis, will be treated as gain from the sale or exchange of those ordinary shares or ADSs. If we were to pay dividends to holders of our ordinary shares, we expect to pay such dividends in NIS; however, dividends paid to holders of our ADSs will be paid in dollars. A dividend paid in NIS, including the amount of any Israeli taxes withheld, will be includible in a U.S. Investor's income as a dollar amount calculated by reference to the exchange rate in effect on the date such dividend is received, regardless of whether the payment is in fact converted into dollars. If the dividend is converted to dollars on the date of receipt, a U.S. Investor generally will not recognize a foreign currency gain or loss. However, if the U.S. Investor converts the NIS into dollars on a later date, the U.S. Investor must include, in computing its income, any gain or loss resulting from any exchange rate fluctuations. The gain or loss will be equal to the difference between (i) the dollar value of the amount included in income when the dividend was received and (ii) the amount received on the conversion of the NIS into dollars. Such gain or loss will generally be ordinary income or loss and United States source for U.S. foreign tax credit purposes. U.S. Investors should consult their own tax advisors regarding the tax consequences to them if we pay dividends in NIS or any other non-U.S. currency.

Subject to certain significant conditions and limitations, including potential limitations under the United States-Israel income tax treaty, any Israeli taxes paid on or withheld from distributions from us and not refundable to a U.S. Investor may be credited against the investor's U.S. federal income tax liability or, alternatively, may be deducted from the investor's taxable income. This election is made on a year-by-year basis and applies to all foreign taxes paid by a U.S. Investor or withheld from amounts paid to a U.S. Investor that year. Dividends paid on the ordinary shares or ADSs generally will constitute income from sources outside the United States and be categorized as "passive category income" or, in the case of some U.S. Investors, as "general category income" for U.S. foreign tax credit purposes.

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

Dividends paid on the ordinary shares and ADSs will not be eligible for the "dividends-received" deduction generally allowed to corporate U.S. Investors with respect to dividends received from U.S. corporations.

Distributions treated as dividends that are received by an individual U.S. Investor from "qualified foreign corporations" generally qualify for a reduced maximum tax rate so long as certain holding period and other requirements are met. Dividends paid by us in a taxable year in which we are not a PFIC are expected to be eligible for the reduced maximum tax rate. However, any dividend paid by us in a taxable year in which we are a PFIC will be subject to tax at regular ordinary income rates. As mentioned above, we have not determined whether we are currently a PFIC or not.

Sale, Exchange or Other Disposition of Ordinary Shares and ADSs. Subject to the discussion under "— Passive Foreign Investment Company" below, a U.S. Investor generally will recognize capital gain or loss upon the sale, exchange or other disposition of ordinary shares or ADSs in an amount equal to the difference between the amount realized on the sale, exchange or other disposition and the U.S. Investor's adjusted tax basis in such ordinary shares or ADSs. This capital gain or loss will be long-term capital gain or loss if the U.S. Investor's holding period in the ordinary shares or ADSs exceeds one year. Preferential tax rates for long-term capital gain will apply to individual U.S. Investors. The deductibility of capital losses is subject to limitations. The gain or loss will generally be income or loss from sources within the United States for U.S. foreign tax credit purposes.

U.S. Investors should consult their own tax advisors regarding the U.S. federal income tax consequences of receiving currency other than Dollars upon the disposition of ordinary shares or ADSs.

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

Passive Foreign Investment Company

In general, a corporation organized outside the United States will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (i) at least 75% of its gross income is "passive income" or (ii) on average at least 50% of its assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in the public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

Under the tests described above, whether or not we are a PFIC will be determined annually based upon the composition of our income and the composition and valuation of our assets, all of which are subject to change.

We believe that we were a PFIC for U.S. federal income tax purposes for taxable years ended prior to December 31, 2009 and for taxable years ended December 31, 2011, 2012 and 2014 through 2017. We were not a PFIC for taxable years ended 2009, 2010 and 2013, and we have not determined whether we will be a PFIC for the taxable year ending December 31, 2018. Because the PFIC determination is highly fact intensive and made at the end of each taxable year, there can be no assurance that we will not be a PFIC for taxable year ending December 31, 2018 or in any subsequent year. Upon request, we will annually inform U.S. Investors if we and any of our subsidiaries were a PFIC with respect to the preceding year.

U.S. Investors should be aware of certain tax consequences of investing directly or indirectly in us if we are a PFIC. A U.S. Investor is subject to different rules depending on whether the U.S. Investor makes an election to treat us as a "qualified electing fund," known as a QEF election, for the first taxable year that the U.S. Investor holds ordinary shares or ADSs, which is referred to in this disclosure as a "timely QEF election," makes a "mark-to-market" election with respect to the ordinary shares or ADSs (if such election is available) or makes neither election.

QEF Election. A U.S. Investor who makes a timely QEF election, referred to in this disclosure as an "Electing U.S. Investor," with respect to us must report for U.S. federal income tax purposes his pro rata share of our ordinary earnings and net capital gain, if any, for our taxable year that ends with or within the taxable year of the Electing U.S. Investor. The "net capital gain" of a PFIC is the excess, if any, of the PFIC's net long-term capital gains over its net short-term capital losses. The amount so included in income generally will be treated as ordinary income to the extent of such Electing U.S. Investor's allocable share of the PFIC's ordinary earnings and as long-term capital gain to the extent of such Electing U.S. Investor's allocable share of the PFIC's net capital gains. Such Electing U.S. Investor generally will be required to translate such income into Dollars based on the average exchange rate for the PFIC's taxable year with respect to the PFIC's functional currency. Such income generally will be treated as income from sources outside the United States for U.S. foreign tax credit purposes. Amounts previously included in income by such Electing U.S. Investor under the QEF rules generally will not be subject to tax when they are distributed to such Electing U.S. Investor. The Electing U.S. Investor's tax basis in ordinary shares or ADSs generally will increase by any amounts so included under the QEF rules and decrease by any amounts not included in income when distributed.

An Electing U.S. Investor will be subject to U.S. federal income tax on such amounts for each taxable year in which we are a PFIC, regardless of whether such amounts are actually distributed to such Electing U.S. Investor. However, an Electing U.S. Investor may, subject to certain limitations, elect to defer payment of current U.S. federal income tax on such amounts, subject to an interest charge. If an Electing U.S. Investor is an individual, any such interest will be treated as non-deductible "personal interest."

Any net operating losses or net capital losses of a PFIC will not pass through to the Electing U.S. Investor and will not offset any ordinary earnings or net capital gain of a PFIC recognized by Electing U.S. Investors in subsequent years (although such losses would ultimately reduce the gain, or increase the loss, recognized by the Electing U.S. Investor on its disposition of the ordinary shares or ADSs).

So long as an Electing U.S. Investor's QEF election with respect to us is in effect with respect to the entire holding period for ordinary shares or ADSs, any gain or loss recognized by such Electing U.S. Investor on the sale, exchange or other disposition of such ordinary shares or ADSs generally will be long-term capital gain or loss if such Electing U.S. Investor has held such ordinary shares or ADSs for more than one year at the time of such sale, exchange or other disposition. Preferential tax rates for long-term capital gain will apply to individual U.S. Investors. The deductibility of capital losses is subject to limitations.

A U.S. Investor makes a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. A QEF election generally may not be revoked without the consent of the IRS. Upon request, we will annually furnish U.S. Investors with information needed in order to complete IRS Form 8621 (which form would be required to be filed with the IRS on an annual basis by the U.S. Investor) and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC. A QEF election will not apply to any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Each U.S. Investor is encouraged to consult its own tax advisor with respect to tax consequences of a QEF election with respect to us.

Mark-to-Market Election. Alternatively, if our ordinary shares or ADSs are treated as "marketable stock," a U.S. Investor would be allowed to make a "mark-to-market" election with respect to our ordinary shares or ADSs, provided the U.S. Investor completes and files IRS Form 8621 in accordance with the relevant instructions and related Treasury Regulations. If that election is made, the U.S. Investor generally would include as ordinary income in each taxable year the excess, if any, of the fair market value of the ordinary shares or ADSs at the end of the taxable year over such holder's adjusted tax basis in the ordinary shares or ADSs. Thus, the U.S. Investor may recognize taxable income without receiving any cash to pay its tax liability with respect to such income. The U.S. Investor would also be permitted an ordinary loss in respect of the excess, if any, of the U.S. Investor's adjusted tax basis in the ordinary shares or ADSs over their fair market value at the end of the taxable year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. A U.S. Investor's tax basis in the ordinary shares or ADSs would be adjusted to reflect any such income or loss amount. Gain realized on the sale, exchange or other disposition of the ordinary shares or ADSs would be treated as ordinary income, and any loss realized on the sale, exchange or other disposition of the ordinary shares or ADSs would be treated as ordinary loss to the extent that such loss does not exceed the net mark-to-market gains previously included in income by the U.S. Investor, and any loss in excess of such amount will be treated as capital loss. Amounts treated as ordinary income will not be eligible for the favorable tax rates applicable to qualified dividend income or long-term capital gains.

Generally, stock will be considered marketable stock if it is "regularly traded" on a "qualified exchange" within the meaning of applicable Treasury Regulations. A class of stock is regularly traded on an exchange during any calendar year during which such class of stock is traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter. A mark-to-market election will not apply to our ordinary shares or ADSs held by a U.S. Investor for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC unless our ordinary shares or ADSs cease to be marketable. A mark-to-market election generally may not be revoked without the consent of the IRS. Such election will not apply to any PFIC subsidiary that we own. Each U.S. Investor is encouraged to consult its own tax advisor with respect to the availability and tax consequences of a mark-to-market election with respect to our ordinary shares or ADSs.

Default PFIC Rules. A U.S. Investor who does not make a timely QEF election or a mark-to-market election, referred to in this disclosure as a "Non-Electing U.S. Investor," will be subject to special rules with respect to (a) any "excess distribution" (generally, the portion of any distributions received by the Non-Electing U.S. Investor on the ordinary shares or ADSs in a taxable year in excess of 125% of the average annual distributions received by the Non-Electing U.S. Investor in the three preceding taxable years, or, if shorter, the Non-Electing U.S. Investor's holding period for the ordinary shares or ADSs), and (b) any gain realized on the sale or other disposition of such ordinary shares or ADSs. Under these rules:

the excess distribution or gain would be allocated ratably over the Non-Electing U.S. Investor's holding period for the ordinary shares or ADSs;

the amount allocated to the current taxable year and any year prior to us becoming a PFIC would be taxed as ordinary income; and

the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year.

If a Non-Electing U.S. Investor who is an individual dies while owning our ordinary shares or ADSs, the Non-Electing U.S. Investor's successor would be ineligible to receive a step-up in tax basis of the ordinary shares or ADSs. Non-Electing U.S. Investors are encouraged to consult their tax advisors regarding the application of the PFIC rules to their specific situation.

A Non-Electing U.S. Investor who wishes to make a QEF election for a subsequent year may be able to make a special "purging election" pursuant to Section 1291(d) of the Code. Pursuant to this election, a Non-Electing U.S. Investor would be treated as selling his or her ordinary shares or ADSs for fair market value on the first day of the taxable year for which the QEF election is made. Any gain on such deemed sale would be subject to tax under the rules for Non-Electing U.S. Investors as discussed above. Non-Electing U.S. Investors are encouraged to consult their tax advisors regarding the availability of a "purging election" as well as other available elections.

To the extent a distribution on our ordinary shares or ADSs does not constitute an excess distribution to a Non-Electing U.S. Investor, such Non-Electing U.S. Investor generally will be required to include the amount of such distribution in gross income as a dividend to the extent of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) that are not allocated to excess distributions. The tax consequences of such distributions are discussed above under "— Taxation of U.S. Investors — Distributions." Each U.S. Investor is encouraged to consult its own tax advisor with respect to the appropriate U.S. federal income tax treatment of any distribution on our ordinary shares or ADSs.

If we are treated as a PFIC for any taxable year during the holding period of a Non-Electing U.S. Investor, we will continue to be treated as a PFIC for all succeeding years during which the Non-Electing U.S. Investor is treated as a direct or indirect Non-Electing U.S. Investor even if we are not a PFIC for such years. A U.S. Investor is encouraged to consult its tax advisor with respect to any available elections that may be applicable in such a situation, including the "deemed sale" election of Code Section 1298(b)(1). In addition, U.S. Investors should consult their tax advisors regarding the IRS information reporting and filing obligations that may arise as a result of the ownership of shares in a PFIC, including IRS Form 8621.

We may invest in the equity of foreign corporations that are PFICs or may own subsidiaries that own PFICs. U.S. Investors will be subject to the PFIC rules with respect to their indirect ownership interests in such PFICs, such that a disposition of the shares of the PFIC or receipt by us of a distribution from the PFIC generally will be treated as a deemed disposition of such shares or the deemed receipt of such distribution by the U.S. Investor, subject to taxation under the PFIC rules. There can be no assurance that a U.S. Investor will be able to make a QEF election or a mark-to-market election with respect to PFICs in which we invest. Each U.S. Investor is encouraged to consult its own tax advisor with respect to tax consequences of an investment by us in a corporation that is a PFIC.

The U.S. federal income tax rules relating to PFICs are complex. U.S. Investors are urged to consult their own tax advisors with respect to the purchase, ownership and disposition of ordinary shares or ADSs, any elections available with respect to such ordinary shares or ADSs and the IRS information reporting obligations with respect to the purchase, ownership and disposition of ordinary shares or ADSs.

Certain Reporting Requirements

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

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

Backup Withholding Tax and Information Reporting Requirements

Generally, information reporting requirements will apply to distributions on our ordinary shares or ADSs or proceeds on the disposition of our ordinary shares or ADSs paid within the United States (and, in certain cases, outside the United States) to U.S. Investors other than certain exempt recipients, such as corporations. Furthermore, backup withholding may apply to such amounts if the U.S. Investor fails to (i) provide a correct taxpayer identification number, (ii) report interest and dividends required to be shown on its U.S. federal income tax return, or (iii) make other appropriate certifications in the required manner. U.S. Investors who are required to establish their exempt status generally must provide such certification on IRS Form W-9.

Backup withholding is not an additional tax. Amounts withheld as backup withholding from a payment may be credited against a U.S. Investor's U.S. federal income tax liability and such U.S. Investor may obtain a refund of any excess amounts withheld by timely filing the appropriate claim for refund with the IRS and furnishing any required information in a timely manner.

U.S. Investors should consult their own tax advisors concerning the tax consequences relating to the purchase, ownership and disposition of the ordinary shares or ADSs.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are currently subject to the information and periodic reporting requirements of the Exchange Act, and file periodic reports and other information with the SEC through its electronic data gathering, analysis and retrieval (EDGAR) system. 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 ISA, or the ISA, as required under Chapter Six of the Israel Securities Law, 1968 and the regulations enacted pursuant thereof, as applicable to a public company which also trades on the Nasdaq. Copies of our filings with the ISA can be retrieved electronically through the MAGNA distribution site of the ISA (*www.magna.isa.gov.il*) and the TASE website (*www.maya.tase.co.il*).

We maintain a corporate website at *www.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 among BioLineRx, The Bank of New York Mellon as depositary, or the Depositary, and the owners and holders from time to time of our ADSs.

Description of the ADSs

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

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

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 after deducting its fees and expenses, 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 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.

Other distributions. If the Depositary or the custodian receives a distribution of anything other than cash or shares, the Depositary will, after consultation with us to the extent practicable, distribute the property or securities to the ADS holder, in proportion to such holder's holdings upon payment of its fees. If, however, the Depositary determines that it cannot distribute the property or securities in this manner or that it is not feasible to do so, then 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 may:

- make the rights available to all or certain holders of ADSs, by means of warrants or otherwise, if lawful and practically feasible; or
- attempt to sell those rights or warrants or other instruments.

In the case of a sale, 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, or the Securities Act, 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 does not 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 the deposited securities, to exercise voting rights pertaining to the shares represented by its ADSs. The Depositary will notify ADS holders of shareholders' meetings and arrange to deliver our voting materials to them if we request. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the Depositary by a date set by the Depositary. The Depositary will try, as far as practical, subject to the laws of Israel and of our Articles of Association, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. The Depositary will only vote or attempt to vote as instructed or as described in the following sentence. If we asked the Depositary to solicit your instructions at least 30 days before the meeting date but the Depositary does not receive voting instructions from you by the specified date, it will consider you to have authorized and directed it to give a discretionary proxy to a person designated by us to vote the number of deposited securities represented by your ADSs. 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. The Depositary's discretionary proxy to vote on all questions to be voted upon will be given to us as described above unless we notify the Depositary that:

- we do not wish to receive a discretionary proxy;
- there is substantial shareholder opposition to the particular question; or
- the particular question would have an adverse impact on our shareholders.

We are required to notify the Depositary if one of the conditions specified above exists.

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, including if the deposit agreement terminates;
- a fee of $.05 or less per ADS (or portion thereof) for any cash distribution made pursuant to the deposit agreement;
- a fee for the distribution of securities pursuant to the deposit agreement;
- in addition to any fee charged for a cash distribution, a fee of $.05 or less per ADS (or portion thereof) per annum for depositary services;

- a fee for the distribution of proceeds of rights that the Depositary sells pursuant to the deposit agreement; and
- any other charges payable by the Depositary, any of the Depositary's agents, or the agents of the Depositary's agents in connection with the servicing of ordinary shares or other Deposited Securities.

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

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

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

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

Liability of Holders for Taxes, Duties or Other Charges

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

ITEM 13. DEFAULTS, DIVIDENDS ARREARAGES AND DELINQUENCIES

Not applicable.

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

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

(a) **Disclosure Controls and Procedures**

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

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

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

Our management, including the CEO and CFO, conducted an evaluation, pursuant to Rule 13a-15(c) promulgated under the Exchange Act, of the effectiveness, as of the end of the period covered by this Annual Report, of its internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013). Based on the results of this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2017.

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

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

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

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERTS

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

ITEM 16B. CODE OF ETHICS

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

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Registered Public Accounting Firm

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

Services Rendered	Year Ended December 31, 2016 (*in thousands of U.S. dollars*)	Year Ended December 31, 2017 (*in thousands of U.S. dollars*)
Audit Fees[1]	$ 110	$ 110
Audit-Related Fees[2]	–	33
Tax Fees[3]	21	27
All Other Fees	–	–
Total	$ 131	$ 170

(1) Audit fees consist of services that would normally be provided in connection with statutory and regulatory filings or engagements, including services that generally only the independent accountant can reasonably provide.
(2) Audit related services relate to reports to the IIA and work regarding a public listing or offering.
(3) Tax fees relate to tax compliance, planning and advice.

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

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

Not applicable.

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

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

Nasdaq Listing Rules and Home Country Practices

The Sarbanes-Oxley Act, as well as related rules subsequently implemented by the SEC, requires foreign private issuers, such as us, to comply with various corporate governance practices. In complying with the 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 ISA and the TASE. In addition, we make our audited financial statements available to our shareholders at our offices. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules.

- *Quorum*. While the 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, 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. If we qualify as an Eligible Company and opt to follow the exemption provided under the Amendment to the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees, we will be required at all times to comply with the U.S. rules and regulations governing the appointment of independent directors and composition of the audit and compensation committees applicable to U.S. domestic issuers instead of complying with the Companies Law provisions relating to external directors and composition of the audit and compensation committees.

- *Audit Committee*. Our Audit Committee complies with all of the requirements under Israeli law, and is composed of two external directors, which are all of our external directors, and only one other director, who cannot be the chairman of our Board of Directors. Consistent with Israeli law, the independent auditors are elected at a meeting of shareholders instead of being appointed by the Audit Committee. If we qualify as an Eligible Company and opt to follow the exemption provided under the Amendment to the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees, we will be required at all times to comply with the U.S. rules and regulations governing the appointment of independent directors and composition of the Audit Committee applicable to U.S. domestic issuers instead of complying with the Companies Law provisions relating to external directors and composition of the Audit Committee.

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

- *Compensation Committee and Compensation of Officers*. Israeli law, and our Articles of Association, do not require that a compensation committee composed solely of independent members of our Board of Directors determine (or recommend to the board of directors for determination) an executive officer's compensation, as required under Nasdaq's listing standards related to compensation committee independence and responsibilities; nor do they require that the Company adopt and file a compensation committee charter. Instead, our Compensation Committee has been established and conducts itself in accordance with provisions governing the composition of and the responsibilities of a compensation committee as set forth in the Companies Law, and is 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. If we qualify as an Eligible Company and opt to follow the exemption provided under the Amendment to the Relief Regulations regarding appointment of external directors and composition of the audit and compensation committees, we will be required at all times to comply with the U.S. rules and regulations governing the appointment of independent directors and composition of the compensation committee applicable to U.S. domestic issuers instead of complying with the Companies Law provisions relating to external directors and composition of the compensation committee. Additionally, we comply with the requirements set forth under the Companies Law, pursuant to which transactions with office holders regarding their terms of office and employment, and 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 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 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[4]	Articles of Association, as amended July 5, 2017
2.2[2]	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 deposit agreement which is Exhibit 2.2 above.
4.5[10]	Employment Agreement with Philip Serlin, dated May 24, 2009, as amended
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[10]	Amended and Restated License and Commercialization Agreement dated August 26, 2009 among the Registrant, Ikaria Development Subsidiary One LLC and BioLine Innovations Jerusalem L.P., as amended and supplemented
4.18[9]	BioLineRx Ltd. Amended and Restated 2003 Share Incentive Plan
4.30[3]	Employment Agreement with David Malek, dated August 8, 2011
4.33[5]	License Agreement entered into as of September 2, 2012 by and between the Registrant and Biokine Therapeutics Ltd.
4.36[6]	Compensation Policy for Executives and Directors
4.37[7]	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[7]†	Investment and Collaboration Agreement entered into as of December 16, 2014 between the Registrant and Novartis Pharma AG

Exhibit Number	Exhibit Description
4.39[8]†	License Agreement entered into as of December 22, 2014 between the Registrant and Wartner Europe BV
4.40[5]†	Clinical Trial Collaboration and Supply Agreement entered into as of January 11, 2016 between the Registrant and Merck Sharp & Dohme B.V.
4.42[10]†	Combination Study Agreement entered into as of September 6, 2016 between the Registrant and Genentech, Inc.
4.43[10]	Employment Agreement with Mali Zeevi, dated September 16, 2009, as amended
4.44[10]	Employment Agreement with Abi Vainstein-Haras, dated April 2, 2014, as amended
4.45[10]	Employment Agreement with Ella Sorani, dated January 11, 2017
4.46[10]†	Amended and Restated Exclusive License Agreement entered into as of April 30, 2013 between the University of Massachusetts and Agalimmune Ltd.
4.47[10]†	Evaluation License and Option Agreement entered into as of March 31, 2015 between Agalimmune Ltd and Kode Biotech Limited
4.48	Employment Agreement with Hillit Mannor Shachar, dated February 8, 2018
8.1	List of Significant Subsidiaries
12.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1	Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2	Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.5	Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Registrant
15.8[11]	Subscription Agreement entered into as of July 26, 2017 among the Registrant and Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS, L.P., Investment 10, LLC and MSI BVF SPV, L.L.C. (the "BVF Investors")
15.9[11]	Form of Series A Warrant issued to the BVF Investors
15.10[11]	Form of Series B Warrant issued to the BVF Investors
15.11[11]	Voting and Standstill Agreement entered into as of July 26, 2017 among the Registrant and the BVF Investors
15.12[12]	At-the-market Sales Agreement entered into October 30, 2017, between the Registrant and BTIG, LLC
101	The following financial information from BioLineRx Ltd.'s Annual Report on Form 20-F for the fiscal year ended December 31, 2017 formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Statements of Financial Position at December 31, 2017 and 2016; (ii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2017, 2016 and 2015; (iii) Statements of Changes in Equity for the years ended December 31, 2017, 2016 and 2015; (iv) Consolidated Cash Flow Statements for the years ended December 31, 2017, 2016 and 2015; and (v) Notes to the Consolidated Financial Statements. Users of this data are advised, in accordance with Rule 406T of Regulation S-T promulgated by the SEC, that this Interactive Data File is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

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

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

(2) Incorporated by reference to Exhibit 1 of the Registration Statement on Form F-6EF (No. 333-218969) filed by the Bank of New York Mellon on June 26, 2017 with respect to the Registrant's American Depositary Shares.

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

(4) Incorporated by reference to the Registrant's Registration Statement on Form F-3 (No. 333-222332) filed on December 28, 2017.

(5) Incorporated by reference to the Registrant's Annual Report on Form 20-F/A filed on May 31, 2016

(6) Incorporated by reference to the Registrant's Form 6-K filed on May 31, 2016.

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

(8) Incorporated by reference to the Registrant's Annual Report on Form 20-F/A filed on September 22, 2015.

(9) Incorporated by reference to the Registrant's Annual Report on Form 20-F filed on March 10, 2016.

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

(11) Incorporated by reference to the Registrant's Form 6-K filed on July 31, 2017.

(12) Incorporated by reference to the Registrant's Form 6-K filed on October 31, 2017.

SIGNATURES

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

BIOLINERX LTD.

By: /s/ Philip A. Serlin
Philip A. Serlin
Chief Executive Officer

Date: March 6, 2018

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Audited Consolidated Financial Statements at December 31, 2017 and 2016 and for each of the three years in the period ended December 31, 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders of
BioLineRx Ltd.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of BioLineRx Ltd. and its subsidiaries as of December 31, 2017 and 2016, and the related consolidated statements of comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2017, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

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

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

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

Definition and Limitations of Internal Control over Financial Reporting

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

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

Tel Aviv, Israel
March 6, 2018

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

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

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31,	
		2016	2017
		in USD thousands	
Assets			
CURRENT ASSETS			
Cash and cash equivalents	5	2,469	5,110
Short-term bank deposits	6	33,154	44,373
Prepaid expenses		255	307
Other receivables	16a	223	586
Total current assets		36,101	50,376
NON-CURRENT ASSETS			
Long-term prepaid expenses	16b	52	61
Long-term investment	7	-	1,000
Property and equipment, net	8	2,605	2,505
Intangible assets, net	9	181	7,023
Total non-current assets		2,838	10,589
Total assets		38,939	60,965
Liabilities and equity			
CURRENT LIABILITIES			
Current maturities of long-term bank loan	10	93	93
Accounts payable and accruals:			
Trade	16c	2,590	5,516
Other	16c	978	1,113
Total current liabilities		3,661	6,722
NON-CURRENT LIABILITIES			
Long-term bank loan, net of current maturities	10	250	157
Warrants	11c	1	1,205
Total non-current liabilities		251	1,362
COMMITMENTS AND CONTINGENT LIABILITIES	14		
Total liabilities		3,912	8,084
EQUITY	11		
Ordinary shares		1,513	2,836
Share premium		199,567	240,682
Capital reserve		10,569	10,337
Other comprehensive loss		(1,416)	(1,416)
Accumulated deficit		(175,206)	(199,558)
Total equity		35,027	52,881
Total liabilities and equity		38,939	60,965

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

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Note	Year ended December 31,		
		2015	2016	2017
		in USD thousands		
RESEARCH AND DEVELOPMENT EXPENSES	16d	(11,489)	(11,177)	(19,510)
SALES AND MARKETING EXPENSES	16e	(1,003)	(1,352)	(1,693)
GENERAL AND ADMINISTRATIVE EXPENSES	16f	(3,704)	(3,984)	(4,037)
OPERATING LOSS		(16,196)	(16,513)	(25,240)
NON-OPERATING INCOME (EXPENSES), NET	16g	1,445	214	(260)
FINANCIAL INCOME	16h	457	480	1,169
FINANCIAL EXPENSES	16i	(106)	(22)	(21)
NET LOSS AND COMPREHENSIVE LOSS		(14,400)	(15,841)	(24,352)
		in USD		
LOSS PER ORDINARY SHARE – BASIC AND DILUTED	13	(0.28)	(0.28)	(0.27)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	13	51,406,434	56,144,727	89,970,713

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

BioLineRx Ltd.

STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	Share premium	Capital reserve	Other comprehensive loss	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2015	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 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
CHANGES IN 2016:						
Issuance of share capital, net	57	2,126	-	-	-	2,183
Employee stock options exercised	1	171	(172)	-	-	-
Employee stock options expired	-	1,069	(1,069)	-	-	-
Share-based compensation	-	-	1,075	-	-	1,075
Comprehensive loss for the year	-	-	-	-	(15,841)	(15,841)
BALANCE AT DECEMBER 31, 2016	1,513	199,567	10,569	(1,416)	(175,206)	35,027
CHANGES IN 2017:						
Issuance of share capital, net	1,322	39,376	-	-	-	40,698
Employee stock options exercised	1	328	(329)	-	-	-
Employee stock options expired	-	1,411	(1,411)	-	-	-
Share-based compensation	-	-	1,508	-	-	1,508
Comprehensive loss for the year	-	-	-	-	(24,352)	(24,352)
BALANCE AT DECEMBER 31, 2017	2,836	240,682	10,337	(1,416)	(199,558)	52,881

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

BioLineRx Ltd.

CONSOLIDATED CASH FLOW STATEMENTS

	Year ended December 31,		
	2015	**2016**	**2017**
	in USD thousands		
CASH FLOWS - OPERATING ACTIVITIES			
Net loss	(14,400)	(15,841)	(24,352)
Adjustments required to reflect net cash used in operating activities (see appendix below)	232	1,328	3,805
Net cash used in operating activities	(14,168)	(14,513)	(20,547)
CASH FLOWS - INVESTING ACTIVITIES			
Long-term investment	-	-	(1,000)
Investments in short-term deposits	(63,130)	(32,982)	(44,016)
Maturities of short-term deposits	50,083	42,334	33,327
Maturities of restricted deposits	166	-	-
Purchase of property and equipment	(2,683)	(52)	(338)
Purchase of intangible assets	(36)	(3)	(3,900)
Net cash provided by (used in) investing activities	(15,600)	9,297	(15,927)
CASH FLOWS - FINANCING ACTIVITIES			
Issuance of share capital and warrants, net of issuance costs	29,053	2,183	38,773
Proceeds of bank loan	467	-	-
Repayments of bank loan	(31)	(93)	(93)
Net cash provided by financing activities	29,489	2,090	38,680
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(279)	(3,126)	2,206
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	5,790	5,544	2,469
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	33	51	435
CASH AND CASH EQUIVALENTS - END OF YEAR	5,544	2,469	5,110

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

BioLineRx Ltd.

CONSOLIDATED CASH FLOW STATEMENTS

	Year ended December 31,		
	2015	2016	2017
	in USD thousands		
APPENDIX			
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization	441	482	481
Long-term prepaid expenses	(9)	6	(9)
Exchange differences on cash and cash equivalents	(33)	(51)	(435)
Loss (gain) on adjustment of warrants to fair value	(1,292)	(207)	127
Share-based compensation	1,152	1,075	1,508
Interest and exchange differences on short-term deposits	(182)	(387)	(530)
Interest and linkage differences on bank loan	1	(1)	-
Warrant issuance costs	-	-	17
	78	917	1,159
Changes in operating asset and liability items:			
Decrease (increase) in prepaid expenses and other receivables	(42)	42	(415)
Increase in accounts payable and accruals	196	369	3,061
	154	411	2,646
	232	1,328	3,805
Supplementary information on interest received in cash	173	453	494
Supplementary non-cash investment (see Note 19)	-	-	2,985

Debt reconciliation for 2017:

	Long-term bank loan	Warrants	Total
Debt as of January 1, 2017	343	1	344
Cash flows	(93)	1,077	984
Other non-cash movements	-	127	127
Debt as of December 31, 2017	250	1,205	1,455

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

NOTE 1 – GENERAL INFORMATION

a. General

BioLineRx Ltd. ("BioLineRx"), headquartered in Modi'in, Israel, was incorporated and commenced operations in April 2003.

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

In March 2017, the Company acquired Agalimmune Ltd. ("Agalimmune"), a privately-held company incorporated in the United Kingdom, with a focus on the field of immuno-oncology. See Note 19.

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 in the past, the Company cannot determine with reasonable certainty when and if it will have sustainable profits.

b. Approval of consolidated financial statements

The consolidated financial statements of the Company for the year ended December 31, 2017 were approved by the Board of Directors on March 6, 2018, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer and the Chief Financial Officer.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation

The Company's consolidated financial statements as of December 31, 2017 and 2016, and for each of the three years in the period ended December 31, 2017, have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). The significant accounting policies described below have been applied on a consistent basis for all years presented, unless noted otherwise.

The consolidated financial statements have been prepared on the basis of historical cost, subject to adjustment of financial assets and liabilities to their fair value through profit or loss.

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

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

a. Basis of presentation (cont.)

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Company's accounting policies. Areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in Note 4. Actual results may differ materially from estimates and assumptions used by the Company's management.

b. Principles of consolidation and equity accounting

Consolidation

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

Equity method

Under the equity method of accounting, investments are initially recognized at cost and adjusted thereafter to recognize the Company's share of the post-acquisition profits or losses of the investee in profit or loss, and the Company's share of movements in other comprehensive income of the investee in other comprehensive income. Dividends received or receivable from associates and joint ventures are recognized as a reduction in the carrying amount of the investment. When the Company's share of losses in an equity-accounted investment equals or exceeds its interest in the entity, including any other unsecured long-term receivables, the Company does not recognize further losses, unless it has incurred obligations or made payments on behalf of the other entity. Unrealized gains on transactions between the Company and its associates and joint ventures are eliminated to the extent of the Company's interest in these entities. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the asset transferred. Accounting policies of equity accounted investees have been changed where necessary to ensure consistency with the policies adopted by the Company. The carrying amount of equity-accounted investments is tested for impairment in accordance with the policy described in Note 2g.

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 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.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

d. 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.

e. Property and equipment

Property and equipment are stated at historical cost less depreciation. Historical cost includes expenditures that are directly attributable to the acquisition of the items. Assets are depreciated by the straight-line method over the estimated useful lives of the assets, provided that the Company's management believes the residual values of the assets to be negligible, as follows:

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

The assets' residual values, methods of depreciation and useful lives are reviewed and adjusted, if appropriate, at each balance sheet date. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Leasehold improvements are amortized by the straight-line method over the shorter of the lease term or the estimated useful life of the improvements.

f. Intangible assets

The Company applies the cost method of accounting for initial and subsequent measurements of intangible assets. Under this method of accounting, intangible assets are carried at cost less any accumulated amortization and any accumulated impairment losses.

Intellectual property

The Company recognizes in its financial statements intangible assets developed by the Company to the extent that the conditions stipulated in o. 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.)

g. 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.

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", and "bank deposits". See Note 2d.

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. Warrants

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

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

j. Share capital

The Company's ordinary shares are classified as equity. Incremental costs directly attributable to the issuance of new shares are shown in equity as a deduction from the issuance proceeds.

k. Trade payables

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

l. Deferred taxes

Deferred taxes are recognized using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred income tax assets are recognized only to the extent that it is probable that future taxable income will be available against which the temporary differences can be utilized.

As the Company is currently engaged primarily in development activities and is not expected to generate taxable income in the foreseeable future, no deferred tax assets are included in the financial statements.

m. Revenue recognition

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 licensee the significant risks and rewards of ownership of the patents and intellectual property.

The Company does not retain either continuing managerial involvement to the degree usually associated with ownership, or 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.

Revenue from reaching additional milestones is recognized upon achievement of the specific milestone, in accordance with the relevant agreement.

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 accrual basis in accordance with the substance of the relevant agreement.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

n. Research and development expenses

Research expenses are charged to profit or loss as incurred.

An intangible asset arising from development (or from the development phase of an internal project) is recognized if all of the following conditions are fulfilled:

technological feasibility exists for completing development of the intangible asset so that it will be available for use or sale.

it is management's intention to complete development of the intangible asset for use or sale.

the Company has the ability to use or sell the intangible asset.

it is probable that the intangible asset will generate future economic benefits, including existence of a market for the output of the intangible asset or the intangible asset itself or, if the intangible asset is to be used internally, the usefulness of the intangible asset.

adequate technical, financial and other resources are available to complete development of the intangible asset, as well as the use or sale thereof.

the Company has the ability to reliably measure the expenditure attributable to the intangible asset during its development.

Other development costs that do not meet the foregoing conditions are charged to profit or loss as incurred. Development costs previously expensed are not recognized as an asset in subsequent periods. As of December 31, 2017, the Company has not yet capitalized development expenses.

o. Employee benefits

1) Pension and severance pay obligations

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

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

The amounts recorded as an employee benefit expense in respect of pension and severance pay obligations for the years 2015, 2016 and 2017 were $466,000, $523,000 and $563,000, respectively.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

o. 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 grants equity instruments (options, restricted stock units and performance stock units) of the Company as additional consideration for services from employees. The fair value of the employee services received in exchange for grant of the equity instruments is recognized as an expense. The total amount to be expensed is determined by reference to the fair value of the equity instruments granted:

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

excluding the impact of any service and non-market performance vesting conditions (for example, profitability, sales growth targets and the employee remaining with the entity over a specified time period).

Non-market performance and service conditions are included in assumptions about the number of equity instruments that are expected to vest. The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied.

When the equity instruments are exercised, the Company issues new shares. The proceeds received, net of any directly attributable transaction costs, are credited to share capital (at par value) and share premium when the equity instruments are exercised.

p. Loss per share

1) Basic

The basic loss per share is calculated by dividing the loss attributable to the holders of ordinary shares by the weighted average number of ordinary shares outstanding during the year.

2) Diluted

The diluted loss per share is calculated by adjusting the weighted average number of outstanding ordinary shares, assuming conversion of all dilutive potential shares. The Company's dilutive potential shares consist of warrants issued to investors, as well as equity instruments granted to employees and service providers. The dilutive potential shares were not taken into account in computing loss per share in 2015, 2016 and 2017, as their effect would have been anti-dilutive.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

q. Changes in accounting policy and disclosures

There were no changes in the accounting policies applied by the Company during 2017.

New standards and interpretations not yet adopted

Certain new accounting standards and interpretations have been published that are not mandatory for reporting periods prior to January 1, 2018, 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 recognition of financial assets and financial liabilities. The complete version of IFRS 9 was issued in July 2014. It replaces the guidance in IAS 39 that relates to the classification and measurement of financial instruments. IFRS 9 retains but simplifies the mixed measurement model and establishes three primary measurement categories for financial assets: amortized cost, fair value through other comprehensive income, and fair value through profit or loss. The basis of classification depends on the entity's business model and the contractual cash flow characteristics of the financial asset. Investments in equity instruments are required to be measured at fair value through profit or loss with the irrevocable option at inception to present changes in fair value in other comprehensive income. Further, the expected credit losses model replaces the incurred loss impairment model used in IAS 39. For financial liabilities, there were no changes to classification and measurement except for the recognition of changes in the Company's own credit risk in other comprehensive income for liabilities designated at fair value through profit or loss. The standard is effective for accounting periods beginning on or after January 1, 2018. Adoption of the standard is not expected to have a material impact on the Company's financial statements.

IFRS 15, "Revenue from Contracts with Customers," which was issued in May 2014, amends revenue recognition requirements and establishes principles for reporting information about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The standard replaces IAS 18, "Revenue" and IAS 11, "Construction Contracts" and related interpretations. The standard is effective for annual periods beginning on or after January 1, 2018. The Company currently does not have any revenues, and will assess the impact of adopting IFRS 15 when relevant.

IFRS 16, "Leases," which was issued in January 2016, 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 standards on the Company's financial statements, and continues to assess the possible impact. The Company will make more detailed assessments 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, 2017 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, 2017				
	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	(216)	(113)	2,376	125	264
Other receivables	(30)	(15)	325	17	36
Trade payables	69	36	(764)	(40)	(85)
Other payables	69	36	(756)	(40)	(84)
Total NIS-linked balances	(108)	(56)	1,181	62	131
Euro-linked trade payables	(94)	(49)	(1,031)	(54)	(115)
Total	(202)	(105)	150	8	16

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

	December 31, 2016				
	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	(33)	(18)	368	19	41
Other receivables	(20)	(11)	223	12	25
Trade payables	40	21	(438)	(23)	(49)
Other payables	82	43	(901)	(47)	(100)
Total NIS-linked balances	69	35	(748)	(39)	(83)
Euro-linked trade payables	36	19	(413)	(21)	(44)
Total	105	54	(1,161)	(60)	(127)

NOTE 3 – FINANCIAL RISK MANAGEMENT (cont.)

a. Market risk (cont.)

1) Concentration of currency risk (cont.)

Set forth below is certain data regarding dollar exchange rates:

	Exchange rate of NIS per $1	Exchange rate of Euro per $1
As of December 31:		
2016	3.845	0.951
2017	3.467	0.835
Percentage increase (decrease) in:		
2016	(1.5)%	3.5%
2017	(9.8)%	(12.2)%

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

	December 31, 2016			December 31, 2017		
	Dollar	NIS	Other currencies	Dollar	NIS	GBP and other
	USD in thousands			USD in thousands		
Assets:						
Current assets:						
Cash and cash equivalents	2,097	368	4	2,623	2,376	111
Short term bank deposits	33,154	-	-	44,373	-	-
Other receivables	-	-	-	117	325	144
Total assets	35,251	591	4	47,113	2,701	255
Liabilities:						
Current liabilities:						
Current maturities of bank loan	93	-	-	93	-	-
Accounts payable and accruals:						
Trade	1,631	438	521	3,018	764	1,734
Other		901	77	99	756	258
Non-current liabilities						
Long-term bank loan, net of current maturities	250	-	-	157	-	-
	1,974	1,340	598	3,367	1,520	1,992
Net asset value	33,277	(749)	(594)	43,746	1,181	(1,737)

NOTE 3 – FINANCIAL RISK MANAGEMENT (cont.)

a. Market risk (cont.)

2) Fair value of financial instruments

As of December 31, 2017, the financial instruments of the Company consist of non-derivative assets and liabilities (primarily working capital items and deposits), as well as warrants classified as a liability.

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

With regard to the warrants classified as a liability, see Note 11c(1) and 11c(2).

3) Exposure to market risk and management thereof

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

4) Interest rate risk

Company management does not consider interest rate risk to be material, as the Company holds deposits and short-term government bonds whose fair value and/or cash flows are not materially affected by changes in interest rates.

b. Credit risk

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

The Company's cash, cash equivalents and short-term bank deposits at December 31, 2016, and 2017 were mainly deposited with highly-rated major Israeli and U.S. banks. In the Company's opinion, the credit risk associated with these balances is remote.

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

	December 31,	
	2016	2017
	in USD thousands	
Assets:		
Cash and cash equivalents	2,469	5,110
Short-term bank deposits	33,154	44,373
Other receivables	223	586
Total	35,846	50,069

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 a number of out-licensing transactions in the past, it cannot determine with reasonable certainty if and when it will become profitable on a current basis. Management believes that the Company's current cash and other resources will be sufficient to fund its projected cash requirements into 2020. Accordingly, in the event that the Company does not generate cash from its operating activities, the Company will need to raise additional capital in the future. Inability to raise additional capital would have a material adverse effect on the financial condition of the Company.

d. Financial instruments

As of December 31, 2016 and 2017, the Company's financial instruments consisted of loans and receivables, and warrants classified as a liability.

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 11c. The fair value of the warrants, which were not traded on an active market, was 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.

In July 2017, the Company completed a direct placement to BVF Partners L.P., its largest shareholder, for aggregate gross proceeds of $9.6 million. The placement consisted of 8,495,575 ADSs, Series A warrants to purchase an additional 2,973,451 ADSs and Series B warrants to purchase an additional 2,973,451 ADSs. See Note 11c(4) for information regarding fair value determination of the warrants at issuance and as of December 31, 2017.

NOTE 4 – CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

As part of the financial reporting process, Company management is required to make estimates that affect the value of assets, liabilities, income, expenses and certain disclosures included in the Company's consolidated financial statements. By their very nature, such estimates are subjective and complex and consequently may differ from actual results.

The accounting estimates used in the preparation of the financial statements are continually evaluated and adjusted based on historical experience and other factors, including expectation of future events that are believed to be reasonable under the circumstances.

Described below are the critical accounting estimates used in the preparation of the financial statements, the formulation of which required Company management to make assumptions as to circumstances and events that involve significant uncertainty. In using its judgment to determine the accounting estimates, the Company takes into consideration, as appropriate, the relevant facts, past experience, the effect of external factors and reasonable assumptions under the circumstances.

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

Development expenses

Development expenses are capitalized in accordance with the accounting policy described in Note 2n. The capitalization of costs is based on management's judgment of technological and economic feasibility, which is usually achieved when a development project reaches a predefined milestone, or when the Company enters into a transaction to sell the know-how that resulted from the development process. In determining the amount to be capitalized, management makes assumptions as to the future anticipated cash inflows from the assets, and the anticipated period of future benefits. Company management has concluded that, as of December 31, 2017, 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 5 – CASH AND CASH EQUIVALENTS

	December 31,	
	2016	2017
	in USD thousands	
Cash on hand and in bank	969	3,960
Short-term bank deposits	1,500	1,150
	2,469	5,110

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

NOTE 6 – SHORT-TERM BANK DEPOSITS

The short-term bank deposits are in US dollars and bear interest at annual rates of between 1.22% and 2.12%.

NOTE 7 – LONG-TERM INVESTMENT

The long-term investment represents the Company's $1.0 million investment, completed in September 2017, in iPharma (H.K.) Limited ("iPharma"), a joint venture with I-Bridge Capital, a Chinese venture capital fund focused on developing innovative therapies in China. iPharma is focusing on the development of innovative clinical and pre-clinical therapeutic candidates to serve the Chinese and global healthcare markets. iPharma expects to raise the funds needed to develop its pipeline primarily from third-party investors.

NOTE 8 – PROPERTY AND EQUIPMENT

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

	Cost				Accumulated depreciation				Net book value 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										
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	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

	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	2015	2016
	In USD thousands				In USD thousands				In USD thousands	
Composition in 2016										
Office furniture and equipment	198	-	-	198	13	12	-	25	185	173
Computers and communications equipment	446	43	-	489	355	53	-	408	91	81
Laboratory equipment	1,194	104	-	1,298	482	188	-	670	712	628
Leasehold improvements	2,025	3	-	2,028	104	201	-	305	1,921	1,723
	3,863	150	-	4,013	954	454	-	1,408	2,909	2,605

NOTE 8 – 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, 2016	December 31, 2017
	In USD thousands				In USD thousands				In USD thousands	
Composition in 2017										
Office furniture and equipment	198	2	-	200	25	35	-	60	173	140
Computers and communications equipment	489	266	-	755	408	30	-	438	81	317
Laboratory equipment	1,298	70	-	1,368	670	159	-	829	628	539
Leasehold improvements	2,028	-	-	2,028	305	214	-	519	1,723	1,509
	4,013	338	-	4,351	1,408	438	-	1,846	2,605	2,505

NOTE 9 – 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	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

	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	2015	2016
	In USD thousands				In USD thousands				In USD thousands	
Composition in 2016										
Intellectual property	193	-	-	193	96	-	-	96	97	97
Computer software	328	57	-	385	273	28	-	301	55	84
	521	57	-	578	369	28	-	397	152	181

	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	2016	2017
	In USD thousands				In USD thousands				In USD thousands	
Composition in 2017										
Intellectual property	193	6,703	-	6,896	96	-	-	96	97	6,800
Computer software	385	182	-	567	301	43	-	344	84	223
	578	6,885	-	7,463	397	43	-	440	181	7,023

NOTE 10 – LONG-TERM BANK LOAN

a. Composition

	December 31,	
	2016	2017
	In USD thousands	
Loan balance	343	250
Less current maturities	(93)	(93)
	250	157

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

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

b. Future repayments

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

2019	93
2020	64
	157

NOTE 11 – EQUITY

a. Share capital

As of December 31, 2016, and 2017 the Company's share capital is composed of ordinary shares, as follows:

	Number of Ordinary Shares	
	December 31,	
	2016	2017
Authorized share capital	150,000,000	250,000,000
Issued and paid-up share capital	57,033,355	105,063,437

	In USD and NIS	
	December 31,	
	2016	2017
Authorized share capital (in NIS)	15,000,000	25,000,000
Issued and paid-up share capital (in NIS)	5,703,336	10,506,344
Issued and paid-up share capital (in USD)	1,513,294	2,836,139

As of December 31, 2017, the market price on NASDAQ of BioLineRx's ADSs was $1.09, and the market price on the Tel Aviv Stock Exchange of BioLineRx's ordinary shares was NIS 3.79.

NOTE 11 – EQUITY (cont.)

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, 2016 and 2017, all outstanding share capital consisted of ordinary shares.

c. Changes in the Company's equity

1) In February 2012, BioLineRx issued as part of private placement, warrants to purchase up to 2,622,157 ADSs at an exercise price of $3.57 per ADS. The warrants were exercisable for a term 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 were therefore 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 two years ended December 31, 2015 and 2016, of approximately $700,000 and $110,000, respectively, have been recorded as non-operating income on the statement of comprehensive loss. The warrants expired in full in February 2017, without being exercised.

   In February 2013, the Company issued as part of a direct placement, warrants to purchase up to 1,600,000 ADSs, at an exercise price of $3.94 per ADS. The warrants were exercisable for a term 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 were therefore 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 changes in fair value for the years ended December 31, 2015 and 2016 of approximately $600,000 and $100,000, respectively, have been recorded as non-operating income on the statement of comprehensive loss. There was no change in fair value in 2017. The warrants expired in full in February 2018, without being exercised.

2) 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.

3) In April 2017, the Company completed an underwritten public offering of 33,823,529 of its ADSs at a public offering price was $0.85 per ADS. The offering raised a total of $28.8 million, with net proceeds of approximately $26.2 million, after deducting fees and expenses.

NOTE 11 – EQUITY (cont.)

4) In July 2017, the Company completed a direct placement to BVF Partners L.P., its largest shareholder, for aggregate gross proceeds of $9.6 million. The placement consisted of 8,495,575 ADSs, Series A warrants to purchase an additional 2,973,451 ADSs and Series B warrants to purchase an additional 2,973,451 ADSs. The Series A warrants have an exercise price of $2.00 per ADS and are exercisable for a term of four years. The Series B warrants have an exercise price of $4.00 per ADS and are also exercisable for a term of four years. Net proceeds from the transaction were approximately $9.5 million, after deducting fees and expenses.

   The warrants issued have been classified as a non-current financial liability due to a net settlement provision. This liability was initially recognized at its fair value on the date the contract was entered into and is subsequently accounted for at fair value at each balance sheet date. The fair value changes are charged to non-operating income and expense in the statement of comprehensive loss.

   The fair value of the warrants is computed using the Black and Scholes option pricing model. The fair value of the warrants upon issuance was computed based on the then current price of an ADS, a risk-free interest rate of 1.66% and an average standard deviation of 57.8%. The fair value of the warrants as of December 31, 2017 was based on the then current price of an ADS, a risk-free interest rate of 2.09% and an average standard deviation of 56.8%.

   The amount of the direct placement consideration initially allocated to the warrants was approximately $1.1 million. Total issuance costs allocable to the warrants were not material. The change in fair value from the date of issuance through December 31, 2017, amounting to approximately $0.1 million, has been recorded as non-operating expense on the statement of comprehensive loss.

5) In October 2017, the Company entered into an at-the-market ("ATM") sales agreement with BTIG, LLC ("BTIG"), pursuant to which the Company may, at its sole discretion, offer and sell through BTIG, acting as sales agent, ADSs having an aggregate offering price of up to $30.0 million throughout the period during which the ATM facility remains in effect. The Company will pay BTIG a commission of 3.0% of the gross proceeds from the sale of ADSs under the facility. From the effective date of the agreement through December 31, 2017, 944,966 ADSs were sold under the program for total net proceeds of approximately $1.0 million, leaving an available balance under the facility of approximately $29.0 million as of December 31, 2017.

NOTE 11 – EQUITY (cont.)

d. Share purchase agreement

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

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

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

During the year ended December 31, 2017, BioLineRx issued a total of 2,124,952 ADSs to LPC for aggregate gross proceeds of $2,130,000. In connection with these issuances, a total of 53,124 ADSs was issued to LPC as a commitment fee and a total of $43,000 was paid to Oberon Securities as a finder's fee.

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

NOTE 11 – EQUITY (cont.)

e. Share-based payments

1) Share Incentive plan – general

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

PSUs represent RSUs that are linked to any one or more performance goals (in addition to, or in lieu of, time-based vesting terms) determined appropriate by the Board of Directors. Once vested, each PSU granted is equivalent to one ordinary share. The specific performance goals, as well as the time period associated with achieving such goals, are approved by the Board and are set forth in the grantee's grant agreement. To date, each PSU grant has had four performance goals on which vesting is based, each such goal being either a specified Company milestone and or the success of a specific project, with vesting of 25% on the achievement of each goal. As of December 31, 2017, it was still not ascertainable whether the performance criteria to which the granted PSUs are linked would be met. The tranche of PSUs associated with a given milestone expires 12 months after the target date established for that milestone.

As of December 31, 2017, there were 10,916,097 ordinary shares issuable upon the exercise of outstanding equity instruments under the Plan.

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

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

In November 2014, December 2015 and December 2017 the Company's Board of Directors approved increases of 1.6 million, 5.0 million and 5.2 million shares, respectively, to the total pool of authorized ordinary shares reserved for purposes of the Plan and any other present or future share incentive plans of the Company, bringing the pool to an aggregate of 14.8 million shares. As of December 31, 2017, there were 3.1 million remaining authorized but unissued ordinary shares in the pool reserved for future share-based incentive grants.

NOTE 11 – EQUITY (cont.)

e. Share-based payments (cont.)

2) Employee share incentive plan:

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

	Year ended December 31,					
	2015		2016		2017	
	Number of options	Weighted average exercise price (in NIS)	Number of options	Weighted average exercise price (in NIS)	Number of options	Weighted average exercise price (in NIS)
Outstanding at beginning of year	3,187,092	9.1	3,500,262	8.7	4,557,927	6.5
Granted*	500,800	6.8	2,505,684	3.8	7,292,560	3.5
Forfeited and expired	(187,630)	11.1	(1,435,990)	7.2	(1,164,961)	6.5
Exercised	-	-	(12,029)	0.4	(34,429)	0.2
Outstanding at end of year	3,500,262	8.7	4,557,927	6.5	10,651,097	4.4
Exercisable at end of year	1,169,540	12.6	1,786,209	9.4	2,356,948	7.6

* As of the December 31, 2016 and 2017, includes 222,428 and 1,178,128 PSUs at an exercise price of 0.10 NIS, for which performance obligations have not been met.

NOTE 11 – EQUITY (cont.)

e. Share-based payments (cont.)

The total consideration received from the exercise of equity instruments during 2015, 2016 and 2017 was not material.

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

	Year ended December 31,					
	2015		2016		2017	
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	2,117,886	5.8	3,502,043	6.5	9,855,697	8.0
10.01-20.00	1,334,866	3.8	1,037,436	2.4	795,400	4.8
20.01-30.00	10,340	0.9	3,278	0.7	-	-
30.01-40.00	10,000	1.6	10,000	0.6	-	-
Over 40.00	27,170	1.0	5,170	0.4	-	-
	3,500,262	5.0	4,557,927	5.5	10,651,097	7.8

The fair value of all other equity instruments granted to employees through December 31, 2017 has been determined using the Black-Scholes option-pricing model. These values are based on the following assumptions as of the applicable grant dates:

	2015	2016	2017
Expected dividend yield	0%	0%	0%
Expected volatility	68%	66%	63%
Risk-free interest rate	2%	2%	2%
Expected life of options (in years)	5	6	6

NOTE 11 – EQUITY (cont.)

e. Share-based payments (cont.)

3) Stock options to consultants

From inception through December 31, 2014, 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.

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

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

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, 2017, 265,000 options to consultants were outstanding with a weighted average exercise price of NIS 4.54 per share and a weighted average contractual life of 8.61 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 2015, 2016 and 2017 amounted to $40,000 each year.

NOTE 12 – TAXES ON INCOME

a. Corporate taxation in Israel

The income of BioLineRx is taxed at the standard Israeli corporate tax rate, which was 26.5% in 2015, 25% in 2016 and 24% in 2017. In December 2016, legislation was enacted to further reduce the Israeli corporate tax rate to 23% for 2018 and thereafter.

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

b. Approved enterprise benefits

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

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

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

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

NOTE 12 – TAXES ON INCOME (cont.)

c. Tax loss carryforwards

As of December 31, 2015, 2016 and 2017, the tax loss carryforwards of BioLineRx were approximately $150 million, $170 million and $210 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 2, paragraph 1.

d. Tax assessments

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

e. Theoretical taxes

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

	Year ended December 31,					
	2015		2016		2017	
		USD in thousands		USD in thousands		USD in thousands
Loss before taxes	26.5%	(14,400)	25.0%	(15,841)	24.0%	(24,352)
Theoretical tax benefit		(3,816)		(3,960)		(5,962)
Disallowed deductions (tax exempt income):						
Loss (gain) on adjustment of warrants to fair value		(342)		(52)		30
Share-based compensation		305		269		369
Other		14		15		21
Increase in taxes for tax losses and timing differences incurred in the reporting year for which deferred taxes were not created		3,839		3,728		5,542
Taxes on income for the reported year		-		-		-

NOTE 13 – LOSS PER SHARE

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

	Year ended December 31,		
	2015	**2016**	**2017**
	In USD thousands		
Loss attributed to ordinary shares	(14,400)	(15,841)	(24,352)
Number of shares used in basic calculation (in thousands)	51,406	56,145	89,971
	in USD		
Basic and diluted loss per ordinary share	(0.28)	(0.28)	(0.27)

NOTE 14 – COMMITMENTS AND CONTINGENT LIABILITIES

a. Commitments

1) Obligation to pay royalties to the State of Israel

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

In accordance with the terms of grants provided by the IIA, the State is entitled to royalties on the sale or license of any product whose development was supported with State participation. These royalties are generally 3% in the first three years from initial repayment, 4% of sales in the three subsequent years and 5% of sales in the seventh year until repayment of 100% of the grants (linked to the dollar) received by the Company, plus annual interest at the LIBOR rate. Under certain circumstances, the royalty rate is calculated according to a formula based on the ratio of participation by the IIA in the project to the total project costs incurred by the Company

In connection with the in-licensing of BL-8040 from Biokine Therapeutics Ltd. (“Biokine”), and as a condition to IIA consent to the transaction, the Company agreed to abide by any obligations resulting from funds previously received by Biokine from the IIA. The contingent liability to the IIA assumed by the Company relating to this transaction amounts to approximately $3.2 million as of December 31, 2017. The Company has a full right of offset for amounts payable to the IIA from payments due to Biokine in the future. Therefore, in the opinion of management, the likelihood of any future Company payment obligation to the IIA with regard to this matter is remote.

NOTE 14 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

2) Licensing agreements

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

The licenses that have been granted to the Company are broad and comprehensive, and generally include various provisions and usage rights as follows: (i) territorial scope of the license (global); (ii) term of the license (unrestricted but not shorter than the life of the patent); and (iii) development of the therapeutic compound (allowing the Company to perform all development activities on its own, or by outsourcing under Company supervision, as well as out-licensing development under the license to other companies, subject to the provisions of the licensing agreements).

According to the provisions of the licensing agreements, the intellectual property rights in the development of any licensed technology, through the date the applicable license agreement is effective, remain with the licensor, while the rights in products and/or other deliverables developed by the Company after the license is granted belong to the Company. In cases where the licensor has a claim to an invention that was jointly developed with the Company, the licensor also co-owns the related intellectual property. In any event, the scope of the license also covers these intellectual property rights.

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

NOTE 14 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

2) Licensing agreements (cont.)

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

The license agreements may be cancelled by the licensor only in specific circumstances, generally upon the occurrence of one of the following events: (a) the Company's failure to meet certain milestones stipulated in the applicable license agreement and appended timetables; (b) default, insolvency, receivership, liquidation, etc. of the Company that is not imposed and/or lifted within the timeframe stipulated in the license agreement; and (c) fundamental breach of the license agreement that is not corrected within the stipulated timeframe. The Company may generally cancel a license agreement with prior notice of 30 to 90 days, due to unsuccessful development or any other cause.

The Company has undertaken to indemnify certain licensors, their employees, officers, representatives or anyone acting on their behalf for any damage and/or expense that they may incur in connection with the Company's use of a license granted to it, all in accordance with the terms stipulated in the applicable license agreements.

Some of the license agreements are accompanied by consulting, support and cooperation agreements, pursuant to which the Company is committed to pay the various licensers a fixed monthly amount over the period stipulated in the agreement for their assistance in the continued research and development under the license.

3) Purchase orders

The Company's outstanding open purchase order commitments as of December 31, 2017 amounted to $6.1 million.

NOTE 14 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

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 $31,000 (including maintenance fees and parking). The Company has the option to extend the lease for 3 additional lease periods totaling up to an additional 10 years, each option at a 5% increase to the preceding lease payment amount.

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

b) The Company has entered into operating lease agreements in connection with a number of vehicles. The lease periods are generally for three years. The annual lease fees, linked to the CPI, are approximately $265,000. To secure the terms of the lease agreements, the Company has made certain prepayments to the leasing companies, representing approximately two months of lease payments. These amounts have been recorded as prepaid expenses. See also Note 16b.

b. Contingent liabilities

To secure the Company's lease obligation on its premises, the Company has provided a bank guarantee in the amount of approximately $100,000 for the benefit of the lessor, which remains outstanding as of December 31, 2017.

See Note 10a regarding equipment pledged as collateral to secure a bank loan.

NOTE 15 – TRANSACTIONS AND BALANCES WITH RELATED PARTIES

Transactions with related parties

Expenses:

	Year ended December 31,		
	2015	**2016**	**2017**
	In USD thousands		
Benefits to related parties:			
Compensation and benefits to senior management, including benefit component of equity instrument grants	1,843	1,912	2,183
Number of individuals to which this benefit related	5	6	6
Compensation and benefits to directors, including benefit component of equity instrument grants	233	316	356
Number of individuals to which this benefit related	7	7	7

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

Transactions with related parties (cont.)

Key management compensation

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

	Year ended December 31,		
	2015	2016	2017
	In USD thousands		
Salaries and other short-term employee benefits	1,412	1,609	1,808
Post-employment benefits	120	129	136
Other long-term benefits	27	30	34
Share-based compensation	517	460	561
	2,076	2,228	2,539

NOTE 16 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

a. Other receivables

	December 31,	
	2016	2017
	In USD thousands	
Institutions	198	446
Other	25	140
	223	586

b. Long-term prepaid expenses

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

NOTE 16 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (cont.)

c. Accounts payable and accruals

	December 31,	
	2016	**2017**
	In USD thousands	
1) Trade:		
Accounts payable:		
Overseas	2,152	4,350
In Israel	438	1,166
	2,590	5,516
2) Other:		
Accrued expenses	560	620
Accrual for vacation and recreation pay	186	215
Payroll and related expenses	217	259
Other	15	19
	978	1,113

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

d. Research and development expenses

	Year ended December 31,		
	2015	**2016**	**2017**
	In USD thousands		
Research and development services	5,455	5,501	12,123
Payroll and related expenses	3,754	3,475	5,097
Lab, occupancy and telephone	926	769	920
Professional fees	772	678	662
Depreciation and amortization	414	452	452
Other	168	302	256
	11,489	11,177	19,510

e. Sales and marketing expenses

	Year ended December 31,		
	2015	**2016**	**2017**
	In USD thousands		
Payroll and related expenses	690	659	817
Marketing	243	600	797
Overseas travel	70	93	79
	1,003	1,352	1,693

NOTE 16 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (cont.)

f. General and administrative expenses

	Year ended December 31,		
	2015	**2016**	**2017**
	In USD thousands		
Payroll and related expenses	2,003	2,172	2,060
Professional fees	1,053	1,144	1,298
Insurance	155	154	210
Depreciation	27	30	29
Other	466	484	440
	3,704	3,984	4,037

g. Non-operating income (expenses), net

	Year ended December 31,		
	2015	**2016**	**2017**
	In USD thousands		
Issuance costs	-	-	(133)
Changes in fair value of warrants	1,292	207	(127)
Cost reimbursement related to prior year	153	-	-
Other	-	7	-
	1,445	214	(260)

h. Financial income

	Year ended December 31,		
	2015	**2016**	**2017**
	In USD thousands		
Interest income and exchange differences	457	469	824
Gain on foreign currency hedging	-	11	345
	457	480	1,169

i. Financial expenses

	Year ended December 31,		
	2015	**2016**	**2017**
	In USD thousands		
Exchange differences	91	8	-
Bank commissions	15	14	21
	106	22	21

NOTE 17 – 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. Under the agreement, Novartis evaluates projects identified and presented by the Company for co-development and future licensing under the collaboration.

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 does not have any governance rights and has agreed to certain standstill provisions. Novartis and the Company jointly evaluate both clinical and pre-clinical stage projects presented by the Company via a Joint Steering Committee, which determines which projects to advance further in development and on what terms. Projects at or reaching the clinical stage are 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 18 – AGREEMENT WITH PERRIGO

In December 2014, the Company entered into an exclusive out-licensing arrangement with Omega Pharma, which was later acquired by Perrigo Company plc. ("Perrigo"), for the rights to BL-5010 for OTC indications in the territory of Europe, Australia and additional selected countries. The Company retains 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 Perrigo, Perrigo is obligated to use commercially reasonable best efforts to obtain regulatory approval in the licensed territory for at least two OTC indications and to commercialize BL-5010 for those two OTC indications. In addition, Perrigo will sponsor and manufacture BL-5010 in the relevant regions. Perrigo 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 19 – AGALIMMUNE ACQUISITION

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

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

Exhibit 4.48

Employment Agreement

This Employment Agreement (this "**Agreement**") is entered into on this 8th day of February, 2018 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 **Hillit Mannor**, whose address is 7 Maharal Street, Tel Aviv 62481 ("**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.

   1.8. Executive acknowledges that the validity of this Agreement is conditioned on its approval by the Compensation Committee and Board of Directors of BioLine and that in the absence of such approvals, this Agreement is null and void. BioLine will inform Executive promptly after the decision of the Board of Directors has been made.

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 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 "**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. **Bonus Plan**

7.1. During the Employment Period, the Executive shall be eligible to receive bonus payments determined in accordance with the terms specified below.

7.2. For the purposes of this section 7:

"**Significant Out-Licensing Deal**" shall mean an agreement between BioLine and a licensee for the out-license or other development and commercialization of a BioLine compound that includes an up-front payment of at least $5,000,000; and

"**Strategic Deal**" shall mean (1) an out-licensing agreement that does not constitute a Significant Out-Licensing Deal, or (2) a partnering or other agreement between BioLine and a third party, designated as strategic by BioLine's CEO in writing and in advance.

7.3. (a) For each Significant Out-Licensing Deal signed and closed, Executive shall be eligible to receive a one-time bonus payment equal to four months' Salary.

(b) For each Strategic Deal signed and closed, Executive shall be eligible to receive a one-time bonus payment equal to two months' Salary.

7.4. The payments payments set forth in section 7.3 shall be payable with a Salary payment following the closure of the deal, and in each case subject to review and approval of BioLine's Board of Directors.

7.5. In addition to the payments set forth in section 7.3, Executive shall be eligible to receive annual or special bonus payments determined in accordance with BioLine's Compensation Policy for Executives and Directors.

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 transfer to the Policy an amount equal to 6.5% for pension payments and disability insurance and 8.33% for severance compensation. If the cost of disability insurance is more than 1.5% of the Salary, the abovementioned 6.5% payment will be increased to a maximum of 7.5% of the Salary. In addition, BioLine shall deduct from the Salary an amount equal to 6% of the Salary and transfer the same to the Policy. In the case of a pension fund, BioLine will transfer an amount equal to 14.833% of the Salary to such Policy, of which 6.5% shall be for pension fund payments and 8.33% shall be for severance compensation, and in addition, BioLine shall deduct from the Salary an amount equal to 6% of the Salary and transfer 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. 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.

8.4. Convalescence. During the Employment Period, Executive shall be entitled to receive convalescence allowance (*Dmei Havra'a*) pursuant to applicable law.

8.5. 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.

8.6. 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.

8.7. 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.

8.8. 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.	**Hillit Mannor**
By: /s/ Philip Serlin	/s/ Hillit Mannor Shachar
Name: Philip Serlin	
Title: Chief Executive Officer	

Exhibit A
Particulars of Employment

1.	Name of Executive:	Hillit Manor
2.	ID No. of Executive	028097525
3.	Address of Executive:	7 Maharal Street, Tel Aviv 62841
4.	Position in BioLine:	Vice President, Business Development
5.	Commencement Date:	April 1, 2018
6.	Notice Period:	60 days
7.	Salary:	NIS 50,000
8.	Equity Compensation	320,000 stock options, subject to Board approval 160,000 performance stock units (PSUs), subject to Board approval
9.	Bonus Plan	As set forth in section 7 of the Employment Agreement
10.	Vacation Days Per Year:	21
11.	Manager's Insurance/Pension Fund	Yes
12.	Disability Insurance	Yes
13.	Advanced Study Fund	Yes
14.	Mobile Phone	Yes
15.	Computer	Yes
16.	Car	Yes, senior manager level

_____ _____

BioLine /s/ Philip Serlin Executive /s/ Hillit Mannor Shachar

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)

None

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 Membersand 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.

[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 8.1

Subsidiaries of BioLineRx Ltd.

Entity Name	Country of Organization
Agalimmune Ltd.	England and Wales

Exhibit 12.1

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

I, Philip A. Serlin, certify that:

1. I have reviewed this annual report on Form 20-F of BioLineRx Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 6, 2018

/s/ Philip A. Serlin
Philip A. Serlin
Chief Executive Officer

Exhibit 12.2

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

I, Mali Zeevi, certify that:

1. I have reviewed this annual report on Form 20-F of BioLineRx Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 6, 2018

/s/ Mali Zeevi
Mali Zeevi
Chief Financial 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, 2017 (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 6, 2018

/s/ Philip A. Serlin
Philip A. Serlin
Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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, 2017 (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 6, 2018

/s/ Mali Zeevi
Mali Zeevi
Chief Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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 and 333-222332) of BioLineRx Ltd. of our report dated March 6, 2018 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 20-F.

Tel-Aviv, Israel
March 6, 2018

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

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel,
P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il