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, 2012**

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)

P.O. Box 45158
19 Hartum Street
Jerusalem 91450, Israel
(Address of principal executive offices)

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19 Hartum Street
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(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 10 ordinary shares, par value NIS 0.01 per share	**Nasdaq Capital Market**
Ordinary shares, par value NIS 0.01 per share	**Nasdaq Capital Market***

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

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

None
(Title of Class)

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

None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report. 183,713,197

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

Yes ☐ No ☒

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

Yes ☐ No ☒

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

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

Yes ☒ No ☐

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

Yes ☐ No ☐

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

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

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

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

Item 17 ☐ Item 18 ☐

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

Yes ☐ No ☒

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

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

Yes ☐ No ☐

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INTRODUCTION

Certain Definitions

In this annual report, unless the context otherwise requires:

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

Forward-Looking Statements

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

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

- the initiation, timing, progress and results of our preclinical studies, clinical trials and other therapeutic candidate development efforts;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials;
- our receipt of regulatory approvals for our therapeutic candidates, and the timing of other regulatory filings and approvals;
- the clinical development, commercialization and market acceptance of our therapeutic candidates;
- our ability to establish and maintain corporate collaborations;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;
- the implementation of our business model and strategic plans for our business and therapeutic candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- competitive companies, technologies and our industry; and
- statements as to the impact of the political and security situation in Israel on our business.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

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

The selected consolidated statements of operations data for the years ended December 31, 2012, 2011 and 2010, and the selected consolidated balance sheet data as of December 31, 2012 and 2011, 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, 2009 and 2008, and the selected consolidated balance sheet data as of December 31, 2010, 2009 and 2008, have been derived from our audited consolidated financial statements not included in this Form 20-F.

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

	Year Ended December 31,					
Consolidated Statements of Operations Data:[1]	**2008**	**2009**	**2010**	**2011**	**2012**	**2012[2]**
			(in thousands, except share and per share data)			
			NIS			**U.S.$**
Revenues	–	63,909	113,160	–	–	–
Cost of revenues	–	(22,622)	(25,571)	–	–	–
Operating expenses:						
Research and development expenses, net	(106,156)	(90,302)	(54,966)	(42,623)	(64,304)	(17,226)
Sales and marketing expenses	–	(3,085)	(4,609)	(3,308)	(3,227)	(864)
General and administrative expenses	(13,083)	(11,182)	(14,875)	(12,722)	(14,026)	(3,757)
Operating income (loss)	(119,239)	(63,282)	13,139	(58,653)	(81,557)	(21,847)
Non-operating income, net	3,658	–	–	–	3,958	1,060
Financial income	13,001	3,928	3,056	12,730	8,819	2,362
Financial expenses	(12,269)	(2,164)	(8,755)	(4,263)	(7,490)	(2,007)
Net income (loss)	(114,849)	(61,518)	7,440	(50,186)	(76,270)	(20,432)
Net earnings (loss) per ordinary share[3]	(1.44)	(0.63)	0.06	(0.41)	(0.45)	(0.12)
Number of ordinary shares used in computing earnings (loss) per ordinary share	78,131,103	96,693,387	123,512,098	123,587,030	169,404,730	169,404,730

	As of December 31,					
Consolidated Balance Sheet Data:	**2008**	**2009**	**2010**	**2011**	**2012**	**2012[2]**
			(in thousands)			
			NIS			**U.S.$**
Cash and cash equivalents	60,379	105,890	111,746	33,061	68,339	18,307
Short-term bank deposits	–	–	28,037	65,782	11,459	3,070
Accounts receivable	–	37,750	–	–	-	-
Property, plant and equipment, net	5,484	4,175	4,509	4,211	3,172	850
Total assets	115,728	159,167	154,613	111,660	90,808	24,326
Total liabilities	37,342	41,230	22,653	25,902	34,879	9,343
Total shareholders' equity	78,386	117,937	131,960	85,758	55,929	14,983

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

(2) Calculated using the exchange rate reported by the Bank of Israel for December 31, 2012 at the rate of one U.S. dollar per NIS 3.733.

(3) The net loss per share was adjusted to reflect the benefit component related to the issuance of rights to investors in 2009.

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

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

	NIS per U.S. $			
Year Ended December 31,	**High**	**Low**	**Average**	**Period End**
2012	4.084	3.700	3.844	3.733
2011	3.821	3.363	3.578	3.821
2010	3.894	3.549	3.730	3.549
2009	4.256	3.690	3.923	3.775
2008	4.022	3.230	3.586	3.802

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

	NIS per U.S. $			
Month	**High**	**Low**	**Average**	**Period End**
March 2013 (through March 5, 2013)	3.733	3.723	3.728	3.732
February 2013	3.733	3.663	3.693	3.708
January 2013	3.791	3.714	3.739	3.728
December 2012	3.835	3.726	3.777	3.733
November 2012	3.952	3.810	3.894	3.810
October 2012	3.895	3.792	3.851	3.878
September 2012	4.029	3.887	3.959	3.912

On March 11, 2013, the closing representative rate was $1.00 to NIS 3.690, as reported by the Bank of Israel.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

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

Risks Related to Our Financial Condition and Capital Requirements

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

We are a clinical stage biopharmaceutical development company that was incorporated in 2003. Since our incorporation, we have been focused on research and development. Our most advanced therapeutic candidates are in clinical development. We, or our licensees, as applicable, will be required to conduct significant additional clinical trials before we or they can seek the regulatory approvals necessary to begin commercial sales of our therapeutic candidates. We have incurred losses since inception, principally as a result of research and development and general administrative expenses in support of our operations. We recorded a net loss of approximately NIS 76.3 million in 2012, a net loss of approximately NIS 50.2 million in 2011 and net income of approximately NIS 7.4 million in 2010. As of December 31, 2012, we had an accumulated deficit of approximately NIS 444.3 million. We anticipate that we will incur significant additional losses as we continue to focus our resources on prioritizing, selecting and advancing our most promising therapeutic candidates. We may never be profitable and we may never achieve significant sustained revenues.

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

We believe that our existing cash and investment balances and other sources of liquidity, not including potential milestone payments under our out-licensing agreement with Ikaria, will be sufficient to meet our requirements through the end of 2014. We have funded our operations primarily through public (in Israel) and private/direct offerings of our securities, and grants from the Office of the Chief Scientist of Israel's Ministry of Industry, Trade and Labor, or the OCS. In addition, we have funded our operations through out-licensing arrangements with respect to our therapeutic candidates. We have entered into an out-licensing arrangement with Ikaria in connection with our BL-1040 therapeutic candidate. Although we had out-licensed to Cypress Bioscience, Inc., or Cypress Bioscience, certain development and commercial rights with respect to our BL-1020 therapeutic candidate, we reacquired the rights from Cypress Bioscience in May 2011. The adequacy of our available funds to meet our operating and capital requirements will depend on many factors including: the number, breadth, progress and results of our research, product development and clinical programs; the costs and timing of obtaining regulatory approvals for any of our therapeutic candidates; the terms and conditions of in-licensing and out-licensing therapeutic candidates; and costs incurred in enforcing and defending our patent claims and other intellectual property rights.

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

Our limited operating history makes it difficult to evaluate our business and prospects.

We have a limited operating history and our operations to date have been limited to organizing and staffing our company, conducting product development activities for our therapeutic candidates and performing research and development with respect to our preclinical programs. We have not yet demonstrated an ability to obtain regulatory approval for or to commercialize a therapeutic candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products or medical devices.

Risks Related to Our Business and Regulatory Matters

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

To date, we have not marketed, distributed or sold an approved product. Currently, we have six clinical-stage therapeutic candidates in development: BL-1020 for the treatment of schizophrenia; BL-1040 for the reduction or prevention of ventricular remodeling following acute myocardial infarctions, or AMI; BL-5010 for the treatment of skin lesions; BL-7040 for the treatment of inflammatory bowel disease, or IBD; BL-8040 for the treatment of acute myeloid leukemia, or AML, and other hematological cancers; and BL-1021 for the treatment of neuropathic pain. Our therapeutic candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization of drugs and devices. We may not obtain marketing approval for any of our therapeutic candidates in a timely manner or at all. In connection with the clinical trials for BL-1020, BL-1040, BL-5010, BL-7040, BL-8040, BL-1021, 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 arrangements, we face the risk that:

- a therapeutic candidate or medical device may not prove safe or efficacious;

- the results with respect to any therapeutic candidate may not confirm the positive results from earlier preclinical studies or clinical trials;
- the results may not meet the level of statistical significance required by the U.S. Food and Drug Administration, or FDA, or other regulatory authorities; and
- the results will justify only limited and/or restrictive uses, including the inclusion of warnings and contraindications, which could significantly limit the marketability and profitability of the therapeutic candidate.

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

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. In 2009, we entered into an exclusive, royalty-bearing worldwide out-licensing arrangement with Ikaria with respect to BL-1040. Under the arrangement, Ikaria is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or a product related thereto. In May 2011, we reacquired from Cypress Bioscience all out-licensed development and commercialization rights to BL-1020. Unless we enter into an out-licensing arrangement with a new partner with respect to BL-1020, we may elect to develop and commercialize BL-1020 internally.

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.

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

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

- we may not be able to control the amount and timing of resources that our licensees devote to our therapeutic candidates;
- our licensees may experience financial difficulties;
- our licensees may fail to secure adequate commercial supplies of our therapeutic candidates upon marketing approval, if at all;
- our future revenues will 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, including Ikaria, 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.

If we are unable to enter into agreements with third parties to develop, market and commercialize our therapeutic candidates, we may not generate product revenue.

We plan to develop, market and commercialize our therapeutic candidates primarily through out-licensing arrangements or, when appropriate, by ourselves. The preclinical and clinical development of our therapeutic candidates, even if undertaken through licensing arrangements with third parties, will require that we expend significant funds and will be subject to the risks of failure inherent in the development of pharmaceutical products. In order to successfully commercialize any of our therapeutic candidates that may be approved in the future by the FDA or other regulatory authorities, we must enter into out-licensing arrangements with third parties to perform these services for us or build internal sales and marketing capabilities. Our ability to commercialize our therapeutic candidates will depend on our ability to:

- attract suitable licensees on reasonable terms;
- obtain and maintain necessary intellectual property rights to our therapeutic candidates;
- where appropriate, enter into arrangements with third parties to manufacture our products, if any, on our behalf; and
- deploy sales and marketing resources effectively or enter into arrangements with third parties to provide these services.

If we are unable to enter into an out-licensing arrangement with respect to BL-1020, BL-5010, BL-7040, BL-8040, BL-1021 or any of our other therapeutic candidates, whether with third parties or independently, our ability to develop a commercially viable product or generate product revenue based on the therapeutic candidate will be adversely affected, and we may not become profitable. We face significant competition in seeking out-licensing arrangements with third parties. We may not be able to negotiate out-licensing arrangements on acceptable terms, if at all. In addition, these out-licensing arrangements may be unsuccessful. If we fail to negotiate and maintain suitable out-licensing arrangements, we may have to limit the size or scope of, or delay, one or more of our development or research programs. If we elect to fund development or research programs independently, we will have to increase our expenditures significantly and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms. We will also need to make significant investments in pharmaceutical product development, marketing, sales and regulatory compliance resources, and we will have to establish or contract for the manufacture of products under applicable regulatory requirements. Any failure to enter into an out-licensing arrangement with respect to the development, marketing and commercialization of any therapeutic candidate, or failure to develop, market and commercialize the therapeutic candidate independently, will 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.

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

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

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

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

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

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

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

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

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address the indications for which we are currently developing therapeutic candidates or for which we may develop therapeutic candidates in the future. Specifically, we are aware of several other companies who currently market and/or are in the process of developing products that address schizophrenia, AMI, skin lesions, IBD, AML and neuropathic pain. There are a number of treatments currently marketed for schizophrenia patients, including atypical anti-psychotics from Johnson & Johnson, Eli Lilly and Company, AstraZeneca, Bristol-Myers Squibb/Otsuka Pharmaceutical Co., Ltd., Pfizer Inc. and others. In addition, there are a number of generic brands of typical and atypical anti-psychotics available for commercial use. We are also aware of a number of potentially competitive compounds under development to treat schizophrenia including: Cariprazine, which is being developed by Forest Laboratories, Inc. and Gedeon Richter; Lurasidone, which is being developed by Dainippon Sumitomo Pharma Co., Ltd. together with Takeda Pharmaceutical Co.; EVP-6124 which is being developed by EnVivo Pharmaceuticals; zicronapine, which is being developed by Lundbeck; bitopertin, which is being developed by Roche and Chugai; and Vyvanse (lisdexamfetamine), which is being developed by Shire. There are a number of therapies currently in development that aim at preventing ventricular remodeling and subsequent congestive heart failure (CHF), including BioHeart, Inc.'s MyoCell® implantation procedure and Paracor Medical, Inc.'s HeartNet™. Skin lesions are generally removed using cryotherapy (liquid nitrogen), laser therapy, photodynamic therapy, electrodessication and curettage and several cream-based treatments. Picato (Leo Pharma) and Metvix® Galderma Pharma SA are cream-based treatments for skin lesions which have been approved in many countries. IBD is often treated with currently marketed steroids, immunomodulators and anti-TNFs (tumor necrosis factors). Approved treatments for IBD currently include anti-TNFs, such as Remicade (infliximab, Janssen Biotech, Inc., a Johnson & Johnson company, Merck & Co. and Mitsubishi Tanabe Pharma) and Humira (adalimumab, Abbott Laboratories and Eisai Co.), in addition to generic brands of mesalazine, a 5-aminosalicylate. Additional market leaders are Cimzia (certolizumab, UCB, Inc.), an anti-TNF, and Tysabri (natalizumab, Biogen Inc.), an integrin inhibitor. We are also aware of a number of potentially competitive compounds under development, including Simponi (golimumab, Janssen Biotech, Inc., Merck & Co. and Mitsubishi Tanabe Pharma), a TNF inhibitor, Xeljanz (tofacitinib, Pfizer Inc.), a Jak 1 inhibitor, and Budesonide MMX (Cosmo Pharmaceuticals, Ferring Pharmaceuticals and Santarus, Inc.). Approved treatments for AML currently include chemotherapy (Doxorubicin, Arsenic dioxide, Cyclophosphamide, Vincristine), radiation therapy and stem cell transplantation. In addition there are a number of potentially competitive compounds under development to treat AML including: AMD 3100 (Mozobil), which is being developed by Genzyme and Sanofi; Dacogen (decitabine), which is being developed by Eisai and J&J; Vidaza (azacitidine), which is being developed by Celgene; Elacytarabine, which is being developed by Clavis Pharma; Vosaroxin, which is being developed by Sunesis Pharmaceuticals; and Fludarabine, which is being developed by Schering. The neuropathic pain market leaders are anticonvulsants, such as Lyrica (Pregabalin, Pfizer) and the generic Gabapentin, together with off-label brands. Additional market leaders are Cymbalta (duloxetine; Eli Lilly/Shionogi), Lidoderm (5% lidocaine patch; Endo/Grünenthal), Qutenza (8% capsaicin patch; NeurogesX/Astellas) and Gralise (extended-release Gabapentin; Depomed). We are also aware of a number of potentially competitive compounds under development, including Nucynta ER (Tapentadol ER; Grünenthal/Johnson & Johnson), DM-1796 (Gabapentin GR; Depomed/Abbott), Horizant (Gabapentin enacarbil; XenoPort/GlaxoSmithKline/Astellas Pharma Inc.), AmiKet (amitriptyline and ketamine; EpiCept), AVP-923 (dextromethorphan hydrobromide/quinidine sulfate; IriSys/Avanir) and Ralfinamide (Newron).

Any therapeutic candidates we may develop in the future are also likely to face competition from other drugs and therapies.

Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing and in obtaining regulatory approvals for drugs. These companies also have significantly greater research and marketing capabilities than we do. If our competitors market products that are more effective, safer or less expensive than our future therapeutic candidates, if any, or that reach the market sooner than our future therapeutic candidates, if any, we may not achieve commercial success.

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

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

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

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

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

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

If we are required to manufacture any of our therapeutic candidates in the future in connection with phase 3 clinical trials or for commercialization, we will be required to incur significant costs and devote significant efforts to establish and maintain manufacturing capabilities.

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

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

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

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

An important element of our strategy is maintaining relationships with universities, medical institutions and biotechnology companies in order to in-license potential therapeutic candidates. We may not be able to maintain relationships with these entities and they may elect not to enter into in-licensing agreements with us or to terminate existing agreements. 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 certain of our therapeutic candidates. We have in-licensed rights from Bar Ilan University (through Bar Ilan Research and Development Company Ltd., or Bar Ilan Research and Development), and Ramot at Tel Aviv University Ltd., or Ramot, with respect to our BL-1020 and BL-1021 therapeutic candidates, from B.G. Negev Technologies and Applications Ltd., the technology transfer company of Ben Gurion University, or B.G. Negev Technologies, with respect to our BL-1040 therapeutic candidate, from Innovative Pharmaceutical Concepts, Inc., or IPC, with respect to our BL-5010 therapeutic candidate, from the Yissum Research Development Company of the Hebrew University of Jerusalem Ltd., or Yissum, with respect to our BL-7040 therapeutic candidate and from Biokine Therapeutics Ltd., or Biokine, with respect to our BL-8040 therapeutic candidate. See "Business — Our Product Pipeline." Our in-license agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these agreements. The royalty rates and revenue sharing payments vary from case to case but generally range from 20% to 29.5% of the consideration we receive from sublicensing the applicable therapeutic candidate. In some instances, we are required to pay a substantially lower percentage (generally less than 5%) if we elect to commercialize the subject therapeutic candidate independently. Due to the relatively advanced stage of development of the compound licensed from Biokine, our license agreement with Biokine provides for royalty payments of between 40-60% of the consideration we receive from sublicensing and between 10-12% of net sales, subject to certain limitations, should we independently sell products. The amount of the royalty for either direct sales or sublicensing is dependent on the aggregate amount of our investment in connection with the Biokine agreement, decreasing as the amount of our investment in the project increases. 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.

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

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

- restrictions on such product, manufacturer or manufacturing process;

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

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

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.

Risks Related to Our Industry

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

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

- difficulty in large-scale manufacturing;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our business exposes us to significant potential clinical trial and product liability risks that are inherent in the development, manufacturing and sales and marketing of human therapeutic products. Although we do not currently commercialize any products, claims could be made against us based on the use of our therapeutic candidates in clinical trials. We currently carry life science liability insurance covering general liability with a coverage amount of $10.0 million per occurrence, products liability with an annual coverage amount of $5.0 million in the aggregate, and clinical trial insurance with a coverage amount of $10.0 million in the aggregate. The maximum indemnity for a single occurrence or circumstances under this policy is $10.0 million. In addition to this policy, we carry excess liability insurance with a coverage amount of $5.0 million which increases the coverage limit provided by our life science insurance package. However, our insurance may not provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage or obtain additional or sufficient insurance at a reasonable cost to protect against losses that could have a material adverse effect on us. If a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as damages awards beyond the coverage of our insurance policies resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any claims, we might be required to direct significant financial and managerial resources to such defense, and adverse publicity is likely to result.

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

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

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

Risks Related to Intellectual Property

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

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

We currently have in-licensing agreements relating to our lead therapeutic candidates under clinical development. In April 2004, we in-licensed the rights to BL-1020 and BL-1021, and one other compound, under a research and license agreement with Bar Ilan Research and Development and Ramot. Under the research and license agreement, we are obligated to use commercially reasonable efforts to develop, commercialize and market the licensed technology, including meeting certain specified diligence goals. In January 2005, we in-licensed the rights to BL-1040 under a license agreement with B.G. Negev Technologies. Under the BL-1040 license agreement, we are obligated to use commercially reasonable efforts to develop the licensed technology in accordance with a specified development plan, including meeting certain specified diligence goals. In November 2007, we in-licensed the rights to develop and commercialize BL-5010 under a license agreement with IPC. Under the IPC license agreement, we are obligated to use commercially reasonable efforts to develop the licensed technology in accordance with a specified development plan, including meeting certain specified diligence goals. In June 2011, we in-licensed the rights to develop, have developed, manufacture, have manufactured, use, market, distribute, export, import and/or sell BL-7040 under a license agreement from Yissum. Under the BL-7040 license agreement, we are responsible for, and are required to exert, reasonable commercial efforts to carry out the development, regulatory, manufacturing, and marketing work necessary to develop and commercialize products under the agreement in accordance with a specified development plan. In September 2012, we in-licensed the rights to BL-8040 under a license agreement from Biokine. Under the BL-8040 license agreement, we are obligated under the agreement to make commercially reasonable good faith efforts to sublicense or commercialize BL-8040 for fair consideration.

Each of the foregoing in-licensing agreements, or the obligation to pay royalties thereunder, will generally remain in effect until the expiration, under the applicable agreement, of all of the licensing, royalty and sublicense revenue obligations to the applicable licensors, determined on a product-by-product and country-by-country basis. We may terminate any in-licensing agreement by providing 60 days' prior written notice to Ramot, in the case of the BL-1020/BL-1021 in-licensing agreement or to B.G. Negev Technologies, in the case of the BL-1040 in-licensing agreement. We may terminate the BL-5010 in-licensing agreement or the BL-7040 in-licensing agreement upon 30 days' prior written notice. We may terminate the BL-8040 licensing agreement upon 90 days' prior written notice to Biokine.

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. Notwithstanding the foregoing, in the case of the BL-1020 in-licensing agreement, Ramot, but not Bar Ilan Research and Development, has the right to provide us with notice of material breach and to terminate the agreement if such breach is not cured within the applicable timeframe. In addition, with respect to the BL-1040 in-licensing agreement, the breaching party is entitled to 60 days' prior written notice of the material breach prior to termination instead of 30 days. Each of the foregoing in-licensing agreements provide that with respect to any termination for material breach, if the breach is not susceptible to cure within the stated period and the breaching party uses diligent, good faith efforts to cure such breach, the stated period will be extended by an additional 30 days. In addition, either party to one of the foregoing in-licensing agreements (except Bar Ilan Research and Development, in the case of the BL-1020 in-licensing agreement) may terminate the agreement upon notice to the other upon the occurrence of certain bankruptcy events.

Patent protection for our products is important and uncertain.

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

We try to protect our proprietary position by, among other things, filing U.S., European, Israeli and other patent applications related to our proprietary products, technologies, inventions and improvements that may be important to the continuing development of our therapeutic candidates. As of December 31, 2012, we owned or exclusively licensed for uses within our field of business 23 patent families that, collectively, contain 60 issued patents, seven allowed patent applications and 86 patent applications relating to our six clinical candidates. We are also pursuing patent protection for other drug candidates in our pipeline.

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

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

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

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

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

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

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

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

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

Our license agreement with Ikaria contains, 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.

The intellectual property associated with certain of our therapeutic candidates is pledged as security for our obligations associated with the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor's biotechnology incubator program.

In May 2004, the OCS invited companies to bid to establish and operate OCS-funded biotechnological incubators to provide a physical, organized and professional platform for commercializing biotechnological research and development projects. We submitted a proposal to operate a biotechnological incubator, and our proposal was selected by the OCS. Accordingly, we entered into an incubator agreement with the OCS in January 2005. The initial agreement was scheduled to expire on December 31, 2010 but at the end of 2010, the OCS agreed to renew the agreement for an additional two years, with an option to renew for another one-year period at the same terms and conditions, subject to OCS approval. In 2012, the OCS approved our exercise of the option to extend the incubator agreement for the final one-year period through December 31, 2013.

The funding provided to us under the incubator agreement is in the form of separate loans for each approved project initiated by our incubator. Each loan is subject to repayment solely out of the revenues generated by that project. If revenues are not achieved with respect to a project, the loan for the project will be forgiven, subject to certain terms and conditions. If revenues are achieved with respect to a project, the loans will be repaid from such revenues, with interest. The interest rates for the loans are prescribed by the OCS at the commencement of each loan, and range from 3.11% to 5.34%, but are doubled if the loan is not repaid within five years of our achievement of certain development milestones, or within two years following the completion of the applicable incubator program. All intellectual property held by our incubator for development through the incubator program is pledged as security for our obligations under the incubator agreement. If we are unable to meet our obligations under the incubator agreement, the intellectual property held by the incubator would be subject to seizure and would not be available for sale for the benefit of or distribution to our creditors or shareholders in the event of a reorganization or insolvency. Any loss of the rights to the intellectual property held by our incubator may have a material adverse effect on our business and prospects. In addition, all intellectual property held by the incubator program is subject to restrictions imposed by the OCS with respect to transfer abroad of rights to manufacture products based on the intellectual property or of rights to the intellectual property itself, as described more fully under "Item 4. Information on the Company — Business Overview — Government Regulation and Funding — Israeli Government Programs — Office of the Chief Scientist."

Risks Related to our Ordinary Shares and ADSs

We may be a passive foreign investment company, or PFIC, for U.S. federal income tax purposes in 2013 or in any subsequent year. There may be negative tax consequences for U.S. taxpayers that are holders of our ordinary shares or our ADSs.

We will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (i) at least 75% of our gross income is "passive income" or (ii) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account. We believe that we were a PFIC during certain prior years and, although we have not determined whether we will be a PFIC in 2013, or in any subsequent year, our operating results for any such years may cause us to be a PFIC. If we are a PFIC in 2013, or any subsequent year, and a U.S. shareholder does not make an election to treat us as a "qualified electing fund," or QEF, or make a "mark-to-market" election, then "excess distributions" to a U.S. shareholder, and any gain realized on the sale or other disposition of our ordinary shares or ADSs will be subject to special rules. Under these rules: (i) the excess distribution or gain would be allocated ratably over the U.S. shareholder's holding period for the ordinary shares (or ADSs, as the case may be); (ii) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (iii) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, if the U.S. Internal Revenue Service, or the IRS, determines that we are a PFIC for a year with respect to which we have determined that we were not a PFIC, it may be too late for a U.S. shareholder to make a timely QEF or mark-to-market election. U.S. shareholders who hold our ordinary shares or ADSs during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to exceptions for U.S. shareholders who made a timely QEF or mark-to-market election. A U.S. shareholder can make a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. A QEF election generally may not be revoked without the consent of the IRS. Upon request, we will annually furnish U.S. shareholders with information needed in order to complete IRS Form 8621 (which form would be required to be filed with the IRS on an annual basis by the U.S. shareholder) and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC.

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

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

- announcements of technological innovations or new products by us or others;
- announcements by us of significant acquisitions, strategic partnerships, in-licensing, out-licensing, joint ventures or capital commitments;

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

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

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

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

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

In February 2012, we issued an aggregate of 5,244,301 of our ADSs for a purchase price of $2.86 per ADS. Purchasers also received an aggregate of 2,622,157 five-year warrants to purchase ADSs at an exercise price of $3.57 per ADS.

In September 2012, we signed a purchase agreement for the sale, from time to time, of up to $15 million of our ADSs to Lincoln Park Capital Fund, LLC, or LPC. During the 36-month term of the purchase agreement, we control the timing and amount of any sales to LPC, if and when we decide, in accordance with the purchase agreement. LPC has no right to require us to sell any ADSs to LPC, but LPC is obligated to make purchases as we direct, subject to certain conditions. The purchase price related to any sales to LPC will be based on the prevailing market prices of our ADSs immediately preceding the notice of sale to LPC, without any fixed discount. The agreement may be terminated by us at any time, at our sole discretion, without any cost or penalty. On a cumulative basis through March 5, 2013, we have issued a total of 1,568,811 ADSs to LPC in accordance with the purchase agreement, and there are an additional 2,629,787 ADSs registered for sale under the agreement that may be issued during the remaining term of the purchase agreement.

In February 2013, we issued 2,666,667 of our ADSs to OrbiMed Israel Partners Limited Partnership, or OrbiMed, for a purchase price of $3.00 per ADS. OrbiMed also received 1,600,000 five-year warrants to purchase ADSs at an exercise price of $3.94 per ADS.

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

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

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

- the failure to obtain regulatory approval or achieve commercial success of our therapeutic candidates, including BL-1020, BL-1040, BL-5010 and BL-7040, BL-8040 and BL-1021;
- our success in effecting out-licensing arrangements with third-parties;
- our success in establishing other out-licensing 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."

Risks Associated with the Nasdaq Listing of our ADSs

Our ordinary shares and our ADSs are traded on different markets and this may result in price variations.

Our ordinary shares have been traded on the TASE since February 2007. Our ADSs have been listed on the Nasdaq Capital Market since July 2011. Trading in our securities on these markets takes place in different currencies (dollars on the Nasdaq Capital Market and NIS on the TASE), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Israel). The trading prices of our securities on these two markets may differ due to these and 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.

We have incurred additional increased costs as a result of the listing of our ADSs for trading on the Nasdaq, and we may need to devote substantial resources to address new compliance initiatives and reporting requirements.

As a public company in the United States, we incur additional significant accounting, legal and other expenses as a result of listing our ADSs on the Nasdaq. These include costs associated with corporate governance requirements of the SEC and the Marketplace Rules of the Nasdaq, as well as requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. These rules and regulations have increased our legal and financial compliance costs, introduced new costs such as investor relations, stock exchange listing fees and shareholder reporting, and made some activities more time consuming and costly. Any future changes in the laws and regulations affecting public companies in the United States and Israel, including Section 404 and other provisions of the Sarbanes-Oxley Act, the rules and regulations adopted by the SEC and the Marketplace Rules of the Nasdaq, as well as applicable Israeli reporting requirements, for so long as they apply to us, will result in increased costs to us as we respond to such changes. These laws, rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our board committees or as executive officers.

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

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

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

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

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

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

Risks Related to our Operations in Israel

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

Our headquarters, all of our operations and some of our suppliers and third party contractors are located in central Israel and our key employees, officers and most of our directors are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could adversely affect our operations and results of operations and could make it more difficult for us to raise capital. During the summer of 2006, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party; and during the winter of 2008-2009 and the autumn of 2012, Israel was engaged in armed conflicts with Hamas, a militia group and political party operating in the Gaza Strip. These conflicts involved missile strikes against civilian targets in various parts of Israel, and negatively affected business conditions in Israel. Recent political uprisings and social unrest in various countries in the Middle East and North Africa are affecting the political stability of those countries. This instability may lead to deterioration of the political relationships that exist between Israel and these countries, and have raised concerns regarding security in the region and the potential for armed conflict. Among other things, this instability may affect the global economy and marketplace through changes in oil and gas process. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations. For example, any major escalation in hostilities in the region could result in a portion of our employees being called up to perform military duty for an extended period of time. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in the agreements.

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

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

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

Many of our male employees in Israel, including members of our senior management, are obligated to perform one month, and in some cases more, of annual military reserve duty until they reach the age of 45 (or older, for reservists with certain occupations) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists, and recently some of our employees have been called up in connection with armed conflicts. It is possible that there will be military reserve duty call-ups in the future. Our operations could be disrupted by the absence of a significant number of our employees or of one or more of our key employees. Such disruption could materially adversely affect our business, financial condition and results of operations.

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

Our reporting and functional currency is the NIS, and we pay a substantial portion of our expenses in NIS. The revenues from our arrangements with Ikaria are payable in U.S. dollars and we expect our revenues from future licensing arrangements to be denominated in U.S. dollars or in Euros. As a result, we are exposed to the currency fluctuation risks relating to the recording of our revenues in NIS. For example, if the NIS strengthens against either the U.S. dollar or the Euro, our reported revenues in NIS may be lower than anticipated. The Israeli rate of inflation has generally not offset or compounded the effects caused by fluctuations between the NIS and the U.S. dollar or the Euro. To date, we have not engaged in hedging transactions. Although the Israeli rate of inflation has not had a material adverse effect on our financial condition during 2010, 2011 or 2012, we may, in the future, decide to enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of the currencies mentioned above in relation to the NIS. These measures, however, may not adequately protect us from material adverse effects.

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

Our research and development efforts, including the operation of our biotechnology incubator, have been financed, in part, through grants and loans that we have received from the OCS. Of our 12 current development projects, five have been or are approved to be funded by the OCS, either directly or through our incubator: BL-1020, BL-1021, BL-1040, BL-5040 BL-7040. Of the five projects funded by the OCS, four have been or are approved to be funded through our incubator. We therefore must comply with the requirements of the Israeli Law for the Encouragement of Industrial Research and Development, 1984, and related regulations, or the Research Law. As of December 31, 2012, we have received approximately NIS 75.9 million ($20.3 million) in funding from the OCS, of which approximately NIS 53.7 million ($14.4 million) was funding provided to our biotechnology incubator. The aggregate funding amount includes funding of approximately NIS 34.1 million ($9.1 million) for projects that have been terminated, which we will not be required to repay. When know-how, technology or products are developed using OCS grants, the terms of these grants and the Research Law restrict the transfer of that know-how (as well as know-how that is derived from funded know-how) and the development or manufacture of those products out of Israel without the prior approval of the OCS. Therefore, the discretionary approval of an OCS committee will be required for any transfer to third parties of our therapeutic candidates developed with OCS funding, for the purpose of the commercialization of our product candidates. There is no assurance that we will receive the required approvals should we wish to transfer this technology or development out of Israel in the future. Furthermore, the OCS committee may impose certain conditions on any arrangement under which we transfer technology or development out of Israel. Transfers of know-how from OCS funded programs, including our biotechnology incubator, even if approved by the OCS, may be subject to restrictions set forth in the Research Law, and may include payments to the OCS, as described more fully under "Item 4. Information on the Company — Business Overview — Government Regulation and Funding — Israeli Government Programs — Office of the Chief Scientist."

The transfer abroad of the manufacturing of any OCS-supported product or technology is also subject to various conditions, including the payment of increased royalties equal to, in the aggregate, up to 300% of the total grant amounts received in connection with the product or technology, plus interest, depending on the portion of total manufacturing that is performed outside of Israel. Payment of the increased royalties would constitute the repayment amount required with respect to the OCS grants received for the development of the products or technology for which the manufacturing is performed outside of Israel. In addition, any decrease in the percentage of manufacture performed in Israel of any product or technology, as originally declared in the application to the OCS with respect to the product or technology, may require us to notify, or to obtain the approval of, the OCS, and may result in increased royalty payments to the OCS of up to 300% of the total grant amounts received in connection with the product or technology, plus interest, depending on the portion of total manufacturing that is performed outside of Israel. These restrictions may impair our ability to sell our technology assets or to outsource or transfer development or manufacturing activities with respect to any product or technology. These restrictions continue to apply even after we have repaid any grants, in whole or in part, unless otherwise agreed by the designated OCS committee.

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

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

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, a majority of each class of securities of the target company must approve a merger. Moreover, a full tender offer can only be completed if the acquirer receives 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, petition the court to alter the consideration for the acquisition (unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights).

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

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

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

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

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

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

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

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

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

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

Our capital expenditures for the years ended December 31, 2010, 2011 and 2012 were $0.5 million, $0.3 million and $0.2 million, respectively. Our current capital expenditures involve acquisitions of laboratory equipment, computers and communications equipment.

B. Business Overview

We are a clinical stage biopharmaceutical development company dedicated to identifying, in-licensing and developing therapeutic candidates that have advantages over currently available therapies or that address unmet medical needs. Our current development pipeline consists of six clinical-stage therapeutic candidates: BL-1020, an orally available drug that we believe may be the first antipsychotic therapeutic to improve cognitive function in schizophrenia patients; BL-1040, a novel polymer solution for use in the prevention of ventricular remodeling following an acute myocardial infarction, or AMI; BL-5010, a customized, proprietary, pen-like applicator containing a novel formulation of two acids, which is being developed in Europe as a medical device for the non-surgical removal of skin lesions; BL-7040, an oligonucleotide for the treatment of inflammatory bowel disease, or IBD; BL-8040, a peptide for the treatment of Acute Myeloid Leukemia (AML) and other hematological cancers; and BL-1021, a new chemical entity in development for the treatment of neuropathic pain, or pain that results from damage to nerve fibers. In addition, we have six therapeutic candidates in the preclinical stages of development. We generate our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. None of our therapeutic candidates have been approved for marketing and, to date, there have been no commercial sales of any of our therapeutic candidates. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies. We also evaluate, on a case by case basis, co-development and similar arrangements and the commercialization of our therapeutic candidates independently.

Our first lead therapeutic candidate, BL-1020, is in development for schizophrenia, a chronic, severe and disabling brain disorder that affects approximately 1.0% of the U.S. adult population as reported by the National Institute of Mental Health. Schizophrenia patients are typically treated with one of several commercially available antipsychotics, all of which are associated with side effects that reduce patient compliance and do not address the deterioration of cognitive function that affects the daily lives of schizophrenia patients. Despite these drawbacks, according to a recent IMS Health report, the spending in the United States on antipsychotics in 2011 was estimated at $18.2 billion. IMS Heath estimated that global spending on antipsychotics could reach $22-25 billion by 2016.

BL-1020 is an orally available drug that effectively reduces psychotic symptoms which we believe may also improve cognition. BL-1020 targets the imbalance of two key neurotransmitters implicated in schizophrenia, dopamine and gamma aminobutyric acid, or GABA. We believe that the reduction in psychotic symptoms is attributed to BL-1020's dopamine antagonism and that the GABAergic activity of the BL-1020 molecule may be involved in improving patient cognition.

In our 363-patient phase 2b EAGLE (Effective Anti-psychosis via GABA Level Enhancement) study which was completed in July 2009, BL-1020 matched the antipsychotic efficacy of Risperdal, one of the leading approved antipsychotics, without evidence of the metabolic side effects associated with the use of atypical antipsychotics. Most significantly, BL-1020 demonstrated a clinically relevant and statistically significant improvement in cognition. Currently, there is no commercially available antipsychotic that improves cognitive function and this remains an important unmet medical need in the treatment of schizophrenia and other psychiatric and neurological diseases.

In June 2011, we commenced a phase 2/3 CLARITY clinical trial with respect to BL-1020. The CLARITY trial is designed to be a randomized, double-blind trial to examine acute (6 weeks) and long-term (24 weeks) antipsychotic and cognitive efficacy, safety and tolerability of BL-1020, compared to Risperdal, on patients with acute schizophrenia. In May 2011, we received approval to commence the CLARITY trial at 14 trial sites in Romania. The initiation of the trial in Romania took place in May 2011 and the first patient was treated in June 2011. In November 2011 we received approval from the Indian regulatory authorities and the Indian local ethics committees to commence the trial at 18 additional clinical sites in India. We started recruitment in November 2011 and the first patient was treated in December 2011. In February 2013, we received approval from the Moldovan regulatory authorities to commence the trial at three clinical sites in Moldova; and in March 2013, we received approval from the Indian regulatory authorities to commence the trial at seven additional sites in India. The study currently includes 31 active sites in Romania, India and Moldova.

In October 2012, we announced our intention to conduct an interim analysis of the CLARITY trial for BL-1020. The interim analysis, which is expected to be finalized during the week of March 18, 2013, will be performed on data of approximately 235 randomized patients from 27 sites in Romania and India. The primary endpoint of the analysis will be the six-week effect of the drug on cognitive function. The interim analysis will be performed by a fully independent, external Data Monitoring Committee, or DMC, which will maintain complete blinding of all study data from us. As a result of the analysis, the DMC will provide us with an estimate of the total number of patients required in the study in order to achieve statistical significance on the cognitive endpoints of the study.

In June 2010, we entered into an exclusive, royalty-bearing out-licensing arrangement with Cypress Bioscience with regard to BL-1020, covering the United States, Canada and Mexico, which became effective in August 2010. We received an upfront fee of $30.0 million from Cypress Bioscience upon effectiveness of the agreement. We are obligated to pay to Bar Ilan Research and Development and Ramot, collectively, a royalty payment equal to 22.5% of the net consideration we receive from the out-licensing of BL-1020. We paid Bar Ilan Research and Development and Ramot $6.75 million, in the aggregate, from the $30.0 million upfront fee. We also paid the OCS $3.0 million as partial repayment of grants previously received for the BL-1020 development program. See "Item 4. Information on the Company — Business Overview — In-Licensing Agreements — BL-1020."

In January 2011, Royalty Pharma acquired Cypress Bioscience. After the acquisition, we had a number of discussions with Cypress Bioscience and Royalty Pharma and they indicated to us that as a result of a change in their strategy, they believed it was in the best interest of BL-1020's future commercial potential to consolidate the worldwide rights with our company. Cypress Bioscience expressed its desire that development of BL-1020 continue in a manner that both optimized Cypress Bioscience's investment in BL-1020 and provided the best long-term commercialization potential. We believe that reacquiring BL-1020 was the best alternative at that time to ensure the timely development of BL-1020 and represents a significant opportunity for our company. Accordingly, on May 10, 2011, we entered into a rights reacquisition agreement with Cypress Bioscience. Under the terms of the rights reacquisition agreement, the out-license agreement terminated on May 31, 2011, and we reacquired all of the rights to develop and commercialize BL-1020. In consideration for the reacquisition of the rights, we agreed to pay Cypress Bioscience a royalty equal to 1% of the future net sales of BL-1020, if any, by us, our affiliates or our sublicensees. Notwithstanding the foregoing, the aggregate royalty payment shall not exceed $80.0 million. In addition, in consideration for costs incurred by Cypress Bioscience in developing BL-1020 during the period of time that it held rights to BL-1020, we agreed to pay Cypress Bioscience up to $10.0 million, payable solely from amounts we receive, if any, pursuant to future agreements relating to the further development or commercialization of a product containing BL-1020, either alone or with other therapeutically active ingredients. We are required to pay Cypress Bioscience 10% of all payments under any such agreement but in any event not more than $10.0 million. If any such agreement requires that we incur the costs of certain proposed clinical trials of BL-1020, the payment schedule will be subject to certain deferrals. We have no other outstanding material obligations to Cypress Bioscience under the original out-license agreement, other than standard indemnification obligations.

Our second lead therapeutic candidate, BL-1040, is a novel resorbable polymer solution for use in the reduction or prevention of ventricular remodeling in patients who suffered an AMI. Preventing ventricular remodeling following an AMI may prevent transition to congestive heart failure and/or improve patient survival over the long term. Following an AMI, BL-1040 is administered via intracoronary injection. Upon contact with damaged cardiac tissue, the liquid BL-1040 transitions into a gel within the infarcted cardiac tissue and is believed to form a "scaffold" that supports, retains the shape of and/or enhances the mechanical strength of the heart muscle during the recovery and repair phases following an AMI. The data from our preclinical trials indicate that, by supporting the damaged heart tissue, BL-1040 preserves the normal functioning of the heart and the data from our clinical trials indicate that BL-1040 should be safe. After consultation by Ikaria with the FDA, BL-1040 is being developed as a class III medical device under the FDA's pre-marketing approval, or PMA, regulatory pathway. In December 2011, Ikaria commenced PRESERVATION 1, a CE Mark registration clinical trial of BL-1040 (now called "Bioabsorbable Cardiac Matrix," or BCM, by Ikaria). PRESERVATION 1 aims to evaluate the safety and effectiveness of BL-1040 (BCM) for prevention of ventricular remodeling when administered following AMI. The trial is a placebo-controlled, randomized, double-blind, multi-country and multi-center trial including approximately 300 patients. The BCM device will be administered to subjects who had successful percutaneous coronary intervention with stent placement after ST-segment elevation myocardial infarction (STEMI).

In 2009, we entered into an out-licensing arrangement with Ikaria with regard to BL-1040. Under the arrangement, Ikaria is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or a product related thereto. To date, we have received $17.0 million from Ikaria, and we are entitled to receive up to an additional $265.5 million from Ikaria upon achievement of certain development, regulatory, and commercial milestones. In addition, we are entitled to receive from Ikaria royalties from net sales of any product developed under the arrangement. We are obligated to pay 28% of all net consideration received under this arrangement to B.G. Negev Technologies, the party from which we in-licensed BL-1020 in 2004. See "Item 4. Information on the Company — Business Overview — In-Licensing Agreements — BL-1040." We have agreed to pay Ramot a portion of the payments we make to B.G. Negev Technologies in connection with the in-license arrangement to satisfy contractual obligations between B.G. Negev Technologies and Ramot with respect to certain intellectual property rights to the licensed technology. We have also agreed to indemnify Ramot and certain of its related parties in connection with our use of the technology we in-licensed from B.G. Negev Technologies.

Our third clinical-stage therapeutic candidate, BL 5010, comprises a customized, proprietary, pen-like applicator containing a novel formulation of two acids, which is being developed for the non-surgical removal of skin lesions. These two acids have already been approved for use in cosmetics. If approved, BL-5010 would be a convenient alternative to invasive, painful and expensive removal treatments for skin lesions and may allow for histological examination. Since treatment with BL-5010 is non-invasive, we believe BL-5010 poses minimal infection risk, and requires no anesthesia or bandaging. In June 2009, we initiated a phase 1/2 clinical trial in 60 patients with seborrheic keratosis 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. In addition, the study was designed to assess the feasibility of preserving the cellular structure of skin lesions for subsequent histological exams. The study was completed in September 2010, and positive results were announced in December 2010. The results of the trial show that for 96.7% of patients, the treated lesion fell off within 30 days of a single application of BL-5010. The results also showed that BL-5010 has a good safety profile, as no persistent irreversible adverse effects were observed at the treated site. In addition, investigators and patients participating in the trial reported that they were very satisfied with the cosmetic outcome of the treatment in the majority of cases (investigators regarded outcome as good or excellent 180 days following treatment in 94.6% of cases and patients in 84% of cases). None of the patients reported moderate or severe drug-related adverse events. Mild adverse events reported included skin and subcutaneous tissue disorders (n=5, 8.3%) and general and administration site disorders (n=2, 3.3%). Pruritus was the only drug-related adverse event reported by more than two patients (n=4, 6.7%). In addition, histological examination of treated lesions indicate BL-5010's efficacy in preserving the cellular structure of treated lesions.

In June 2011, we received European confirmation from the British Standards Institution Notified Body (BSI) in the UK, of the regulatory pathway classification of BL-5010 as a Class IIa medical device. During 2012, we devoted our efforts to developing the unique applicator for the product and strengthening its patent protection. We are currently planning to commence a pivotal CE-Mark registration trial for European approval as a medical device in the second half of 2013.

Our fourth clinical-stage therapeutic candidate, BL-7040, is an oligonucleotide being developed for the treatment of Inflammatory Bowel Disease (IBD). The compound has already been the subject of phase 1 safety and pharmacokinetics studies and a phase 2a study examining the efficacy of the compound for the treatment of Myasthenia Gravis, an autoimmune, neurodegenerative disease. BL-7040 showed a high level of safety and efficacy in those trials. The compound has been found to target the innate inflammatory pathway. Therefore, we intend to develop the compound for the treatment of IBD and other inflammatory diseases. We have commenced a phase 2 study of BL-7040 to evaluate its effectiveness for the treatment of ulcerative colitis. This is a proof-of-concept study of up to 30 patients, which is expected to be completed in April 2013.

Our fifth clinical-stage therapeutic candidate, BL-8040, is a short peptide that functions as a high-affinity antagonist for CXCR4, which we intend to develop for AML and other hematological cancers. CXCR4 is a chemokine receptor that is directly involved in tumor progression, angiogenesis (growth of new blood vessels in the tumor), metastasis (spread of tumor to other organs) and cell survival. CXCR4 is over-expressed in more than 70% of human cancers and its over-expression often correlates with poor prognosis. We believe BL-8040 works by mobilizing cancer cells from the bone marrow – exposing them to anti-cancer therapies – and by inducing apoptosis of cancer cells. Multiple pre-clinical studies have shown the safety and efficacy of BL-8040. These studies have shown that BL-8040 is effective, both alone and in combination with various anti-cancer drugs. In a phase 1/2, open-label, dose escalation, safety and efficacy clinical trial in 16 multiple myeloma patients, BL-8040 demonstrated an excellent safety profile and was well tolerated at all doses tested. On the basis of data obtained from this study, the FDA has approved an IND application. We plan to commence a phase 2 clinical trial in the second quarter of 2013.

Our sixth clinical-stage therapeutic candidate, BL-1021, is a new chemical entity in development for the treatment of neuropathic pain, or pain that results from damage to nerve fibers. The efficacy of BL-1021 has been demonstrated in preclinical studies. BL-1021 showed significant reduction in symptoms of neuropathic pain with reduced side effects in animal models. The BL-1021 molecule was administered orally in such animal studies and was found to be superior to available treatments in efficacy and/or side effect measures. In December 2011, we completed a phase 1a clinical trial to assess safety, tolerability and pharmacokinetics of a single administration of BL-1021 at doses between 10 mg and 80 mg in healthy volunteers. This clinical trial was a single-site, double-blind, placebo-controlled study, carried out at the Hadassah Clinical Research Center (HCRC) in Jerusalem, Israel. The study aimed at assessing the safety, tolerability and pharmacokinetics of a single administration of BL-1021 (between 10 mg and 80 mg) in healthy male subjects. Study results demonstrated that a single administration of BL-1021 in the dose range examined was safe and well tolerated, with no significant changes noted in vital signs, ECG or laboratory safety parameters at any dose when compared either to baseline measurements or to the placebo group. In addition, preliminary modeling of the pharmacokinetic data collected in this trial predicts that a once daily administration of BL-1021 at the dose levels assessed will enable reaching effective doses in patients. We are currently evaluating various alternatives with this therapeutic candidate from a clinical and business perspective, including potential development collaborations with other parties, as well as focusing on a more specific therapeutic indication within the general area of neuropathic pain.

As part of our business strategy, we continue to actively source, rigorously evaluate and in-license selected therapeutic candidates. We establish and maintain close relationships with research institutes, academic institutions and biotechnology companies in Israel, including, in some instances, a formal right of first offer for therapeutic compounds in their portfolios. More recently, we have extended our sourcing activities to other countries. Before in-licensing, each therapeutic candidate must pass through our thorough screening process. Our Scientific Advisory Board and disease-specific third-party advisors are active in evaluating each therapeutic candidate. Our approach is consistent with our objective of proceeding only with therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. To date, we have screened over 2,000 compounds, presented more than 70 candidates to our Scientific Advisory Board for consideration, initiated development of 43 therapeutic candidates and terminated 31 feasibility programs.

Our Strategy

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

- continually build our pipeline of therapeutic candidates;
- advance those therapeutic candidates with the greatest potential;

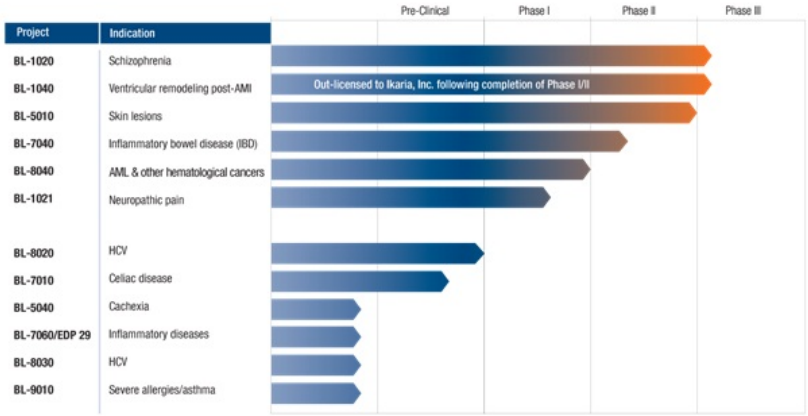
- quickly identify, and terminate the development of, unattractive therapeutic candidates; and
- avoid dependency on a small number of therapeutic candidates.

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

- **Support the successful development and commercialization of BL-1040 by Ikaria.** Although our licensee, Ikaria, is responsible for developing and commercializing BL-1040, we meet with Ikaria on at least a quarterly basis to lend our assistance and provide our expertise in their development and commercialization efforts as necessary.
- **Commercialize additional therapeutic candidates through out-licensing arrangements or, where appropriate, by ourselves.** We intend to commercialize many of our products through out-licensing arrangements with third parties who may perform any or all of the following tasks: completing development, securing regulatory approvals, manufacturing and/or marketing. If appropriate, we may 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 proprietary screening methodology to evaluate in-licensing opportunities.** In order to review and select among various candidates efficiently and effectively, we employ a rigorous screening system we developed. Our Scientific Advisory Board and disease-specific third-party advisors evaluate each candidate. We intend to in-license a sufficient number of therapeutic candidates to allow us to move a new therapeutic candidate into clinical development every 12 to 24 months.
- **Leverage and expand our relationships with research institutes, academic institutions and biotechnology companies, including the specific strategic relationships that we have developed with Israeli research and academic institutions, to identify and in-license promising therapeutic candidates.** To date, we have successfully in-licensed compounds from many major Israeli universities, as well as from many Israeli hospitals, technology incubators and biotechnology companies. We continue to maintain close contacts with university technology transfer offices, research and development authorities, university faculty, and many biotechnology companies to actively seek out early stage compounds. In addition, we actively source and evaluate non-Israeli compounds.

Our Product Pipeline

The table below summarizes our current pipeline of therapeutic candidates, as well as the target indication and status of each candidate:



Lead Therapeutic Candidates

BL-1020

BL-1020 is an orally administered antipsychotic for the treatment of schizophrenia. We believe that BL-1020 will deliver antipsychotic effectiveness equal to currently available treatments. Furthermore, we believe BL-1020 may be the first antipsychotic drug that improves cognitive function in schizophrenia patients. Based on our preclinical and clinical trials, we believe that BL-1020 works mainly by blocking the dopamine receptors in the brain and activating the gamma aminobutyric acid, or GABA, receptors. We believe that the dopamine antagonism in BL-1020 is responsible for reducing psychotic symptoms. The GABAergic activity of the BL-1020 molecule may be involved in improving patient cognition. In July 2009, we successfully completed our 363-patient phase 2b EAGLE (Effective Anti-psychosis via GABA Level Enhancement) study. We in-licensed the worldwide, exclusive rights to research, develop and commercialize BL-1020 from Bar Ilan Research and Development and Ramot.

In June 2011, we commenced the phase 2/3 CLARITY clinical trial with respect to BL-1020. The CLARITY trial is designed to be a randomized, double-blind trial to examine both acute (6 weeks) and long-term (24 weeks) cognitive and antipsychotic efficacy, safety and tolerability of BL-1020 on patients with acute schizophrenia. In May 2011, we received approval to commence the CLARITY trial at 14 trial sites in Romania. The initiation of the trial in Romania took place in May 2011 and the first patient was treated in June 2011. In November 2011 we received approval from the Indian regulatory authorities and the Indian local ethics committees to commence the trial at 18 additional clinical sites in India. We started recruitment in November 2011 and the first patient was treated in December 2011. In February 2013, we received approval from the Moldovan regulatory authorities to commence the trial at three clinical sites in Moldova; and in March 2013, we received approval from the Indian regulatory authorities to commence the trial at seven additional sites in India. The study currently includes 31 active sites in Romania, India and Moldova.

In October 2012, we announced that we intend to conduct an interim analysis of the CLARITY trial for BL-1020. The interim analysis, which is expected to be finalized during the week of March 18, 2013, will be performed on data of approximately 235 randomized patients from 27 sites in Romania and India. The primary endpoint of the analysis will be the six-week effect of the drug on cognitive function. The interim analysis will be performed by a fully independent, external Data Monitoring Committee, or DMC, which will maintain complete blinding of all study data from us. As a result of the analysis, the DMC will provide us with an estimate of the total number of patients required in the study in order to achieve statistical significance on the cognitive endpoints of the study.

Schizophrenia. Schizophrenia is a chronic, severe, and disabling brain disorder that affects approximately 1% of the U.S. adult population as reported by the National Institute of Mental Health. According to IMS Health, a leading provider of market intelligence, the spending in the United States alone on antipsychotics in 2011 was estimated at $18.2 billion. IMS Heath estimated that global spending on antipsychotics could reach $22-25 billion by 2016.

Schizophrenia is characterized by impairments in the perception or expression of reality, most commonly manifesting as auditory hallucinations, paranoid or bizarre delusions or disorganized speech and thinking. Schizophrenia patients also suffer from significant cognitive dysfunction. This results in difficulty of daily functioning, decreased ability to maintain normal social relationships and impaired job performance. Schizophrenia is a multi-factorial disease that involves an imbalance in some key chemicals that transmit signals between neurons and other cells, known as neurotransmitters, for example dopamine and GABA.

Currently available treatments for schizophrenia include two broad classes of antipsychotics: "typical" and "atypical." Both classes of medications are similarly effective at treating schizophrenia but have varying and severe side effects that limit patient compliance. Typical antipsychotics generally cause debilitating movement disorders known as Extra-Pyramidal Side (EPS) effects. Atypical antipsychotics are the current standard of care for schizophrenia patients, but may cause increased risks of obesity, diabetes and high blood cholesterol. In addition, atypical antipsychotics have also been shown to have EPS effects. In any event, both classes of antipsychotics do not adequately address cognitive function, and improvement in cognition represents an unmet medical need for patients of schizophrenia and other psychiatric and neurological diseases.

There are a number of different medications available to treat schizophrenia. The most commonly used atypical antipsychotics available on the market are Abilify, Risperdal, Zyprexa and Seroquel. Abilify is marketed by Bristol-Myers Squib and Otsuka Pharmaceutical Co, Ltd., and sales in 2011 were estimated at over $5 billion, according to Thomson Cortellis. Risperdal is marketed by Janssen, a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., a Johnson & Johnson company. Thompson Cortellis reported sales of Risperdal of $1.6 billion for 2011. Zyprexa is marketed by Lilly USA, LLC, a company of Eli Lilly and Company. Annual sales of Zyprexa were $4.6 billion for 2011, according to Thomson Cortellis. Seroquel is marketed by AstraZeneca Pharmaceuticals LP. Its annual sales according to Thomson Cortellis were $6.1 billion for 2011. Approximately 10% to 30% of schizophrenia patients do not respond to, or do not tolerate, a particular medication and, accordingly, will often be switched through a series of medications until medical practitioners identify the best treatment for them, as described in an article by Daniel E. Casey et. al. published in 2003 in the journal *Pharmacology*.

Development and Commercialization

In June 2010, we entered into an exclusive, royalty-bearing out-licensing arrangement with Cypress Bioscience with regard to BL-1020, covering the United States, Canada and Mexico, which became effective in August 2010. We received an upfront fee of $30.0 million from Cypress Bioscience upon the effectiveness of the agreement. We are obligated to pay to Bar Ilan Research and Development and Ramot, collectively, a royalty payment equal to 22.5% of the net consideration we receive from the out-licensing of BL-1020. We paid Bar Ilan Research and Development and Ramot $6.75 million, in the aggregate, from the $30.0 million upfront fee. We also paid the OCS $3.0 million as partial repayment of grants previously received for the BL-1020 development program. See "Business — In Licensing Agreements — BL 1020."

In January 2011, Royalty Pharma acquired Cypress Bioscience. Several months after the acquisition, we had a number of discussions with Cypress Bioscience and Royalty Pharma and they indicated to us that as a result of a change in their strategy, they believed it was in the best interest of BL-1020's future commercial potential to consolidate the worldwide rights with our company. Cypress Bioscience expressed its desire that development of BL-1020 continue in a manner that both optimized Cypress Bioscience's investment in BL-1020 and provided the best long-term commercialization potential. We believe that reacquiring BL-1020 was the best alternative at that time to ensure the timely development of BL-1020 and represents a significant opportunity for our company. Accordingly, on May 10, 2011, we entered into a rights reacquisition agreement with Cypress Bioscience. Under the terms of the rights reacquisition agreement, the out-license agreement terminated effective May 31, 2011, and we reacquired all of the rights to develop and commercialize BL-1020. In consideration for the reacquisition of the rights, we agreed to pay Cypress Bioscience a royalty equal to 1% of the future net sales of BL-1020, if any, by us, our affiliates or our sublicensees. Notwithstanding the foregoing, the aggregate royalty payment shall not exceed $80.0 million. In addition, in consideration for costs incurred by Cypress Bioscience in developing BL-1020 during the period of time that it held rights to BL-1020, we agreed to pay Cypress Bioscience up to $10.0 million payable solely from amounts we receive, if any, pursuant to future agreements relating to the further development or commercialization of a product containing BL-1020, either alone or with other therapeutically active ingredients. We are required to pay Cypress Bioscience 10% of all payments under any such agreement but in any event, not more than $10.0 million. If any such agreement requires that we incur the costs of certain proposed clinical trials of BL-1020, the payment schedule will be subject to certain deferrals. We have no other outstanding material obligations to Cypress Bioscience under the original out-license agreement, other than standard indemnification obligations. We intend to continue to consider potential out-licensing opportunities for BL-1020, as well as the potential to develop and commercialize BL-1020 internally.

Clinical and Preclinical Results. We conducted a phase 2b clinical trial, which we refer to as the EAGLE trial, in order to assess the efficacy, safety and tolerability of BL-1020 compared to placebo. Risperdal, a commonly prescribed antipsychotic, was used in the trial, at a dose of 2-8 mg, as a positive control to validate the study's results. The EAGLE trial was conducted under an FDA Investigational New Drug (IND) application process at 40 sites in the United States, Europe and India and included patients suffering from acute exacerbation of schizophrenia. In this six-week study, 363 patients were randomized for treatment with a low (10 mg/day) or high (20-30 mg/day dose of BL-1020, based on tolerability); Risperdal (2-8 mg/day, based on tolerability); or placebo. The study was designed to demonstrate statistically significant superiority of BL-1020 to placebo on the Positive and Negative Symptom Scale (PANSS), the primary efficacy measure. The key secondary efficacy measures included the Clinical Global Impression of Severity (CGI-S) and the Clinical Global Impression of Improvement (CGI-I), which are recognized measures of severity and improvement in schizophrenia. The secondary efficacy measures also included the Readiness to Discharge Questionnaire (RDQ) and the Strauss Carpenter Level of Functioning Scale. A pre-specified exploratory end point of the study was cognition as measured by the "Brief Assessment of Cognition in Schizophrenia" (BACS) test. The study was completed in July 2009 and we announced the results of the study in September 2009.

The results show that the BL-1020 high dose group (20-30 mg/day) experienced a significant improvement in primary and secondary efficacy measures. For the primary efficacy measure, the high dose group (20-30 mg/day) showed a reduction in PANSS in comparison to placebo (LS mean -23.6 vs. -14.4; p=0.002) and no significant change in comparison to Risperdal. The superiority of BL-1020 (20 – 30mg/day) over placebo was also supported by secondary efficacy measures including CGI-S and CGI-I. Furthermore, statistically significant increases in the number of patients rated as "responders" in the BL-1020 (20-30 mg/day) group compared to placebo on the PANSS, CGI-S and CGI-I was in line with all other efficacy measures.

The following table presents a summary of the EAGLE trial results for efficacy:

Endpoint	Placebo	BL-1020 (20 – 30mg)	Risperdal
PANSS	-14.4	-23.6 P=0.002 (vs. placebo) P=0.39 (vs. Risperdal)	-26.2 P<0.001 (vs. placebo)
CGI-S	-0.68	-1.27 P<0.001 (vs. placebo) P=0.607 (vs. Risperdal)	-1.35 P<0.001 (vs. placebo)
Strauss Carpenter Level of Functioning Scale	0.20	1.93 P=0.017 (vs. placebo) P=0.563 vs. Risperdal	2.35 P=0.003 (vs. placebo)
Clinical Responders	47.3%	70.8% P=0.01 (vs. placebo) P= 0.796 vs. Risperdal	72.5% P<0.001 (vs. placebo)

Cognitive function in the EAGLE trial was assessed by the BACS test. The BACS test comprises the following six components: verbal memory, digit sequencing, token motor task, verbal fluency, symbol coding and the "Tower of London" puzzle. The EAGLE trial results indicate that patients treated for up to six weeks with the 20-30 mg dose of BL-1020 exhibited a clinically relevant and statistically significant improvement of 9.27 points in the BACS score as opposed to the placebo control group (6.01 points). The Risperdal control group (with 6.2 points change) did not improve cognitive function when compared to placebo. BL-1020 exhibited statistical significance in comparison to both the placebo and Risperdal control groups (P=0.027 for both).

The following table presents a summary of the EAGLE trial results for cognition:

Parameter	Placebo	BL-1020 (20-30 mg)	Risperdal
BACS			
(LS mean, LOCF)	6.01	9.27	6.2
P value vs. placebo		P=0.027	P=0.893
P value vs. Risperdal		P=0.027	

Analysis of safety did not indicate any increased serious toxicity associated with BL-1020 treatment in comparison with the placebo. There was no incidence of SAEs (Severe Adverse Events) in the BL-1020 (20-30 mg/day) group but the Risperdal and placebo groups experienced SAE rates of 3.3% and 6.5%, respectively. Discontinuations due to Adverse Events (AEs) were similar in the BL-1020 (20-30 mg/day) group (4.5%) and in the placebo group (4.3%) but higher in the Risperdal group (8.8%). There were no statistically significant or clinically relevant AEs of body weight gain, glucose increases, and changes in lipids, all indicating that BL-1020 has no metabolic AE propensity. BL-1020 at its high dose level induced a slight increase in the Extra-Pyramidal Symptoms Rating Scale (ESRS), and the maximal change did not differ significantly from Risperdal, a second generation antipsychotic drug. The incidence of cardiovascular, sexual, psychiatric, autonomic and gastrointestinal AEs was low and was not increased compared to placebo. There were no statistically significant or clinically relevant changes in the measurements of the ECG, laboratory or vital signs.

The following table presents a summary of the EAGLE trial results for safety:

Parameter	Placebo	BL-1020 (20 – 30mg)	Risperdal
Serious Adverse Events			
(% patients)	6.5	0	3.3
Discontinuation due to Adverse Events			
(% patients)	4.3	4.5	8.8
Maximal change in ESRS	1.6	10.8	10.8
Metabolic – weight gain			
(% notable gain)	3.6	4.9	7.3
Metabolic – cholesterol	No change	No change	No change

In January 2010, we announced the results of a six-week extension trial of BL-1020. In the extension trial, 75 patients that completed the phase 2b EAGLE clinical trial were randomized as follows: patients that were treated with either BL-1020 or Risperdal in the phase 2b EAGLE clinical trial continued their treatment and patients that were treated with placebo in the phase 2b EAGLE clinical trial were re-randomized to one of the BL-1020 groups. Patients in the extension trial maintained and even increased the levels of improvement in PANSS and CGI identified in the phase 2b EAGLE clinical trial. In addition, patients showed additional improvement in cognition with the extension trial and there were no clinically relevant changes in the measurements of ECG, laboratory or vital signs (blood pressure, heart rate and temperature).

In February 2009, we announced the results of our open label, six-week phase 2a trial of BL-1020 in Romania. The study was designed to determine the safety and maximum tolerated dose, or MTD, of BL-1020 in schizophrenia patients and was conducted on 36 chronically ill hospitalized patients. Only four patients dropped out of the trial, which we believe is a relatively low dropout rate. Patients were initially treated with 20mg of BL-1020 and received increasing dosages over the first seven days. Patients that were treated with BL-1020 experienced a statistically significant improvement from baseline in the PANSS, CGI-S and CGI-I. This improvement was seen as early as seven days after the onset of treatment. There was a statistically significant ($p<0.001$) improvement on the Mean PANSS total (baseline+84.9; day 42=63.8), and the positive (baseline+22.3; day 42=15.1), negative (baseline=20.9; day 42=16.6) and general psychopathology subscales (baseline=42.4; day 42=32.1). More than 80% of the patients showed a statistically significant improvement as reflected by the CGI-S and CGI-I. No severe or unexpected adverse effects occurred in the trial. There was no significant increase in extra-pyramidal symptoms at the end of the trial, and no clinically relevant change in weight. There were no notable findings on ECG, laboratory values or vital signs. All adverse events were characterized as minimal and not treatment limiting.

In July 2007, we completed a phase 1b clinical trial which examined the ability of BL-1020 to bind dopamine receptors in the brain. The level of dopamine receptors binding in the brain is directly related to antipsychotic efficacy. This study was conducted pursuant to an FDA IND application process and an application to conduct clinical trials in Sweden that was submitted to the Swedish Ministry of Health. The study investigated the ability of BL-1020 to bind dopamine receptors in the human brain and provided additional safety and tolerability data. The study was a single-center, randomized, open label study performed on three dosage groups, each with four healthy volunteers who received a single dose of either 16mg, 24mg or 32mg of BL-1020. We assessed receptor occupancy using positron emission tomography (PET scan), which is able to register the activity of various parts of the brain following the administration of a labeled dopamine binder. The data derived from the study demonstrated a dose dependent increase in dopamine binding with computer modeling showing receptor occupancy of between 80% and 90% at the 20mg dose upon repeated administrations. The antipsychotic efficacy of dopamine blockers is presumed to occur at dopamine binding levels of 65% or more. BL-1020 did not produce any significant changes in the subjects' electrocardiogram test results, vital signs, clinical chemistry levels or hematology levels.

In October 2006, we completed a phase 1 clinical trial conducted under the supervision of the Israel Ministry of Health. The study was a single dose escalating, double-blind, placebo-controlled trial. Six dosage groups of BL-1020 were tested, 4 mg, 8 mg, 16 mg, 24 mg, 32 mg and 40 mg. Each group consisted of eight volunteers with two receiving a placebo and six receiving BL-1020. The study subjects exhibited no cardiac, neurological or psychological side effects. Few expected AEs appeared with the 32 mg dose and the MTD was determined to be 40 mg. We believe that the findings are indicative of the safety and tolerability of BL-1020.

Extensive preclinical testing indicated that BL-1020 successfully demonstrated antipsychotic efficacy in animal models of schizophrenia and did not cause Extra-Pyramidal Side Effects at the therapeutic levels. Preclinical studies also demonstrated the potential for BL-1020 to improve cognition and provided support for our belief that the GABAergic effects of the compound resulted in cognitive improvement.

BL-1040

BL-1040 is a novel resorbable polymer solution being developed to reduce or prevent the ventricular remodeling that may occur in patients that suffered an AMI. AMIs result from an occlusion in the coronary artery and affect the left ventricle of the heart, or the LV. Patients with severe injury to the LV may be at risk for developing harmful changes in the size, shape and function of the LV, or ventricular remodeling, that may lead to congestive heart failure (CHF). In the clinical trial, BL-1040 is deployed via the coronary artery and settles into the damaged heart muscle. The liquid BL-1040 transforms into a gel within the infarcted cardiac tissue and is believed to form a "scaffold" that supports, retains the shape of and/or enhances the mechanical strength of the heart muscle during recovery, which we believe prevents the pathological enlargement of the ventricle following an AMI. By supporting the damaged heart tissue during the natural healing process, we expect that BL-1040 will reduce or prevent the progressive ventricle enlargement that often follows AMIs. After discussions between Ikaria and the FDA, it has been determined that BL-1040 should be developed as a medical device, specifically under the PMA pathway in the United States. There can be no assurance, however, that the FDA or comparable foreign agencies will not determine that BL-1040 needs to be assessed as a drug instead of a medical device.

BL-1040 is being developed to treat patients that suffered an AMI and are at a high risk to develop significant ventricular remodeling. Based on our review of data regarding the incidence of myocardial infarctions in the United States, we believe that 20% of AMI patients may progress to heart failure due to ventricular remodeling. Prevention of ventricular remodeling may prevent transition to CHF and/or improve patient survival over the long term.

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

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

Acute Myocardial Infarction. AMI is a leading cause of mortality and morbidity among both men and women. According to the publication entitled "Morbidity and Mortality: 2012 Chart Book on Cardiovascular, Lung and Blood Diseases," made available by the National Heart, Lung and Blood Institute of the U.S. National Institutes of Health, the annual occurrence of AMI cases in the United Stated is estimated at 1,255,000. AMI is caused by a severe narrowing of coronary arteries, known as atherosclerotic occlusion, often exacerbated by the formation of clots. The narrowing and/or blockage in the coronary artery disrupts the blood supply to cardiac tissue, resulting in extensive cell death that constitutes the AMI. As a result, the affected region of the heart muscle is generally replaced by scar tissue over a six-to eight-week period. The scarred region often dilates progressively in the days and months following an AMI, leading to abnormalities in heart chamber shape, size and functional capacity as described in an article by Paul W.M. Fedak published in 2005 in the journal *Cardiovascular Pathology*. Those surviving the acute phase of an AMI (i.e., the first 30 days) are at greater risk for sudden death due to arrhythmias and progressive congestive heart failure. There are a number of different approaches to prevent ventricular remodeling that have been, or currently are, the subject of preclinical and clinical trials. Certain medications, including ACE inhibitors and beta-blockers have been shown to reduce ventricular remodeling. Despite the wide use of these medications, based on our review of data regarding patients with large anterior infarcts, at least 20% of those patients may progress to heart failure due to ventricular remodeling and a subsequent reduction in ejection fraction, or the fraction of blood pumped out of a ventricle with each heart-beat.

Development and Commercialization Arrangement. In 2009, we entered into a licensing arrangement with Ikaria, pursuant to which we granted Ikaria an exclusive, worldwide license to develop, manufacture and commercialize BL-1040 for use in the prevention, mitigation and treatment of injury to the myocardial tissue of the heart. Ikaria is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or a product related thereto. We were responsible for the costs of the completed phase 1/2 trial. Ikaria is responsible for the costs associated with conducting all other development and regulatory activities of BL-1040, including those costs relating to the completion of its clinical development, the conduct and funding of its commercialization and the prosecution and maintenance of patents. We have received $17.0 million from Ikaria and we are entitled to receive up to an additional $265.5 million from Ikaria upon achievement of certain development, regulatory, and commercial milestones. In addition, we are entitled to receive from Ikaria royalties from net sales of any product developed under the agreement ranging from 11% to 15%, depending on net sales levels achieved by Ikaria, and its affiliates and sublicensees. However, if Ikaria is required to obtain a license from a third party in order to exercise its rights under the agreement with Ikaria, the royalty we receive on net sales may be less than 11%.

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

After consultation by Ikaria with the FDA, BL-1040 is being developed as a class III medical device under the FDA's pre-marketing approval, or PMA, regulatory pathway. In December 2011, Ikaria commenced PRESERVATION 1, a CE Mark registration clinical trial of BL-1040 (BCM), outside of the United States. The purpose of PRESERVATION 1 is to evaluate the safety and effectiveness of BL-1040 (BCM) for prevention of ventricular remodeling when administered following AMI. The trial is a placebo-controlled, randomized, double-blind, multi-country and multi-center trial including approximately The BCM device will be administered to subjects who had successful percutaneous coronary intervention with stent placement after ST-segment elevation myocardial infarction (STEMI).

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

Other Clinical Therapeutic Candidates

BL-5010

BL-5010 comprises a customized, proprietary, pen-like applicator containing a novel formulation of two acids, which is being developed for the non-surgical removal of skin lesions. Other formulations of the components of BL-5010 have already been approved for use in cosmetics. If approved, BL-5010 would be a convenient alternative to painful, invasive and expensive removal treatments for skin lesions and may allow for histological examination. Since treatment with BL-5010 is non-invasive, we believe BL-5010 poses minimal infection risk, and requires no anesthesia or bandaging. BL-5010 is applied topically on a skin lesion for a few minutes with the pen-like applicator and causes the lesion to dry out gradually and shed from the skin within a few weeks. We in-licensed the exclusive, worldwide rights to develop, market and sell BL-5010 from IPC in November 2007.

In June 2011, we received European confirmation from the BSI in the UK of the regulatory pathway classification of BL-5010 as a Class IIa medical device. We are currently planning to commence a pivotal CE-Mark registration trial for European approval as a medical device in the second half of 2013.

Skin Lesions. 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 examples of skin lesions. Currently, skin lesions are removed using either cryotherapy (liquid nitrogen), electro-coagulation (electrical burning), laser treatments or through surgery. Cryotherapy, electro-coagulation and laser treatments do not preserve the lesions' cellular structure and are used for removing benign superficial lesions. These methods are often associated with pain and inflammation that can last for several months. Surgery is used when histological examination of skin lesions is required. Surgery has to be conducted under sterile conditions and requires anesthesia. Furthermore, the cosmetic outcome of surgical removal is generally undesirable.

Clinical Trial. In June 2009, we initiated a phase 1/2 clinical trial in 60 patients with seborrheic keratosis 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. In addition, the study was designed to assess the feasibility of preserving the cellular structure of skin lesions for subsequent histological exams. The study was completed in September 2010, and positive results were announced in December, 2010. The results of the trial show that for 96.7% of patients, the treated lesion fell off within 30 days of a single application of BL-5010. The results also showed that BL-5010 has a good safety profile, as no persistent irreversible adverse effects were observed at the treated site. None of the patients reported moderate or severe drug-related adverse events. Mild adverse events reported included skin and subcutaneous tissue disorders (n=5, 8.3%) and general and administration site disorders (n=2, 3.3%). Pruritus was the only drug-related adverse event reported by more than two patients (n=4, 6.7%). In addition, investigators and patients participating in the trial reported that they were very satisfied with the cosmetic outcome of the treatment in the majority of cases (investigators regarded outcome as good or excellent 180 days following treatment in 94.6% of cases and patients in 84% of cases). In addition, histological examination of treated lesions indicate BL-5010's efficacy in preserving the cellular structure of treated lesions.

BL-7040

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

We in-licensed the exclusive, worldwide rights to develop, and/or sell BL-7040 from Yissum in June 2011. Yissum had previously out-licensed the compound to Ester Neurosciences who performed phase 1 safety and pharmacokinetics studies and a phase 2a study examining the efficacy of the compound for the treatment of Myasthenia Gravis, an autoimmune, neurodegenerative disease. We intend to develop the compound for the treatment of IBD and other inflammatory diseases.

Inflammatory Bowel Disease. IBD, including Crohn's disease and ulcerative colitis, is a chronic inflammatory gastrointestinal disease characterized by chronic inflammatory conditions, abdominal pain, intestinal hemorrhaging, reduced nutritional uptake, bloating and alteration of bowel habits. According to Datamonitor, in 2009 there were estimated to be 890,000 people with Crohn's disease, over half of them in the United States, and there are estimated to be 1.4 million cases of ulcerative colitis in the seven major markets. There are few specific treatment options available to treat IBD and many of the treatments are either insufficiently effective, very expensive or have serious side effects. Approved treatments include steroids, which treat inflammation, and immunomodulators, which have an effect on the immune system. Many patients are referred to surgical treatment due to lack of effect by pharmacological agents. Biologics, which are therapeutics that are created by biologic processes rather than chemical synthesis, especially anti-TNFs (tumor necrosis factors which are actively involved in the inflammatory process), have become critical induction and maintenance agents. Remicade (infliximab), a treatment marketed by Janssen Biotech, Inc., a Johnson & Johnson company, Merck & Co. and Mitsubishi Tanabe Pharma, is the first approved anti-TNF for the treatment of IBD and is considered the gold standard of treatment. However, it is administered by IV, has a black box warning for serious infections and cancer and, like other biologics, is very expensive. Another approved treatment for IBD is Humira (adalimumab), which is self-administered by sub-cutaneous injection, giving it an advantage over treatments with other forms of administration. Humira is marketed by Abbot Laboratories and Eisai Co. Sales of existing drugs to treat IBD are estimated by Datamonitor to be $3.5 billion annually in the seven major markets.

Clinical and Preclinical Results. In March 2012, we commenced a phase 2 proof-of-concept study of BL-7040 to evaluate the effectiveness of BL-7040 for the treatment of IBD. Our phase 2 trial is an open-label study to evaluate the efficacy, pharmacodynamics, safety and tolerability of oral BL-7040 in up to 30 patients with moderately active ulcerative colitis, a type of IBD. Patients are treated for up to five weeks with BL-7040: 12mg/day for up to three weeks followed by 40mg/day for two additional weeks. The clinical trial is being carried out at five sites in Israel: Sourasky Medical Center (Ichilov Hospital) in Tel Aviv; Hadassah Medical Center in Jerusalem; Shaare Zedek Medical Center in Jerusalem; Rambam Medical Center in Haifa; and Soroka Medical Center in Beer Sheva. This study is expected to be completed in April 2013.

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

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

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

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

BL-8040

BL-8040 is a short peptide that functions as a high-affinity antagonist for CXCR4, which we intend to develop for AML and other hematological cancers. CXCR4 is a chemokine receptor that is directly involved in tumor progression, angiogenesis, metastasis and cell survival. CXCR4 is over-expressed in more than 70% of human cancers and its over-expression often correlates with poor prognosis. We in-licensed BL-8040 from Biokine in September 2012.

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

Pre-clinical and Clinical Results. In vitro and in vivo data show that BL-8040 binds CXCR4 at the low nanomolar range (1-2.5nM) and occupies it for prolonged periods of time (>24h). These studies have shown that BL-8040 mobilizes cancer cells from the bone marrow, thereby exposing them to anti-cancer therapies, and also directly induces apoptosis of cancer cells. BL-8040 was found effective, both alone and in combination with various anti-cancer drugs. In a phase I/II, open-label, dose escalation, safety and efficacy clinical trial in 16 multiple myeloma patients, BL-8040 demonstrated an excellent safety profile and was well tolerated at all doses tested. On the basis of data obtained from this study, the FDA has approved an IND application. We plan to commence a phase 2 clinical trial in the second quarter of 2013.

BL-1021

BL-1021 is a new chemical entity in development for the treatment of neuropathic pain, or pain that results from damage to nerve fibers. Multiple preclinical *in vitro* and *in vivo* animal studies have proven the safety and efficacy of BL-1021. We licensed exclusive, worldwide rights to research, develop and commercialize BL-1021 from Bar Ilan Research and Development and Ramot.

Neuropathic Pain. Neuropathic pain is a complex, chronic state of pain that results from dysfunctional or injured nerve fibers. Over time, the body establishes recurring "pain signaling cycles" that persist for a long time after the healing of the nerve injury that first caused the pain. Neuropathic pain is associated with various conditions, including shingles and diabetes, and, according to a 2011 Global Industry Analysis report, cited by the American Academy of Pain Medicine, 3-4.5% of the world's population suffers from neuropathic pain. According to a 2011 DataMonitor report, the market for neuropathic pain treatments was $2.4 billion (in the seven major markets — the United States, Japan, France, Germany, Italy, Spain, and the United Kingdom) and is expected to reach $4.1 billion in 2018. Neuropathic pain may cause extreme discomfort for extended periods of time. Patients describe the symptoms as burning, stabbing, electric shock or itching sensations. Medical professionals treat neuropathic pain with a variety of medications, including the antidepressants amitriptyline and duloxetine and the anti-seizure medicines gabapentin and pregabalin. However, these medications have significant side effects and are not always effective.

Preclinical and Clinical Results. The efficacy of BL-1021 has been demonstrated in preclinical studies. BL-1021 showed significant reduction in symptoms of neuropathic pain with reduced side effects in animal models. The BL-1021 molecule was administered orally in such animal studies and was found to be superior to available treatments in efficacy and/or side effect measures.

In June 2011, we commenced a phase 1 clinical trial of BL-1021 in Israel, and commenced treatment of the first patient in the trial. In December 2011, we completed a phase 1a clinical trial to assess safety, tolerability and pharmacokinetics of a single administration of BL-1021 at doses between 10mg and 80mg in healthy volunteers. This clinical trial was a single-site, double-blind, placebo-controlled study, carried out at the Hadassah Clinical Research Center (HCRC) in Jerusalem, Israel. The study aimed at assessing the safety, tolerability and pharmacokinetics of a single administration of BL-1021 (between 10 mg and 80 mg) in healthy male subjects. Study results demonstrated that a single administration of BL-1021 in the dose range examined was safe and well tolerated, with no significant changes noted in vital signs, ECG or laboratory safety parameters at any dose when compared either to baseline measurements or to the placebo group. In addition, preliminary modeling of the pharmacokinetic data collected in this trial predicts that a once daily administration of BL-1021 at the dose levels assessed will enable reaching effective doses in patients. We are currently evaluating various alternatives with this therapeutic candidate from a clinical and business perspective, including potential development collaborations with other parties, as well as focusing on a more specific therapeutic indication within the general area of neuropathic pain.

Therapeutic Candidates in Preclinical Development

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

Therapeutic Candidate	Description	Indication	Status	In-Licensing Source
BL-8020	Small molecule	Hepatitis C	Phase 1-ready	Genoscience
BL-7010	Polymer	Celiac disease	Preclinical studies	Gestion Univalor, Limited Partnership
BL-5040	Protein	Cachexia	Preclinical studies	Yissum
BL-7060/ EDP 29	Peptide	Inflammatory diseases	Preclinical studies	Compugen Ltd.
BL-8030	Small molecule	Hepatitis C	Preclinical studies	Genoscience and RFS Pharma
BL-9010	Bi-specific antibody	Severe allergies/Asthma	Preclinical studies	Yissum and University of Genoa, Italy

In March 2013, we terminated three projects for scientific considerations in light of experimental results: BL-6030/1, BL-7020 and BL-8010. BL-6030/1 was intended to treat bacterial infection; BL-7020, psoriasis; and BL-8010, retinopathy. Until their termination, BL-6030/1 and BL-7020 were conducted by our incubator.

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 12 therapeutic candidates with an additional 12 therapeutic candidates in our EDP pipeline, a program primarily funded by one of our shareholders to support a portion of our early feasibility work on therapeutic candidates. See “Item 7. Related Party Transactions — Early Development Program Agreement.”

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

Once we identify a candidate, it enters our internal evaluation system and undergoes our rigorous selection process. We employ internal research efforts to evaluate candidates. We evaluate each compound’s potential for success by looking at the candidate’s efficacy, safety, total estimated development costs, technological novelty, patent status, market potential and approvability. Following evaluation and diligence, each therapeutic candidate is evaluated by our Scientific Advisory Board and by disease-specific advisors for external scientific review. Following a Scientific Advisory Board meeting, the compound is referred to either the EDP or more advanced feasibility testing. Candidates that have successfully progressed through our EDP will generally be subject to a shorter feasibility period once the compound is introduced to our pipeline as fewer studies will be required. At each step of the process, a therapeutic candidate is subjected to critical evaluation and potential termination. Our approach is consistent with our objective of proceeding only with therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. To date, we estimate we have screened over 2,000 compounds, and we have introduced more than 70 candidates to our Scientific Advisory Board for consideration, initiated development of 43 therapeutic candidates and terminated 31 feasibility programs.

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

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

Out-Licensing Agreement with Ikaria

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

Pursuant to the agreement, Ikaria paid us an initial up-front payment equal to $7.0 million on the effective date of the agreement and in April 2010 paid us a milestone payment of $10.0 million. We are entitled to receive up to an additional $265.5 million from Ikaria upon achievement of certain development, regulatory, and commercial milestones. In addition, we are entitled to receive from Ikaria royalties from net sales of any product developed under the agreement ranging from 11% to 15%, depending on net sales levels achieved by Ikaria or its sublicensees, as applicable. However, if Ikaria is required to obtain a license from a third party in order to exercise its rights under the agreement with us, the royalty we receive on net sales may be less than 11%. We must pay 28% of all net consideration we receive from Ikaria to B.G. Negev Technologies, the institution from whom we initially in-licensed the development rights to BL-1040. See “Item 4. Information on the Company — Business Overview — In-Licensing Agreements — BL-1040.” Certain payments we may receive from Ikaria in the future, if at all, may be subject to a 15% withholding tax in the United States. We believe that we may be able to get a refund of withholding taxes paid in connection with future payments from the U.S. government but there can be no assurance that we will be able to get such a refund. In addition, we may be able to use U.S. taxes withheld from future payments as credits against Israeli corporate income tax, when we have income, if at all, but there can be no assurance that we will be able to realize the credits. Payments to B.G. Negev Technologies are to be made from the net amounts received from Ikaria (i.e., net of the withholding taxes). We have agreed to pay Ramot a portion of the payments we make to B.G. Negev Technologies in connection with the in-license arrangement to satisfy contractual obligations between B.G. Negev Technologies and Ramot with respect to certain intellectual property rights to the licensed technology.

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

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

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

In-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 sub-licenses.

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

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

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

The royalty and revenue sharing rates we agree to pay in our in-licensing agreements vary from case to case but in most cases range from 20% to 29.5% of the consideration we receive from sublicensing the applicable therapeutic candidate. We are required to pay a substantially lower percentage, generally less than 5%, if we elect to commercialize the subject therapeutic candidate independently. In addition, milestone payments are not generally payable if revenue-sharing from an out-licensing transaction is greater than any relevant payments due under our in-licensing agreements.

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

BL-1020 and BL-1021

In April 2004, we in-licensed the rights to BL-1020 under a research and license agreement with Bar Ilan Research and Development and Ramot. Under the research and license agreement, the licensors granted us an exclusive, worldwide, sub-licensable license to develop, manufacture, market and sell certain technology relating to conjugated anti-psychotic drugs and the uses of the technology relating thereto. In addition to BL-1020, this agreement allows us to develop two other earlier stage therapeutic candidates, BL-1021 for the treatment of neuropathic pain and a second candidate for which development has been terminated. Under the research and license agreement, we agreed to fund further research in respect of the licensed technology during a specified research period, subject to certain exceptions. In addition, we have the right to grant sublicenses for the licensed technology, subject to certain restrictions.

Under the research and license agreement, we are obligated to use commercially reasonable efforts to develop, commercialize and market the licensed technology. We pay an annual license fee of $25,000 and are required to make low, single digit royalty payments on the net sales of the licensed technology, subject to certain limitations. To date, we have paid $175,000 under the in-license agreement in connection with our obligations to make annual payments. Our royalty payment obligations are payable on a product-by-product and country-by-country basis, for the longer of 15 years from the date of first commercial sale in such country, the last expiration of any patent in such country, and the expiration of the licensed product's "orphan drug" status in such country. If we sublicense our rights under the research and license agreement, we are required to pay the licensors a payment equal to 22.5% on the amounts we receive from any third-party sublicensees, subject to certain limitations. A portion of the CLARITY trial and other costs that we have incurred, or may incur in the future, may be deducted from the sublicense receipts upon which such payment is calculated.

We are required to consult the licensors regarding the preparation, filing and prosecution of all patent applications and the maintenance of all patents included within the licensed patent rights. We have the right to take action in the prosecution, prevention, or termination of any patent infringement of the licensed technology. We are responsible for the expenses of any patent infringement suit that we bring, including the expenses incurred by the licensors in connection with the prosecution of such suits or the settlement thereof.

We are entitled to reimbursement from any sums recovered in such suit for all costs and expenses involved in its prosecution. After such reimbursement, we and the licensors are each entitled to a certain percentage of any remaining sums.

The research and license agreement remains in effect until the expiration of all of our royalty and sublicense revenue obligations to licensors, determined on a product-by-product and country-by-country basis, unless we terminate the license agreement earlier. We may terminate the license agreement by providing 60 days' prior written notice to Ramot. If we materially breach any of our obligations under the agreement and fail to cure such breach within 30 days after receiving written notice of the material breach from Ramot, Ramot may terminate the agreement immediately. If either Bar Ilan Research and Development or Ramot materially breach their respective obligations under the agreement and fail to cure such breach within 30 days after receiving written notice of the material breach from us, we may terminate the agreement immediately. With respect to any termination for material breach, if the breach is not susceptible to cure within the stated period and the breaching party uses diligent, good faith efforts to cure such breach, the stated period will be extended by an additional 30 days. In addition, we and Ramot may terminate the agreement upon notice to the other upon the occurrence of certain bankruptcy events.

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

BL-1040

In January 2005, we in-licensed the rights to BL-1040 under a license agreement with B.G. Negev Technologies. Under the agreement, B.G. Negev Technologies granted us an exclusive, worldwide, sublicensable license to develop, manufacture, market and sell certain technology relating to injectable alginate biomaterials and the uses thereof. Upon execution of the agreement, we were obligated to make an initial payment and to make annual payments equal to $30,000, subject to certain conditions. To date we have paid $700,000 under the BL-1040 in-license agreement, to cover the initial fee and annual fees. 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 Ikaria. We have agreed to pay Ramot a portion of the payments we make to B.G. Negev Technologies in connection with the in-license arrangement to satisfy contractual obligations between B.G. Negev Technologies and Ramot with respect to certain intellectual property rights to the licensed technology. We have also agreed to indemnify Ramot and certain of its related parties in connection with our use of the technology we in-licensed from B.G. Negev Technologies.

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

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

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

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

BL-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 in the low, double digits based on the revenues we receive as consideration in connection with any sublicensing, development, manufacture, marketing, distribution or sale of the licensed technology.

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

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

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

BL-7040

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

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

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

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

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

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

BL-8040

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

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

- during the initial 12-month period following execution of the agreement; $100,000 per month;
- after the initial 12-month period and continuing until the earlier of (i) completion of the clinical trials contemplated under the agreement or (ii) grant of a sublicense; $65,000 per month for the following 12 months, $60,000 per month for the next six months and $50,000 per month thereafter until the earlier of the completion of the two clinical trials contemplated by the parties or the grant of a sublicense pursuant to the agreement..

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

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

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

The agreement also grants us the right to grant sublicenses for the licensed technology. In such event, we are required to pay Biokine a royalty payment of between 40-60% of the amounts we receive as consideration in connection with any sublicensing, development, manufacture, marketing, distribution or sale of the licensed technology. The amount of the royalty for either direct sales or sublicensing is dependent on the aggregate amount of our investment in connection with the agreement, decreasing as the amount of our investment in the project increases.

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

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

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

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

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 to develop and maintain our proprietary position.

Patents

As of March 5, 2012, we owned or exclusively licensed for uses within our field of business 23 patent families that, collectively contain over 61 issued patents, 10 allowed patent applications and over 96 pending patent applications relating to our five clinical candidates. We are also pursuing patent protection for other drug candidates in our pipeline. Patents related to our therapeutic candidates may provide future competitive advantages by providing exclusivity related to the composition of matter, formulation, and method of administration of the applicable compounds and could materially improve the value of our therapeutic candidates. The patent positions for our five leading 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-1020, we have an exclusive license to a patent family that covers the molecule that is the active ingredient of our proprietary anti-psychotic drug and methods of its use for the treatment of, e.g., schizophrenia. Patents of this family have been granted or received notice of allowance in the United States, Israel, Europe, Australia, Japan, China, India and South Korea. The patents and any patents to issue in the future based on pending patent applications in this family will expire in September 2022, plus any applicable patent term extension. In addition, we have an exclusive license to a patent family claiming the use of BL-1020 for improving cognitive functions. Any patents to issue in the future based on this international patent application will expire in 2030. Lastly, we have an exclusive license to a patent granted in the United States which covers the novel crystalline form of BL-1020. Corresponding patent applications are pending in Europe, Japan, India, China, Mexico, Brazil, Canada, Australia and Israel. Any patents to issue in the future based on this international patent application will expire in 2031, plus any applicable patent term extension.

- With respect to BL-1040, we have an exclusive license to a patent family directed to the BL-1040 composition and methods of its use for the treatment of myocardial infarction. Patents of this family have been granted or received notice of allowance in the United States, India, China, Australia, Mexico and South Korea. Additional member patent applications are pending in Israel, Europe, Japan, Canada and South Korea. The U.S. composition of matter patent will expire in 2029, plus any applicable patent term extension, and the U.S. method of treatment patent will expire in 2024. A broad method of manufacturing patent is issued and expires in 2025.

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

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

- With respect to BL-8040, we have an exclusive license to two patent families that cover the molecule that is the active ingredient of our proprietary drug. Patents and patent applications of these families have been granted or are pending in the United States, Europe, Japan and Canada. The patents and any patents to issue in the future based on pending patent applications in these families will expire in 2023 (in the United States) and 2021 (in other countries) , plus any applicable patent term extension. In addition, we have an exclusive license to five other patent families pending worldwide directed to the use of BL-8040 for the treatment of certain types of cancer and thrombocytopenia.

- With respect to BL-1021, we have an exclusive license to a patent family that claims the molecule that is the active ingredient of our proprietary drug. Patents and patent applications corresponding to the international patent application have been granted or are pending in the United States, Israel, Europe, Australia, Japan, Canada, China, India, South Korea and Mexico. The patents and any patents to issue in the future based on pending patent applications in this family will expire in 2022, plus any applicable patent term extension. We also have an exclusive license to a patent family claiming the use of BL-1021 for the treatment of pain. Patents and patent applications corresponding to the international patent application are pending in the United States, Israel, Europe, Australia, Japan, Canada, China, India, South Korea and Mexico. The patents and any patents to issue in the future based on pending patent applications in this family will expire in 2027, plus any applicable patent term extension.

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

Scientific Advisory Board

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

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

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

Name	Position/Institutional Affiliation
J. Aaron Ciechanover, M.D., Ph.D.	Professor Ciechanover is a Distinguished University Professor in the Faculty of Medicine of the Technion. He is a recipient of the Nobel Prize in Chemistry (2004), of the Israel Prize in Biological Research (2003) and the Albert Lasker Award (2000). He is a member (foreign) of the National Academy of Sciences (U.S.), The Institute of Medicine of the National Academies (U.S.) and the Israel Academy of Sciences and Humanities.
Aliza Eshkol, Ph.D.	Dr. Eshkol is an independent scientific advisor for pharmaceutical development. She retired as Vice President for Scientific Affairs, Serono International SA, Geneva, Switzerland. Dr. Eshkol is a member of several national and international professional societies.
Gianni Gromo, M.D., Ph.D.	Dr. Gromo is the founder of Gromo Consulting, whose focus is primarily on R&D strategies for discovering new medicines. Until November 2012, Dr. Gromo headed various R&D units at F. Hoffmann-La Roche Ltd., mainly in the areas of metabolic and vascular diseases. His last position at the company was as head of the R&D organization in China.
David Ladkani, M.D.	Dr. Ladkani held roles of increasing responsibility in R&D, business development and medical affairs at senior levels for 32 years at Teva. He retired from Teva as Chief Scientific Officer. Dr. Ladkani is the recipient of the Rothschild Award for innovation and is widely published in the field of multiple sclerosis treatments.
Yaakov Naparstek, M.D.	Professor Naparstek is the Chairman of Medicine of Hadassah University Hospital. His main research interests are in the field of autoimmunity, systemic lupus erythematosus and autoimmune arthritis.
Moshe Phillip, M.D.	Professor Phillip has been our Vice President of Medical Affairs and Senior Clinical Advisor and a member of our Scientific Advisory Board since 2004. Professor Phillip is the Director of the Institute for Endocrinology and Diabetes of the Israel National Center for Childhood Diabetes at Schneider Children's Medical Center of Israel and the Vice Dean for Research and Development at the Sackler School of Medical Education at Tel Aviv University.
Itamar Shalit, M.D.	Professor Shalit is Associate Professor in Pediatrics, Sackler Faculty of Medicine, Tel-Aviv University. In addition, he is founder, consultant and board member of NasVax Ltd., an Israeli biotechnology company; a board member of Mor Institute for Medical Information; CEO of The Galilee Bio-Medical Research Administration; and delegate of the Israeli Ministry of Health to the European SAB of Infect-Era.
Yosef Yarden, Ph.D.	Professor Yarden is the head of the Signal Transduction and Growth Factors Laboratory of the Weizmann Institute of Science. He is member of the Israel Academy of Sciences and Humanities and President of the Federation of the Israel Societies of Experimental Biology (FISEB). Among his many awards, in the last two years he received the Susan G. Komen for the Cure® Brinker Award for Scientific Distinction in Basic Research, and the Ernst W. Bertner Memorial Award of the MD Anderson Cancer Center.

Manufacturing

Our laboratories, which are located in our headquarters in Jerusalem, Israel, are compliant with both current good manufacturing practices, or cGMP, and Good Laboratory Practices, or GLP, and allow us to manufacture drug products for our current clinical trials. The suppliers of the drug substances used for our current clinical trials have the necessary approvals as well. See "Item 4. Information on the Company — Business Overview — Property, Plant and Equipment." If we decide to perform any phase 3 clinical trial with respect to, or commercialize, any therapeutic candidate on our own, we anticipate that we will rely on third parties to produce the therapeutic supplies. We have limited personnel with experience in drug or medical device manufacturing and we lack the resources and capabilities to manufacture any of our therapeutic candidates on a commercial scale.

Under our out-licensing agreement with Ikaria with regard to BL-1040, we have the option to manufacture at least 20% of BL-1040 products pursuant to the terms of a supply agreement to be negotiated in good faith with Ikaria. See "Item 4. Business Overview — Out-Licensing Agreement with Ikaria." There can be no assurance that our therapeutic candidates, if approved, can be manufactured in sufficient commercial quantities, in compliance with regulatory requirements and at an acceptable cost. We and our contract manufacturers are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products or medical devices. We and our contract manufacturers must ensure that all of the processes, methods and equipment are compliant with cGMP, for drugs or QSR for devices on an ongoing basis, mandated by the FDA and other regulatory authorities, and conduct extensive audits of vendors, contract laboratories and suppliers.

Contract Research Organizations

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

Competition

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

BL-1020

If approved, BL-1020 will compete with currently marketed atypical anti-psychotics from Johnson & Johnson, Eli Lilly and Company, AstraZeneca, Bristol-Myers Squibb/Otsuka Pharmaceutical Co., Ltd., Pfizer Inc. and others, as well as with generic brands of typical and atypical anti-psychotics. We are also aware of a number of potentially competitive compounds under development including: Cariprazine, which is being developed by Forest Laboratories, Inc. and Gedeon Richter; Lurasidone, which is being developed by Dainippon Sumitomo Pharma Co., Ltd. together with Takeda Pharmaceutical Co.; zicronapine, which is being developed by Lundbeck; bitopertin, which is being developed by Roche and Chugai; and Vyvanse (lisdexamfetamine), which is being developed by Shire. None of these anti-psychotics are indicated to improve cognition.

BL-1040

We are not aware of any marketed products for the prevention of ventricular remodeling following an AMI that, like BL-1040, are injectable and form a protective scaffold that supports the heart muscle during recovery and repair. If approved, BL-1040 will face competition from a number of therapies aimed at preventing ventricular remodeling and subsequent congestive heart failure (CHF) in different ways. Other treatments for ventricular remodeling include BioHeart, Inc.'s MyoCell® implantation procedure, Paracor Medical, Inc.'s HeartNet™ and LoneStar Heart's Algisyl-VR. These devices are indicated for different patient populations than BL-1040 and require surgery. For example, CorCap™ is indicated for patients already suffering from congestive heart failure and requires surgery to apply the device.

BL-5010

If approved, BL-5010 will compete with a variety of approved destructive and non-destructive treatments for skin lesions. Surgery is currently the most common approved non-destructive treatment for skin lesions but is invasive and painful, and generally results in cosmetically undesirable outcomes. Destructive treatments are associated with pain. Destructive treatments include cryotherapy, laser therapy, electrodessication, curettage and several cream-based treatments including Imiquimod, Disclofenac sodium, 5-Fluorouracil, Picato (Leo Pharma) and Metvix® (Galderma Pharma SA). Picato involves repeated administrations for 2-3 days. Metvix involves exposure of the skin lesion to red light after the application of the cream. Both have been approved in many countries. BL-5010 requires a single application and does not require the use of any equipment. We are not aware of any marketed products or procedures for the preservation of skin lesions besides surgical removal.

BL-7040

If approved, BL-7040 will compete with currently marketed steroids, immunomodulators and anti-TNFs (tumor necrosis factors). The IBD market leaders are anti-TNFs such as Remicade (infliximab, Janssen Biotech, Inc., a Johnson & Johnson company, Merck & Co. and Mitsubishi Tanabe Pharma) and Humira (adalimumab, Abbott Laboratories and Eisai Co.), in addition to generic brands of mesalazine, a 5-aminosalicylate. Additional market leaders are Cimzia (certolizumab, UCB, Inc.), an anti-TNF, and Tysabri (natalizumab, Biogen Inc.), an integrin inhibitor. We are also aware of a number of potentially competitive compounds under development including Simponi (golimumab, Janssen Biotech, Inc., Merck & Co. and Mitsubishi Tanabe Pharma), a TNF inhibitor, Xeljanz (tofacitinib, Pfizer Inc.), a Jak 1 inhibitor, and Budesonide MMX (Cosmo Pharmaceuticals, Ferring Pharmaceuticals and Santarus, Inc.).

BL-8040

If approved, BL-8040 will compete with current treatments for AML including chemotherapy (Doxorubicin, Arsenic dioxide, Cyclophosphamide, Vincristine), radiation therapy and stem cell transplantation. We are also aware of a number of potentially competitive compounds under development to treat AML including: AMD 3100 (Mozobil), which is being developed by Genzyme and Sanofi; Dacogen (decitabine), which is being developed by Eisai and J&J; Vidaza (azacitidine), which is being developed by Celgene; Elacytarabine, which is being developed by Clavis Pharma; Vosaroxin, which is being developed by Sunesis Pharmaceuticals; and Fludarabine, which is being developed by Schering.

BL-1021

If approved, BL-1021 will compete with currently marketed anticonvulsants, antidepressants and narcotic analgesics. The neuropathic pain market leaders are anticonvulsants, such as Lyrica (Pregabalin, Pfizer) and the generic Gabapentin, together with off-label brands. Additional market leaders are Cymbalta (duloxetine; Eli Lilly/Shionogi), Lidoderm (5% lidocaine patch; Endo/Grünenthal), Qutenza (8% capsaicin patch; NeurogesX/Astellas) and Gralise (extended-release Gabapentin; Depomed). We are also aware of a number of potentially competitive compounds under development including Nucynta ER (Tapentadol ER; Grünenthal/Johnson & Johnson), DM-1796 (Gabapentin GR; Depomed/Abbott), Horizant (Gabapentin enacarbil; XenoPort/GlaxoSmithKline/Astellas Pharma Inc.), AmiKet (amitriptyline and ketamine; EpiCept), AVP-923 (dextromethorphan hydrobromide/quinidine sulfate; IriSys/Avanir) and Ralfinamide (Newron). None of these compounds is considered revolutionary in terms of fulfilling all the critical clinical factors such as high efficacy, improved dosing regimen and improvement of related side effects.

Insurance

We maintain insurance for our offices and laboratory in Israel. This insurance covers approximately $3.8 million of equipment, consumables and lease improvements against risk of fire, lightning, natural perils and burglary (the latter coverage limited to $250,000), and $1.5 million of consequential damages (covering fixed damages and extra expenses). For our clinical trial activities, we carry life science liability insurance covering general liability with a coverage amount of $10.0 million per occurrence, product liability with an annual coverage amount of $5.0 million in the aggregate, and clinical trial insurance with a coverage amount of $10.0 million in the aggregate. The maximum indemnity for a single occurrence or circumstances under this policy is $10.0 million. In addition to this policy, we carry excess liability insurance with a coverage amount of $5.0 million which increases the coverage limit provided by our life science insurance package. In addition, we maintain the following insurance: employer liability with coverage of approximately $10.0 million; third party liability with coverage of approximately $5.0 million; all risk coverage of approximately $1.9 million for electronic and mechanical equipment; and directors and officers' liability with coverage of $20.0 million.

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

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

Environmental Matters

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

Government Regulation and Funding

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

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

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

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

A summary of the U.S., EU and Israeli regulatory process follows below.

United States

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

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

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

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

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

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

Clinical Trials

Clinical trials involve the administration of the investigational drug to people under the supervision of qualified investigators. 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 protocol to the FDA as part of the IND.

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

NDAs and BLAs

After successful completion of the required clinical testing, an NDA, or in the case of certain biological products a Biological Product Application, or BLA, is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before product marketing may begin in the United States. The NDA/BLA must include the preclinical and clinical testing results and a compilation of detailed information relating to the product's pharmacology, toxicology, chemistry, manufacture and manufacturing controls. In certain cases, an application for marketing approval may include information regarding the safety and efficacy of a proposed drug that comes from trials not conducted by, or for, the applicant and for which trials the applicant has not obtained a specific right to reference. Such an application, known as a 505(b)(2) NDA, is permitted for new drug products that incorporate previously approved active ingredients, even if the proposed new drug incorporates an approved active ingredient in a novel formulation or for a new indication. A 505(b)(2) type application is not available for drugs subject to BLAs. 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. Fees are now assessed as well for an Abbreviated New Drug Application, or ANDA.

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

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

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

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

Post-Marketing Requirements

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

Generic Competition

Once an NDA, including a 505(b)(2) NDA, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA, which relies on bioequivalence studies that compare the generic drug to a reference listed drug to support approval. Currently, ANDAs are not eligible for drugs covered by BLAs. 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.

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

FDA Approval or Clearance of Medical Devices

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

- Class I: general controls, such as labeling and adherence to Quality System Regulations, or QSRs;
- Class II: general controls, pre-market notification (510(k)), and specific controls such as performance standards, patient registries, and postmarket surveillance; and
- Class III: general controls and approval of a PMA.

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

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

European Economic Area

A medicinal product may only be placed on the market in the European Economic Area, or EEA, composed of the 27 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 recently amended by Directive 2004/27/EC), or an authorization has been granted under the centralized procedure in accordance with Regulation (EC) No. 726/2004 or its predecessor, Regulation 2309/93. There are essentially three EU procedures created under prevailing European pharmaceutical legislation that, if successfully completed, allow an applicant to place a medicinal product on the market in the EEA.

Centralized Procedure

Regulation 726/2004/EC now governs the centralized procedure when a marketing authorization is granted by the European Commission, acting in its capacity as the European Licensing Authority on the advice of the European Medicines Agency, or EMA. That authorization is valid throughout the entire EEA and directly or (as to Norway, Iceland and Liechtenstein) indirectly allows the applicant to place the product on the market in all member states of the EEA. The EMA is the administrative body responsible for coordinating the existing scientific resources available in the member states for evaluation, supervision and pharmacovigilance of medicinal products. Certain medicinal products, as described in the Annex to Regulation 726/2004, must be authorized centrally. These are products that are developed by means of a biotechnological process in accordance with Paragraph 1 to the Annex to the Regulation. Medicinal products for human use containing a new active substance for which the therapeutic indication is the treatment of acquired immune deficiency syndrome, or AIDS, cancer, neurodegenerative disorder or diabetes must also be authorized centrally. Starting on May 20, 2008, the mandatory centralized procedure was extended to autoimmune diseases and other immune dysfunctions and viral diseases. Finally, all medicinal products that are designated as orphan medicinal products pursuant to Regulation 141/2000 must be authorized under the centralized procedure. 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. 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. 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)). 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.

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 and Volume 4 of the "Rules Governing Medicinal Products in the European Community." 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 Directive 2001/20/EC, which implements good clinical practice in the conduct of clinical trials on medicinal products for human use. Clinical trials conducted outside the EU and used to support applications for marketing within the EU must have been conducted in a way consistent with the principles set out in Directive 2001/20/EC. The conduct of a clinical trial in the EU requires, pursuant to Directive 2001/20/EC, authorization by the relevant national competent authority where a trial takes place, and an ethics committee to have issued a favorable opinion in relation to the arrangements for the trial. It also requires that the sponsor of the trial, or a person authorized to act on his behalf in relation to the trial, be established in the EU.

There are various types of applications for marketing authorizations:

Full Applications. A full application is one that is made under any of the EU procedures described above and "stands alone" in the sense that it contains all of the particulars and information required by Article 8(3) of Directive 2001/83 (as amended) to allow the competent authority to assess the quality, safety and efficacy of the product and in particular the balance between benefit and risk. Article 8(3)(l) in particular refers to the need to present the results of the applicant's research on (1) pharmaceutical (physical-chemical, biological or microbiological) tests, (2) preclinical (toxicological and pharmacological) studies and (3) clinical trials in humans. The nature of these tests, studies and trials is explained in more detail in Annex I to Directive 2001/83/EC, currently set forth in Directive 2003/63/EC of 25 June 2003. Full applications would be required for products containing new active substances not previously approved by the competent authority, but may also be made for other products.

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

Cross-referral to Innovator's Data

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

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

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

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

Well-established Medicinal Use

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

Informed Consent

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

Law Relating to Pediatric Research

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

Post-authorization Obligations

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

Approval of Medical Devices

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

Israel

Israel Ministry of the Environment — Toxin Permit

In accordance with the Israeli Dangerous Substances Law - 1993, the Ministry of the Environment is required to grant a permit in order to use toxic materials. Because we utilize toxic materials in the course of operation of our laboratories, we were required to apply for a permit to use these materials. Our current toxin permit will remain in effect until January 2015.

Clinical Testing in Israel

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

Other Countries

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

Related Matters

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

Israeli Government Programs

Israel Office of the Chief Scientist

Research and Development Grants. A number of our therapeutic products have been financed, in part, through funding from the OCS in accordance with the Israeli Law for the Encouragement of Industrial Research and Development, 1984 and related regulations, or the Research Law. As of December 31, 2012, we received approximately NIS 75.9 million ($20.3 million) million in aggregate funding from the OCS, which amount includes approximately NIS 22.2 million ($5.9 million) of funding for particular projects, and approximately NIS 53.7 million ($14.4 million) of funding in the framework of our biotechnology incubator. The aggregate funding amount includes approximately NIS 34.1 ($9.1 million) of funding received in connection with terminated programs. We are not required to repay funding for terminated programs. Under the Research Law and the terms of the grants, royalties on the revenues derived from sales of products developed with the support of the OCS are payable to the Israeli government, generally at the rate of 3% during the first three years of repayment, 4% during the subsequent three years and 5% from the seventh year onwards, although these terms are different in the event we out-license the products or receive the OCS approval for the transfer the manufacture or to transfer the rights to manufacture our products developed with OCS grants outside of Israel. The obligation to make these payments terminates upon repayment of the amount of the received grants as adjusted for fluctuation in the U.S. dollar/shekel exchange rate, plus interest and any additional amounts as described below. However, we may be required to pay an increased total amount of royalties (possibly up to 300% of the grant amounts plus interest) if we receive approval to manufacture or to transfer the rights to manufacture our products developed with OCS grants outside of Israel, depending on the portion of total manufacturing that is performed outside of Israel, as further described below, and we may be required to pay additional amounts in respect of the technology developed under these projects that is otherwise transferred outside of Israel, as further described below. The amounts received bear interest equal to the 12-month London Interbank Offered Rate applicable to dollar deposits that is published on the first business day of each calendar year.

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

In addition, under the Research Law, we are prohibited from transferring our OCS financed technologies, technologies derived therefrom and related intellectual property rights outside of Israel except under limited circumstances and only with the approval of the OCS and upon making a payment to the OCS. We may not receive the required approvals for any proposed transfer and, if received, we may be required to pay the OCS a portion of the consideration that we receive upon any sale or transfer of such technology to a non-Israeli entity. The scope of the support received, the royalties that we may have already paid to the OCS, the amount of time that has elapsed between the date on which the technology was transferred and the date on which the OCS grants were received and the sale price and the form of transaction will be taken into account in order to calculate the amount of the payment to the OCS. The repayment amount is now subject to a maximum limit calculated in accordance with a formula set forth in regulations enacted during 2012. In addition, approval of the transfer of technology to residents of Israel is required, and may be granted in specific circumstances, only if the recipient agrees to abide by the provisions of applicable laws, including the restrictions on the transfer of know-how and the obligation to pay royalties. No assurances can be made that approval to any such transfer, if requested, will be granted.

The State of Israel does not own intellectual property rights in technology developed with OCS funding and there is no restriction on the export of products manufactured using technology developed with OCS funding. The technology is, however, subject to transfer of technology and manufacturing rights restrictions as described above. For a description of such restrictions, please see "Item 3. Risk Factors — Risks Relating to Our Operations in Israel." OCS approval is not required for the export of any products resulting from the research or development.

Biotechnology Incubator Program. In 2001, the OCS launched a biotechnology incubator program for advancing Israel's biotechnology industry. The program was significantly changed by the OCS in May 2004, pursuant to which the OCS invited companies to submit proposals to establish and operate OCS-funded biotechnology incubators to provide a physical, organized and professional platform for commercializing biotechnological research and development projects. We submitted a proposal to operate a biotechnology incubator, and our proposal was accepted by the OCS. Accordingly, we entered into the incubator agreement with the OCS in January 2005. The initial agreement was scheduled to expire on December 31, 2010 but at the end of 2010, the OCS agreed to renew the agreement for an additional two years, with an option to renew for another one-year period at the same terms and conditions, subject to OCS approval. We formed BIJ L.P. to act as the incubator entity. Our wholly-owned subsidiary, BIJ Ltd., is the general partner of BIJ L.P., also referred to as the incubator, and owns 1% of BIJ L.P.'s partnership interests, while BioLineRx is a limited partner of BIJ L.P. and owns the remaining 99% of BIJ L.P.'s partnership interests.

As of December 31, 2012, we received approximately $14.4 million from the OCS under the incubator agreement to fund 23 different development projects, 18 of which have terminated. Of our 12 current development projects, three have been or will be funded under the incubator agreement: BL-1021, BL-1040 and BL-5040. Other projects may also be funded by the OCS outside of the incubator agreement. As of March 5, 2013, one request is on file to fund an additional project outside of the incubator agreement but such request has not yet been approved by the OCS.

Israel Ministry of Health

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

C. Organizational Structure

Our corporate structure consists of BioLineRx and three wholly-owned entities: BioLine Innovations Jerusalem Limited Partnership, or BIJ L.P.; BioLine Innovations Jerusalem Ltd., or BIJ Ltd.; and BioLineRx USA Inc. BIJ Ltd. and BIJ L.P. are engaged in the operation of our biotechnology incubator. See "Item 10. Additional Information — Material Contracts — Incubator Agreement." BioLineRx USA Inc. has been inactive since the beginning of 2011, as a result of a decision by our Board of Directors to transfer all business development functions back to Israel, in order to reorganize our business development efforts and administer such efforts from our headquarters.

D. Property, Plant, and Equipment

We are headquartered in Jerusalem, Israel. We lease one facility pursuant to a lease agreement with Caps-Pharma Ltd. that expires on December 15, 2014, with an option to renew through December 2016. The Jerusalem headquarters consists of approximately 1,700 square meters of space and lease payments are approximately $21,600 per month. This facility houses both our administrative and research operations and our central laboratory. The central laboratory consists of approximately 600 square meters and includes an analytical chemistry laboratory, a formulation laboratory and a tissue culture laboratory. Our central laboratory is compliant with both cGMP and GLP, which allows us to manufacture therapeutic supplies for our current clinical trials. We are currently outfitting a section of the central laboratory as a Class 1000 Clean Room for the synthesis of compounds that require a clean environment for development. All of our employees are based in this facility.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this annual report. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this annual report, particularly those in "Item 3. Key Information — Risk Factors."U.S. dollar amounts herein (other than amounts that were originally receivable or payable in dollars) have been translated for the convenience of the reader from the original NIS amounts at the representative rate of exchange as of December 31, 2012 ($1 = NIS 3.733). The dollar amounts presented should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated.

We are a clinical stage biopharmaceutical development company dedicated to identifying, in-licensing and developing therapeutic candidates that have advantages over currently available therapies or address unmet medical needs. Our current development pipeline consists of six clinical therapeutic candidates: BL-1020, BL-1040, BL-5010, BL-7040, BL-8040 and BL-1021. In addition, we have six therapeutic candidates in pre-clinical development. We generate our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. We also operate, with substantial financial support of the Office of the Chief Scientist of the Israeli Ministry of Trade and Industry (OCS), a biotechnology incubator to evaluate therapeutic candidates. As of December 31, 2012, we received approximately NIS 53.7 million ($14.4) million in funding from the OCS to operate the incubator, which does not include NIS 22.2 million ($5.9 million) in funding we have received from the OCS outside of the incubator agreement as of that date. Such amounts include aggregate funding of approximately NIS 34.1 million ($9.1 million) for terminated programs. We are not required to repay funds received for terminated programs. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case by case basis, the commercialization of our therapeutic candidates independently.

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

- BL-1020 is an orally available drug in development for the treatment of schizophrenia. In September 2009, we announced positive topline results from the phase 2b EAGLE trial of BL-1020. In June 2011, we commenced the CLARITY trial of BL-1020, which is currently being carried out at 31 clinical sites in Romania, India and Moldova.

- BL-1040 is a novel resorbable polymer solution for use in the prevention of ventricular remodeling that may occur in patients who have suffered an acute myocardial infarction, or AMI. BL-1040 is being developed as a medical device. In March 2010, we announced encouraging results from a phase 1/2 clinical trial. We have entered into an exclusive, worldwide, royalty-bearing out-licensing arrangement with Ikaria, Inc., or Ikaria, with respect to the development, manufacture and commercialization of BL-1040. In December 2011, Ikaria commenced PRESERVATION 1, a CE Mark registration clinical trial of BL-1040 (now called "Bioabsorbable Cardiac Matrix," or BCM, by Ikaria).

- BL-5010 comprises a customized, proprietary pen-like applicator containing a novel formulation of two acids, which is being developed for the non-surgical removal of skin lesions. In December 2010, we announced positive results from a phase 1/2 clinical trial of BL-5010. We have received European confirmation from the British Standards Institution Notified Body in the UK of the regulatory pathway classification of BL-5010 as a Class IIa medical device. We are planning to commence a pivotal CE-Mark registration trial for European approval in the second half of 2013.

- BL-7040 is an orally available synthetic oligonucleotide which we are developing for the treatment of inflammatory bowel disease, or IBD. We are currently conducting a phase 2 proof-of-concept study to evaluate the effectiveness of BL-7040 for the treatment of IBD at five sites in Israel.

- BL-8040 is a short peptide that functions as a high-affinity antagonist for CXCR4, which we intend to develop for acute myeloid leukemia, or AML, and other hematological cancers. We plan to commence a phase 2 clinical trial in the first half of 2013.

- BL-1021 is a new chemical entity in development for the treatment of neuropathic pain. We are currently evaluating potential development collaborations with other parties in order to continue development of this compound.

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

In June 2010, we entered into an exclusive, royalty-bearing out-licensing arrangement with Cypress Bioscience with regard to BL-1020, covering the United States, Canada and Mexico, which became effective in August 2010. We received an upfront fee of $30.0 million from Cypress Bioscience upon the effectiveness of the agreement. In May 2011, following the acquisition of Cypress Bioscience by Royalty Pharma earlier in the year, we reacquired all of the rights to develop and commercialize BL-1020 from Cypress Bioscience and currently hold full global rights to the product. We are continuing to develop BL-1020, and commenced the phase 2/3 CLARITY trial in June 2011, which is currently being carried out at clinical sites in Romania, India and Moldova. Concurrent with the conduct of the trial and in accordance with our business strategy, we have continued to hold discussions with potential out-licensing partners for the further development and commercialization of BL-1020 at its more advanced stages.

History of Losses

Since inception in 2003, we have generated significant losses in connection with our research and development, including the clinical development of BL-1020. As of December 31, 2012, we had an accumulated deficit of NIS 444.3 million. Although we have previously recognized revenues in connection with our out-licensing arrangement with Ikaria for BL-1040 and our former out-licensing arrangement with Cypress Bioscience for BL-1020, we may continue to generate losses in connection with the research and development activities relating to our pipeline of therapeutic candidates. Such research and development activities are budgeted to expand over time and will require further resources if we are to be successful. As a result, we may continue to incur operating losses, which may be substantial over the next several years, and we may need to obtain additional funds to further pursue our research and development programs.

We have funded our operations primarily through the sale of equity securities (both in private and direct placements and in three public offerings on the TASE), funding received from the OCS, payments received under the licensing arrangements with Ikaria and Cypress Bioscience, and interest earned on investments. We expect to continue to fund our operations over the next several years through our existing cash resources, potential future milestone payments that we expect to receive from Ikaria, potential future upfront or milestone payments that we may receive from out-licensing transactions for our other therapeutic candidates, interest earned on our investments and additional capital to be raised through public or private equity offerings or debt financings. As of December 31, 2012, we held approximately $21.4 million of cash, cash equivalents and short-term bank deposits, based on the exchange rate reported by the Bank of Israel as of December 31, 2012. In February 2013, we completed a direct placement for net proceeds of $7.7 million. See “Item 5. Operating and Financial Review and Prospects – Liquidity and Capital Resources.”

Revenues

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

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

We expect our revenues for the next several years to be derived primarily from payments under our current agreement with Ikaria, as well as additional collaborations that we may enter into in the future, including with regard to BL-1020, BL-5010, BL-7040, BL-8040, BL-1021 or other therapeutic candidates. Furthermore, we may receive future royalties on product sales, if any, under our agreement with Ikaria, as well as under any future agreement relating to BL-1020, BL-5010, BL-7040, BL-8040, BL-1021 or other compounds.

Research and Development

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

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

Project	Status	Expected or Recent Near Term Milestone
BL-1020	Phase 2/3 CLARITY trial	CLARITY study interim results – week of March 18, 2013; CLARITY study final results – second half of 2013
BL-1040	CE registration pivotal trial	PRESERVATION 1 study results in 2014
BL-5010	Completed phase 1/2	Completion of unique applicator prototype by second quarter of 2013; commencement of pivotal CE Mark registration trial in second half of 2013
BL-7040	Phase 2 trial	Study results – April 2013
BL-8040	Completed phase 1/2	Phase 2 study expected to commence during the second quarter of 2013
BL-1021	Completed phase 1a	Potential co-development collaboration

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

We record costs for each development project on a “direct cost” basis only. Direct costs, which include contract research organization expenses, consulting expenses, patent expenses, materials, and other, similar expenses, are recorded to the project for which such expenses are incurred. However, salary and overhead costs, including, but not limited to, salary expenses (including salaries for research and development personnel), facilities, depreciation, and stock-based compensation, are considered overhead, and are shared among all of our projects and are not recorded on a project-by-project basis. We do not allocate direct salaries to projects due to the fact that our project managers are generally involved in several projects at different stages of development, and the related salary expense is not significant to the overall cost of the applicable projects. In addition, indirect labor costs relating to our departments that support the research and development process, such as chemistry, manufacturing and controls (CMC), pre-clinical analysis, laboratory testing and initial drug sample production, as well as rent and other administrative overhead costs, are shared by many different projects and have never been considered by management to be of significance in its decision-making process with respect to any specific project. Accordingly, such costs have not been specifically allocated to individual projects. Set forth below is a summary of the gross direct costs allocated to our main projects on an individual basis, as well as the gross direct costs allocated to our less significant projects on an aggregate basis, for the years ended December 31, 2010, 2011 and 2012 and on an aggregate basis since project inception. Certain of such costs are covered by OCS funding, although OCS funds received have not been deducted from the direct project costs in the table.

	Year Ended December 31,			Total Costs Since Project Inception
	2010	2011	2012	
	(U.S. $ in thousands)			
BL-1020	450	2,765	7,448	51,558
BL-1040	167	3	–	10,227
BL-5010	384	94	132	2,136
BL-1021	924	466	68	7,127
BL-7040	–	465	500	965
BL-8040	–	–	723	723
Other projects	1,704	3,262	3,855	25,739
Total gross direct project costs[1]	3,629	7,055	12,726	98,475

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

As indicated in the table above, a significant portion of our research and development costs have been incurred in connection with the BL-1020 project. We expect to continue to incur significant additional costs on the BL-1020 project through 2013, as a result of the phase 2/3 CLARITY study that we are currently conducting.

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

From our inception through December 31, 2012, we have incurred research and development expense of approximately NIS 514.1 million ($137.7 million). We expect that a large percentage of our research and development expense in the future will be incurred in support of our current and future preclinical and clinical development projects. Due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage of our preclinical product development projects, we are unable to estimate with any certainty the costs we will incur in the continued development of the therapeutic candidates in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test our product candidates in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for each product candidate. If we are not able to enter into an out-licensing arrangement with respect to any therapeutic candidate prior to the commencement of later stage clinical trials, we may fund the trials for the therapeutic candidate ourselves.

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

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

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

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

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

Sales and Marketing Expenses

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

General and Administrative Expenses

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

Non-Operating Expense and Income

Non-operating expense and income includes fair-value adjustments of derivative liabilities on account of the warrants issued in the private placement which we conducted in February 2012. 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 placement related to the warrants. In addition, non-operating expense and income includes the initial commitment and finder's fees, as well as other one-time expenses, associated with the initial set-up of the LPC share purchase agreement.

Financial Expense and Income

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

Critical Accounting Policies and Estimates

We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the year ended December 31, 2012. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

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

Functional Currency

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

Revenue Recognition

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

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

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

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

Accrued Expenses

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

Investments in Financial Assets

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

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

Government Participation in Research and Development Expenses

We receive research and development funding from the State of Israel through the OCS, both in the form of loans extended to our biotechnology incubator, as well as in the form of grants. In accordance with the OCS programs, we are entitled to a specific grant or loan with respect to a development project only after we incur development costs related to the project. Such loans and grants qualify as "forgivable loans" in accordance with IAS 20, "Accounting for Government Grants and Disclosure of Government Assistance," since they are repayable only if we generate revenues related to the underlying project.

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

Liabilities to the OCS in respect of out-licensing transactions are generally discussed and negotiated with the OCS, due to the fact that such licensing transactions do not fit into the standard development funding model contemplated by the Israeli Research and Development Law. In June 2010, we received a notification regarding the payment due in connection with the BL-1040 project, which we have paid in full. Accordingly, we have no further liabilities to the OCS with respect to BL-1040. We have accrued a liability of $1.6 million to the OCS in connection with the BL-1020 out-licensing transaction ($3.0 million was paid in August 2010), representing the full amount of the grants received from the OCS in respect of the BL-1020 project. This represents our best estimate of the liability to the OCS related to BL-1020. We may incur additional liabilities to the OCS, depending on the portion of total manufacturing that is performed outside of Israel in respect of BL-1020. Such liabilities will only accrue, if at all, with respect to any payment received in connection with BL-1020, when we determine that it is more likely than not that the payment will become payable.

Stock-based Compensation

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

Warrants

In December 2009, we issued Series 2 Warrants exercisable for 7,528,946 ordinary shares. The Series 2 Warrants had a fixed exercise price and were classified as shareholders' equity. All Series 2 warrants expired in December 2011 without exercise.

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

In connection with the direct placement to Orbimed of approximately 2.67 million of our ADSs in February 2013, we issued warrants to purchase 1.6 million of our ADSs at an exercise price of $3.94, subject to typical adjustments. The warrants are exercisable for a period of five years from the date of issuance. Since the exercise price was not deemed to be fixed, the warrants are not qualified for classification as an equity instrument and will therefore been classified as a non-current financial liability, commencing with our March 31, 2013 quarterly financial statements.

Recent Accounting Pronouncements

A number of new standards and amendments to standards and interpretations are effective for annual periods beginning after January 1, 2012, and have not been applied in preparing these consolidated financial statements. None of these is expected to have a significant effect on our consolidated financial statements, except the following set out below, for which the impact has not been fully assessed.

Amendment to IAS 1, "Financial Statement Presentation." This amendment, regarding other comprehensive income, is effective for annual financial statement periods commencing on or after July 1, 2012. The main change resulting from this amendment is a requirement for entities to group items presented in other comprehensive income on the basis of whether they are potentially re-classifiable to profit or loss subsequently (reclassification adjustments).

IFRS 13, "Fair Value Measurement." This standard, effective for financial statement periods commencing on or after January 1, 2013, aims to improve consistency and reduce complexity by providing a precise definition of fair value and a single source of fair value measurement and disclosure requirements for use across IFRSs. The requirements, which are largely aligned between IFRSs and U.S. GAAP, do not extend the use of fair value accounting, but provide guidance on how it should be applied where its use is already required or permitted by other standards within IFRSs or U.S. GAAP.

Amendment to IAS 19, "Employee Benefits." This amendment, effective for financial statement periods commencing on or after January 1, 2013, changes the methodology for calculating long-term employee benefit liabilities. The impact on the Company will be to immediately recognize all past service costs, and to replace interest cost and expected return on plan assets with a net interest amount that is calculated by applying the discount rate to the net defined benefit liability (asset). Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are to be charged to equity.

IFRS 9, "Financial instruments." This standard, effective for financial statement periods commencing on or after January 1, 2015, addresses the classification, measurement and recognition of financial assets and financial liabilities. IFRS 9 was issued in November 2009 and October 2010. It replaces the parts of IAS 39 that relate to the classification and measurement of financial instruments. IFRS 9 requires financial assets to be classified into two measurement categories: those measured at fair value and those measured at amortized cost. The determination is made at initial recognition. The classification depends on the entity's business model for managing its financial instruments and the contractual cash flow characteristics of the instrument. For financial liabilities, the standard retains most of the IAS 39 requirements. The main change is that, in cases where the fair value option is taken for financial liabilities, the part of a fair value change due to an entity's own credit risk is recorded in other comprehensive income rather than the income statement, unless this creates an accounting mismatch. The Company has not yet assessed the full impact of IFRS 9. The Company will also consider the impact of the remaining phases of IFRS 9 when completed.

IFRS 10, "Consolidated Financial Statements." This standard, effective for financial statement periods commencing on or after January 1, 2013, builds on existing principles by identifying the concept of control as the determining factor in whether an entity should be included within the consolidated financial statements of the parent company. The standard provides additional guidance to assist in the determination of control where this is difficult to assess. The Company has not yet assessed the full impact of IFRS 10.

Results of Operations -- Overview

Revenues

In August 2010, we received a payment of $30.0 million in connection with our out-licensing arrangement with Cypress Bioscience, which was recorded as revenue in the third quarter of 2010. We did not record any revenues during the years ended December 31, 2011 and 2012.

Cost of revenues

Cost of revenues consists of payments due to the licensors under the in-licensing agreement related to BL-1020. We did not record any cost of revenues during the years ended December 31, 2011 and 2012.

Research and development expenses

At December 31, 2010, our drug development pipeline consisted of 10 therapeutic candidates. During 2011, we added six new compounds to our pipeline, and discontinued the development of one compound from the pipeline, so that our drug development pipeline as of December 31, 2011 consisted of 15 therapeutic candidates. During 2012, we added four new compounds to our pipeline and discontinued the development of five compounds from the pipeline, so that our drug development pipeline as of December 31, 2012 consisted of 14 therapeutic candidates. Subsequent to December 31, 2012, we added one new compound to our pipeline and discontinued the development of three additional compounds from the pipeline, so that our drug development pipeline as of the date of this report consists of 12 therapeutic candidates.

Comparison of the Year Ended December 31, 2012 to the Year Ended December 31, 2011

Research and development expenses

Research and development expenses for the year ended December 31, 2012 were NIS 64.3 million ($17.2 million), an increase of NIS 21.7 million ($5.8 million), or 51%, compared to NIS 42.6 million ($11.4 million) for the year ended December 31, 2011. The increase resulted primarily from significantly higher expenses in 2012 associated with the CLARITY clinical trial in respect of BL-1020, which commenced at the end of June 2011 and was still in its initial ramp-up stages during the third and fourth quarters of 2011, as well as a ramp-up in spending on other clinical-stage projects introduced during the second half of 2011 and in 2012.

Sales and marketing expenses

Sales and marketing expenses for the year ended December 31, 2012 were NIS 3.2 million ($0.9 million), a negligible decrease compared to NIS 3.3 million ($0.9 million) for the year ended December 31, 2011. We invested additional resources in our overall business development efforts in 2012, which were primarily offset by savings from efficiencies realized this year due to the reorganization of our business development team, as well as professional services incurred last year related to the reacquisition of the rights to BL-1020 from Cypress Bioscience. Sales and marketing expenses are expected to increase in the foreseeable future, as we continue to increase our business development efforts in respect of BL-1020, as well as a number of our other assets.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2012 were NIS 14.0 million ($3.8 million), an increase of NIS 1.3 million ($0.4 million) or 10%, compared to NIS 12.7 million ($3.4 million) for the year ended December 31, 2011. The increase resulted primarily from professional fees and other expenses associated with being a listed company on Nasdaq for a full year in 2012 compared to only five months in 2011, as well as an increase in excise taxes recorded in 2012 in respect of certain non-deductible expenses.

Non-operating income (expense), net

Non-operating income, net, for the year ended December 31, 2012 consists of a NIS 7.3 million ($2.0 million) fair-value adjustment of derivative liabilities on account of the warrants issued in the private placement which we conducted in February 2012, offset by issuance expenses in the amount of NIS 1.2 million ($0.3 million) from the private placement related to the warrants, as well as the initial commitment and finder's fees and other one-time expenses in the aggregate amount of NIS 2.1 million ($0.5 million) associated with the LPC share purchase agreement.

Financial income (expense), net

We recognized net financial income of NIS 1.3 million ($0.4 million) for the year ended December 31, 2012, a decrease of NIS 7.2 million ($1.9 million), compared to net financial income of NIS 8.5 million ($2.3 million) for the year ended December 31, 2011. Net financial income for both years results primarily from changes in the average exchange rate of the dollar in relation to the NIS, which were much more pronounced in 2011 than in 2012, and had a positive effect on our net assets denominated in dollars.

Comparison of the Year Ended December 31, 2011 to the Year Ended December 31, 2010

Research and development expenses

Research and development expenses for the year ended December 31, 2011 were NIS 42.6 million, a decrease of NIS 12.4 million, or 23%, compared to NIS 55.0 million for the year ended December 31, 2010. Research and development expenses for the 2010 period included payments to the OCS of NIS 17.4 million, which were a repayment of funds previously received from the OCS in respect of BL-1020. Those funds had been previously reflected in prior periods as a reduction in research and development expenses. Without regard to these non-recurring payments, research and development expenses for the year ended December 31, 2011 increased by NIS 5.1 million, or 14%, over the year ended December 31, 2010. The increase resulted primarily from the commencement of the CLARITY clinical trial in respect of BL-1020 at the end of June 2011.

Sales and marketing expenses

Sales and marketing expenses for the year ended December 31, 2011 were NIS 3.3 million, a decrease of NIS 1.3 million, or 28%, compared to NIS 4.6 million for the year ended December 31, 2010. The decrease resulted primarily from a shorter period of time devoted to strategic partnering efforts in connection with BL-1020 during 2011 as compared to 2010, as well as from a reduction in expenses due to the transfer of our business development activities from the U.S. to Israel during the first half of 2011 and the resulting closure of our U.S. office.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2011 were NIS 12.7 million, a decrease of NIS 2.2 million, or 15%, compared to NIS 14.9 million for the year ended December 31, 2010. The decrease resulted primarily from expenses associated with our proposed initial public offering in 2010.

Financial income (expense), net

We recognized net financial income of NIS 8.5 million for the year ended December 31, 2011, an increase of NIS 14.2 million, compared to net financial expense of NIS 5.7 million for the year ended December 31, 2010. The increase in net financial income resulted primarily from the increase in the average exchange rate of foreign currencies in relation to the NIS during the year ended December 31, 2011, which had a positive effect on our net assets denominated in such foreign currencies during that period.

Quarterly Results of Operations

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

	Three Months Ended							
	March 31	June 30	Sept. 30	Dec. 31	March 31	June 30	Sept. 30	Dec. 31
	2011				2012			
	(in thousands of NIS)							
Consolidated Statements of Operations								
Revenues	–	–	–	–	–	–	–	–
Cost of revenues	–	–	–	–	–	–	–	–
Sales and marketing expenses	(750)	(1,323)	(358)	(877)	(766)	(948)	(912)	(601)
Research and development expenses, net	(6,384)	(10,405)	(13,255)	(12,579)	(14,675)	(16,000)	(15,848)	(17,781)
General and administrative expenses	(2,926)	(3,348)	(3,272)	(3,176)	(3,525)	(2,956)	(2,834)	(4,711)
Operating income (loss)	(10,060)	(15,076)	(16,885)	(16,632)	(18,966)	(19,904)	(19,594)	(23,093)
Non-operating income (expenses), net	–	–	–	–	2,819	2,712	(3,180)	1,607
Financial income, net	1,183	637	8,965	2,432	446	6,050	1,827	496
Financial expenses, net	(2,767)	(1,965)	(18)	–	(2,231)	(172)	(1,649)	(3,438)
Net income (loss)	(11,644)	(16,404)	(7,938)	(14,200)	(17,932)	(11,314)	(22,596)	(24,428)

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

Liquidity and Capital Resources

Since inception, we have funded our operations primarily through public (in Israel), private and direct offerings of our equity securities, grants and loans from the OCS, and payments received under our strategic licensing arrangements. At December 31, 2012, we held approximately NIS 79.8 million ($21.4 million) in cash, cash equivalents and short-term bank deposits, and have invested substantially all of our available cash funds in short-term bank deposits.

In February 2013, we completed a direct placement to a leading healthcare investor, OrbiMed Israel Partners Limited Partnership, an affiliate of OrbiMed Advisors LLC. The placement consisted of 2,666,667 ADSs and warrants to purchase an additional 1,600,000 ADSs, at a unit price of $3.00. The warrants have an exercise price of $3.94 per ADS and are exercisable for a term of five years. The offering raised a total of $8,000,000, with net proceeds of approximately $7,700,000, after deducting fees and expenses.

Pursuant to the share purchase agreement with LPC signed in September 2012, we may sell, from time to time, and at our discretion, up to $15 million of our ADSs to LPC during the 36-month term of the purchase agreement. From the effective date of the purchase agreement through March 5, 2013, we have sold an aggregate of approximately $4.7 million of our ADSs to LPC, leaving an available balance under the facility of approximately $10.3 million.

Net cash used in operating activities was NIS 75.1 million for the year ended December 31, 2012 and NIS 42.7 million for the year ended December 31, 2011, compared with cash provided by operating activities of NIS 40.7 million for the year ended December 31, 2010. The NIS 32.4 million increase in net cash used in operating activities during 2012 was primarily the result of increased research and development spending. The net cash provided by operating activities in 2010 primarily reflects the $30.0 million upfront payment we received from Cypress Bioscience.

Net cash provided by investing activities for the year ended December 31, 2012 was NIS 51.3 million, compared to net cash used in investing activities of NIS 37.6 million for the year ended December 31, 2011 and NIS 29.5 million for the year ended December 31, 2010. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits and other investments during the respective periods.

Net cash provided by financing activities for the year ended December 31, 2012 was NIS 58.9 million, compared to insignificant amounts of cash flows related to financing activities for the years ended December 31, 2011 and 2010. The net cash provided by financing activities relates primarily to the private placement we completed in February 2012.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Although we believe our existing cash and other resources will be sufficient to fund our projected cash requirements through the end of 2014, we will require significant additional financing in the future to fund our operations. Additional financing may not be available on acceptable terms, if at all. Our future capital requirements will depend on many factors, including:

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

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

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

Off-Balance Sheet Arrangements

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

Contractual Obligations

The following table summarizes our significant contractual obligations at December 31, 2012:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
			(in thousands of NIS)		
Car leasing obligations	1,326	885	441	–	–
Premises leasing obligations	2,285	916	1,369	–	–
Purchase commitments	5,973	5,973	-	–	–
Total	9,584	7,774	1,810	–	–

The foregoing table does not include our in-licensing agreements. Under our in-licensing agreements, we are obligated to make certain payments to our licensors upon the achievement of agreed upon milestones. We are unable at this time to estimate the actual amount or timing of the costs we will incur in the future under these agreements; however, we do not expect any material milestones to be achieved within the next 12 months. If all of the milestones are achieved over the life of each in-licensing agreement, we will be required to pay approximately $8.0 million, in the aggregate, to the applicable licensors. Some of the in-licensing agreements are accompanied by consulting, support and cooperation agreements, pursuant to which we are required to pay the licensors a fixed monthly amount, over a period stipulated in the applicable agreement, for their assistance in the continued research and development under the applicable license. All of our in-licensing agreements are terminable at-will by us upon prior written notice of 30 to 90 days. We are unable at this time to estimate the actual amount or timing of the costs we will incur in the future under these agreements. See “Item 4. Information on the Company — Business Overview — In-Licensing Agreements.”

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth information for our executive officers and directors as of March 5, 2013.* Unless otherwise stated, the address for our directors and officers is c/o BioLineRx Ltd., P.O. Box 45158, 19 Hartum Street, Jerusalem 9777518, Israel.

Name	Age	Position(s)
Kinneret Savitsky, Ph.D.	46	Chief Executive Officer
Philip Serlin, CPA, MBA	52	Chief Financial and Operating Officer
Moshe Phillip, M.D.	58	Vice President of Medical Affairs and Senior Clinical Advisor
Leah Klapper, Ph.D.	48	General Manager, BioLine Innovations Jerusalem
David Malek, MBA	35	Vice President of Business Development
Aharon Schwartz, Ph.D.	70	Chairman of the Board
Michael J. Anghel, Ph.D.	73	Director
Nurit Benjamini, MBA	46	External Director
Raphael Hofstein, Ph.D.	63	Director
Avraham Molcho, M.D.	55	External Director

* From 2007 until March 4, 2013, Yakov Friedman served as a director. On that date, Mr. Friedman gave notice of his resignation, effective immediately.

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

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

Moshe Phillip, M.D., has been our Vice President of Medical Affairs and Senior Clinical Advisor and a member of our Scientific Advisory Board since 2004. Professor Phillip is the Director of the Institute for Endocrinology and Diabetes of the Israel National Center for Childhood Diabetes at the Schneider Children's Medical Center of Israel, has served as the Vice Dean and Head of School for Continuing Medical Education and currently is the Vice Dean for Research and Development at the Sackler School of Medical Education at Tel Aviv University. Professor Phillip served as the Chairman of the Israel Diabetes Association's Committee for Type 1 Diabetes, serves as the Chair of Type 1 Diabetes in the Diabetes National Councils of Health and as a member of the Pediatric National Council of Health. Professor Phillip is also on the editorial board of three medical journals, including Pediatric Diabetes and Hormone Research. Since 2008, Professor Phillip has served as a director of CGU3, a privately-held company. Professor Phillip holds an M.D. from the Ben Gurion University of the Negev and received a fellowship in pediatric endocrinology at the University of Maryland School of Medicine.

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

David Malek, MBA, has served as our Vice President of Business Development since October 2011. Prior to joining the Company, from 2007 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 BA in Statistics and Political Science from the University of Haifa.

Aharon Schwartz, Ph.D., has served as the Chairman of our Board of Directors since 2004. He served in a number of positions in Teva from 1975 through 2011, the most recent being Vice President, Head of Teva Innovative Ventures from 2008. Dr. Schwartz also served as Chairman of DenX Ltd. and Immudar. He is currently a non-executive member of the boards of numerous life science companies, including Clal Biotechnology Industries Ltd. (TASE:CBI), Proteologic Ltd. and Mediwound Ltd. Dr. Schwartz received his Ph.D. in organic chemistry from the Weizmann Institute, his M.Sc. in organic chemistry from the Technion and a B.Sc. in chemistry and physics from the Hebrew University of Jerusalem.

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. (TASE:EVGN), Gravity Visual Effects and Design Ltd., Dan Hotels Ltd. (TASE:DANH), Orbotech Ltd. (Nasdaq:ORBK, GSM:ORBK) and the Strauss Group Ltd. (TASE:STRS). He is 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 May 2011, Ms. Benjamini has served as the Chief Financial Officer of Wixpress Ltd. Prior to that, from 2007 through 2011, she served as the Chief Financial Officer of CopperGate Communications Ltd. From 2000 through 2007, Ms. Benjamini served as the Chief Financial Officer of Compugen Ltd. (Nasdaq: CGEN). Prior to that, from 1998 through 2000, Ms. Benjamini served as the Chief Financial Officer of Phone-Or Ltd. and from 1993 through 1998, Ms. Benjamini served as the Chief Financial Officer of Aladdin Knowledge Systems Ltd. Ms. Benjamini serves on the board of directors, and as chairperson of the audit committee, of Allot Communications Ltd. (Nasdaq:ALLT, TASE:ALLT). Ms. Benjamini holds a B.A. in Economics and Business and an M.B.A. in Finance, both from Bar Ilan University, Israel.

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

Avraham Molcho, M.D., MBA, has served as an external director on our Board of Directors and on our Audit Committee since 2010. In addition, Dr. Molcho has served on our Compensation Committee since 2012. Dr. Molcho is the Founder and Chairman of Biologic Design, a technology platform that encourages human antibody discoveries, and is a venture partner at Forbion Capital Partners, a Dutch life sciences venture capital firm. In 2012, he became the co-founder, CEO and director of 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.

B. Compensation

Employment Agreements

We have entered into written employment agreements with each of our executive officers. 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.

Compensation of Directors and Senior Management

The following table presents all compensation we paid to all of our directors and senior management as a group for the year ended December 31, 2012. The table does not include any amounts we paid to reimburse any of such persons for costs incurred in providing us with services during this period.

	Salaries, fees, commissions and bonuses (NIS)	Pension, retirement, options and other similar benefits (NIS)
All directors and senior management as a group, consisting of 9 persons	3,960,000	1,943,000

C. Board Practices

Board of Directors

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

Under the Companies Law, we are not required to have a majority of independent directors. We are required to appoint at least two external directors. See "— External Directors." The audit committee of a publicly-traded company must consist of a majority of unaffiliated directors. See "— Audit Committee."

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 six directors, including two external directors as required by the Companies Law. Pursuant to our Articles of Association, other than the external directors, for whom special election requirements apply under the Companies Law as detailed below, our directors are elected at a general or special meeting of our shareholders and serve on the Board of Directors until they are removed by the majority of our shareholders at a general or special meeting of our shareholders or upon the occurrence of certain events, in accordance with the Companies Law and our Articles of Association. In addition, our Articles of Association allow our Board of Directors to appoint directors to fill vacancies on the Board of Directors to serve until the next general meeting or special meeting, or earlier if required by our Articles of Association or applicable law. We have held elections for each of our non-external directors at each annual meeting of our shareholders since our initial public offering in Israel. External directors are elected for an initial term of three years and may be elected, under certain conditions, to two additional terms. 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 May 2012. 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, will 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 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 director, general manager, chief business manager, deputy general manager, vice general manager, executive vice president, vice president, any other manager directly subordinate to the general manager or any other person assuming the responsibilities of any of the foregoing positions, without regard to such person's title. Each person listed above under "Executive Officers and Directors" is an office holder.

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. Furthermore, a person who is directly or indirectly subordinate to a chief executive officer of a company may not serve as the chairman of the board of directors of that company and the chairman of the board of directors may not otherwise serve in any other capacity in a company or in a subsidiary of that company other than as the chairman of the board of directors of such a subsidiary.

External Directors

Under Israeli law, the boards of directors of companies whose shares are publicly traded are required to include at least two members who qualify as external directors. Each of our current external directors, Dr. Avraham Molcho and Ms. Nurit Benjamini, was elected as an external director by our shareholders in July 2010. Their initial terms expire in July 2013.

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 reelected 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 reelection and such reelection is approved by a majority vote at a shareholders' meeting, subject to the conditions described above for election of external directors, or (b) the reelection 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. The term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including the Nasdaq Capital Market, may be extended beyond the initial three terms permitted under the Companies Law indefinitely in increments of additional three-year terms, provided in each case that the following conditions are met: (a) the audit committee and the board of directors confirm that, in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the reelection for such additional period(s) is beneficial to the company; (b) the reelection is approved by the shareholders by a special majority required for the election of external directors; and (c) the proposed terms of compensation of the external directors, and the considerations of the audit committee and the Board of Directors in deciding to recommend reelection of the external directors, are presented to the shareholders prior to the vote on reelection. 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, except that the audit committee must include all external directors then serving on the board of directors. Under the Companies Law external directors of a company are prohibited from receiving, directly or indirectly, any compensation from the company other than for their services as external directors pursuant to the provisions and limitations set forth in regulations promulgated under the Companies Law.

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

The term affiliation includes:

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

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

In addition, no person may serve as an external director if that person's professional activities create, or may create, a conflict of interest with that person's responsibilities as a director or otherwise interfere with that person's ability to serve as an external director or if the person is an employee of the Israel Securities Authority or of an Israeli stock exchange. Furthermore, a person may not continue to serve as an external director if he or she received direct or indirect compensation from us for his or her role as a director. This prohibition does not apply to compensation paid or given in accordance with regulations promulgated under the Companies Law or amounts paid pursuant to indemnification and/or exculpation contracts or commitments and insurance coverage. If at the time an external director is appointed all current members of the board of directors not otherwise affiliated with the company are of the same gender, then that external director must be of the other gender. In addition, a director of a company may not be elected as an external director of another company if, at that time, a director of the other company is acting as an external director of the first company.

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

Audit Committee

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

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

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

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

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

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

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

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

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

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

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

- oversight of the company's independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of the our independent registered public accounting firm to the board of directors in accordance with Israeli law;
- recommending the engagement or termination of the office of the our internal auditor; and
- recommending the terms of audit and non-audit services provided by the independent registered public accounting firm for pre-approval by the board of directors.

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. The audit committee also oversees the audit efforts of our independent accountants and takes those actions as it deems necessary to satisfy itself that the accountants are independent of management. Pursuant to the Companies Law, the audit committee of a company shall be responsible for: (i) determining whether there are delinquencies in the business management practices of a company, including in consultation with an internal auditor or independent auditor, and making recommendations to the company's board of directors to improve such practices; (ii) determining whether to approve certain related party transactions (including compensation of office holders or transactions in which an office holder has a personal interest and whether such transaction is material or otherwise an extraordinary transaction); (iii) where the company's board of directors approves the working plan of the internal auditor, examining such working plan before its submission to the board and proposing amendments thereto; (iv) examining internal controls and the internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of his responsibilities (taking into consideration the special needs and size of a company); (v) examining the scope of the auditor's work and compensation and submitting its recommendation with respect thereto to the corporate body considering the appointment thereof (either the board or the general meeting of shareholders); and (vi) establishing procedures for the handling of employees' complaints as to the management of the business and the protection to be provided to such employees. Under the Companies Law, the approval of the audit committee is required for specified actions and transactions with office holders and controlling shareholders. See "— Approval of Related Party Transactions under Israeli Law."

Compensation Committee

In December 2012, the recently adopted 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, provided, that the majority of the members present at such meeting are unaffiliated directors, as such term "unaffiliated director" is defined under the Companies Law, as described in the section discussing the Company's Audit Committee above, and at least one of such members is an external director.

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 recommend 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 recommend 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 recommend 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 recommend 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, the Board of Directors established a Compensation Committee, comprised of Nurit Benjamini and Dr. Avraham Molcho, our two external directors, and Dr. Raphael Hofstein. Nurit Benjamini serves as the Chairperson of our Compensation Committee.

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

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

The board of directors of a 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.

Public Israeli companies are required to comply with the requirements of Amendment 20 and to adopt a compensation policy by no later than September 12, 2013. Until such time that a company adopts a compensation policy, compensation of officers must be approved in accordance with transition rules set forth in Amendment 20 which apply to the approval of officer compensation prior to the adoption and approval of a compensation policy by a company, as such are detailed above.

We are currently preparing a compensation policy applicable to all of our officers, with the aim of having our Compensation Committee and Board of Directors review the terms of compensation of our officers and approve such a policy and bringing such policy for approval of our shareholders prior to September 12, 2013 as required under Amendment 20.

Nominating Committee

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

Financial Statement Examination Committee

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

Investment Monitoring Committee

Our Board of Directors has established an Investment Monitoring Committee consisting of four members: Directors Michael Anghel and Nurit Benjamini; Philip Serlin, our Chief Financial Officer and Chief Operating Officer; and Raziel Fried, our Treasurer. The function of the Investment Monitoring Committee includes providing recommendations to the 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 the 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).

Approval of Related Party Transactions under Israeli Law

Fiduciary duties of office holders

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Under the Companies Law, the disclosure requirements that apply to an office holder also apply to a controlling shareholder of a public company. See "— Audit Committee" for a definition of controlling shareholder. 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 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 inserted 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.

A recent amendment to the Israeli Securities Law, 5728-1968 (the "Israeli Securities Law"), and a corresponding amendment to the Companies Law, authorizes the Israeli Securities Authority to impose administrative sanctions against companies like ours, and their office holders for certain violations of the Israeli Securities Law or the Companies Law. These sanctions include monetary sanctions and certain restrictions on serving as a director or senior officer of a public company for certain periods of time. The amendments to the Israeli Securities Law and to the Companies Law provide that only certain types of such liabilities may be reimbursed by indemnification and insurance. Specifically, legal expenses (including attorneys' fees) incurred by an individual in the applicable administrative enforcement proceeding and certain compensation payable to injured parties for damages suffered by them are permitted to be reimbursed via indemnification or insurance, provided that such indemnification and insurance are authorized by the company's articles of association, and receive the requisite corporate approvals.

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

Our office holders are currently covered by a directors and officers' liability insurance policy. As of the date of this Annual Report on Form 20-F, no claims for directors and officers' liability insurance have been filed under this policy and we are not aware of any pending or threatened litigation or proceeding involving any of our directors or officers in which indemnification is sought. Pursuant to the approval of our shareholders which was obtained on November 5, 2009, we carry directors and officers' insurance covering each of our directors and executive officers for acts and omissions. See also "Certain Transactions and Related Party Transactions — Indemnification Agreements."

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

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

D. Employees

As of December 31, 2012, we had 52 employees, all of whom are employed in Israel. Of our employees, 22 hold M.D. or Ph.D. degrees.

	December 31,		
	2010	**2011**	**2012**
Management and administration	12	12	13
Research and development	34	37	37
Sales and marketing	3	3	2

While none of our employees are party to any collective bargaining agreements, 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 order of the Israel Ministry of Labor. These provisions primarily concern the length of the workday, minimum daily wages for professional workers, pension fund benefits for all employees, insurance for work-related accidents, procedures for dismissing employees, determination of severance pay and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimums.

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

E. Beneficial Ownership of Executive Officers and Directors

The following table sets forth information regarding the beneficial ownership of our outstanding ordinary shares as of March 5, 2013 of each of our directors and executive officers individually and as a group.

	Number of Shares Beneficially Held	Percent of Class
Directors		
Aharon Schwartz	–	–
Michael J. Anghel	–	–
Nurit Benjamini(1)	45,837	*
Raphael Hofstein(2)	162,500	*
Avraham Molcho(3)	45,837	*
Executive officers		
Kinneret Savitsky(4)	1,422,202	*
Philip Serlin(5)	277,100	*
Leah Klapper(6)	340,779	*
David Malek(7)	–	*
Moshe Phillip(8)	978,799	*
All directors and executive officers as a group (11 persons)(9)	3,273,054	1.5%

* Less than 1.0%.

(1) Includes 45,837 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2013. Does not include 4,163 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2013.

(2) Includes 162,500 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2013. Does not include 37,500 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2013.

(3) Includes 45,837 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2013. Does not include 4,163 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2013.

(4) Includes 506,170 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2013. Does not include 1,150,000 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2013.

(5) Includes 277,100 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2013. Does not include 777,100 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2013.

(6) Includes 149,505 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2013. Does not include 571,980 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2013.

(7) Does not include 550,000 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2013.

(8) Includes 393,836 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2013. Does not include 485,675 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2013.

(9) Includes 1,580,785 ordinary shares issuable upon exercise of outstanding options within 60 days of March 5, 2013. Does not include 3,580,581 ordinary shares issuable upon exercise of outstanding options that are not exercisable within 60 days of March 5, 2013.

Stock Option Plans

2003 Share Option Plan

In 2003, we adopted the BioLineRx Ltd. 2003 Share Option Plan, or the Plan. The Plan provides for the granting of options and ordinary shares to our directors, employees, consultants and service providers, and to the directors, employees, consultants and service providers of our subsidiaries and affiliates. The Plan provides for options to be issued at the determination of our Board of Directors in accordance with applicable law. As of December 31, 2012, there were 13,575,811 ordinary shares issuable upon the exercise of outstanding options under the Plan.

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

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

Administration of Our Share Option Plan

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

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

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

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth certain information regarding the beneficial ownership of our outstanding ordinary shares as of March 5, 2013, 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 218,650,038 ordinary shares outstanding as of March 5, 2013 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, 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. Except where otherwise indicated, we believe, based on information furnished to us by such owners, that the beneficial owners of the ordinary shares listed below have sole investment and voting power with respect to such ordinary shares. To our knowledge, none of our shareholders of record are U.S. holders. Our principal shareholders do not have different or special voting rights.

	Number of Shares Beneficially Held	Percent of Class
Pan Atlantic Bank and Trust Limited(1)	28,703,966	12.7
OrbiMed Israel Partners Limited Partnership(2)	26,666,670	12.2
Ayer Capital Management, LP(3)	15,734,270	7.0
Teva Pharmaceutical Industries Ltd.(4)	11,889,535	5.4

(1) Based upon information provided by the shareholder in its Schedule 13D/A filed with the SEC on March 8, 2013. Pan Atlantic Bank and Trust Limited is a wholly owned subsidiary of FCMI Financial Corporation (FCMI). All of the outstanding shares of FCMI are owned by Albert D. Friedberg, members of his family and trusts for the benefit of members of his family. Mr. Friedberg retains possession of the voting and dispositive power over the FCMI shares held by members of the Friedberg family and trusts for the benefit of members of his family and, as a result, controls and may be deemed the beneficial owner of 100% of the outstanding shares of and sole controlling person of FCMI. By virtue of his control of FCMI, Mr. Friedberg may be deemed to possess voting and dispositive power over the shares owned directly by its wholly-owned subsidiary, Pan Atlantic Bank and Trust Limited. The principal executive offices of Pan Atlantic Bank and Trust Limited are at "Whitepark House," 1st Floor, Whitepark Road, St. Michael BB11135, Barbados, West Indies.

(2) Based upon information provided by the shareholder in its Schedule 13G filed with the SEC on February 15, 2013. OrbiMed Israel GP Ltd. ("OrbiMed Israel") is the general partner of OrbiMed Israel BioFund GP Limited Partnership ("OrbiMed BioFund"), which is the general partner of the shareholder, OrbiMed Israel Partners Limited Partnership, an Israel limited partnership ("OrbiMed Partners"). OrbiMed Israel, as the general partner of OrbiMed BioFund, and OrbiMed BioFund, as the general partner of OrbiMed Partners, may be deemed to share voting and investment power with respect to the ordinary shares underlying the securities held by OrbiMed Partners.

(3) Includes the securities held by Ayer Capital Partners Master Fund, L.P., Ayer Capital Partners Kestrel Fund, LP and Epworth-Ayer Capital. Ayer Capital Management, LP is the investment manager of, and may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended) of, the securities held by each of these entities. ACM Capital Partners, LLC and Jay Venkatesan each have voting control over Ayer Capital Management, LP. As a result, each of ACM Capital Partners, LLC and Jay Venkatesan, may be deemed to have beneficial ownership of the securities held by Ayer Capital Management, LP.

(4) Based upon information provided by the shareholder in its Schedule 13G filed with the SEC on February 14, 2012. Teva is a publicly-traded Israeli company. Its principal executive offices are at 5 Basel Street, PO Box 3190, Petach Tikva 49131, Israel.

B. Related Party Transactions

Early Development Program Agreement

We entered into an agreement with Pan Atlantic pursuant to which Pan Atlantic committed to provide up to $5.0 million of funding for us to in-license and develop early development stage therapeutic candidates. Pursuant to this early development program, we were entitled to request from Pan Atlantic twice a year up to $625,000 for an aggregate of up to approximately $1.25 million per year, unless otherwise agreed by Pan Atlantic, for our early development research projects, provided that we match the program funds at a rate of $0.20 per every dollar invested by Pan Atlantic. Pan Atlantic fulfilled its entire $5,000,000 funding obligation under this program during 2012. Pan Atlantic does not have any rights to any products developed through our early development projects. As part of the agreement, Pan Atlantic will have the right to invest up to $5.0 million in our first public offering outside of Israel. See "Item 10. Additional Information — Material Contracts — Early Development Program Agreement."

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

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and other Financial Information

See Item 18.

Legal Proceedings

We are not involved in any material legal proceedings.

Dividend Distributions

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

B. Significant Changes

None.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Price Range of our Ordinary Shares

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

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

	NIS		U.S.$	
	Price Per Ordinary Share		Price Per Ordinary Share	
	High	Low	High	Low
Annual:				
2012	2.12	0.89	0.56	0.23
2011	3.24	1.13	0.91	0.30
2010	4.75	2.86	1.26	0.80
2009	5.68	0.86	1.53	0.23
2008	4.25	0.69	1.10	0.17
Quarterly:				
Fourth Quarter 2012	1.34	0.94	0.34	0.25
Third Quarter 2012	1.18	0.91	0.30	0.23
Second Quarter 2012	1.12	0.89	0.30	0.23
First Quarter 2012	2.12	1.06	0.56	0.28
Fourth Quarter 2011	1.48	1.14	0.41	0.30
Third Quarter 2011	1.92	1.13	0.56	0.30
Second Quarter 2011	2.54	1.58	0.74	0.45
First Quarter 2011	3.24	2.15	0.91	0.60
Most Recent Six Months:				
March 2013 (through March 5, 2013)	1.43	1.37	0.38	0.37
February 2013	1.80	1.38	0.49	0.37
January 2013	1.73	0.97	0.41	0.26
December 2012	1.13	0.94	0.30	0.25
November 2012	1.23	1.04	0.32	0.27
October 2012	1.34	0.97	0.34	0.25
September 2012	1.04	0.92	0.28	0.22

On March 11, 2013, the last reported sales price of our ordinary shares on the TASE was NIS 1.42 per share, or $0.38 per share (based on the exchange rate reported by the Bank of Israel for such date). On March 11, 2013, the exchange rate of the NIS to the dollar was $1.00 = NIS 3.690, as reported by the Bank of Israel. As of March 11, 2013 there were three shareholders of record of our ordinary shares. The number of record holders is not representative of the number of beneficial holders of our ordinary shares.

Price Range of our ADSs

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

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

	U.S.$ Price Per ADS	
	High	**Low**
Annual:		
2012	5.55	2.23
2011 (from July 25, 2011)	5.59	2.75
Quarterly:		
Fourth Quarter 2012	3.35	2.47
Third Quarter 2012	3.00	2.23
Second Quarter 2012	2.85	2.30
First Quarter 2012	5.55	2.75
Fourth Quarter 2011	4.21	3.01
Third Quarter 2011(from July 25, 2011)	5.59	2.75
Most Recent Six Months:		
March 2013 (through March 5, 2013)	3.79	3.68
February 2013	4.75	3.66
January 2013	4.74	3.94
December 2012	3.05	2.47
November 2012	3.16	2.55
October 2012	3.35	2.55
September 2012	2.76	2.25

On March 11, 2013, the last reported sales price of our ADSs on the Nasdaq Capital Market was $3.92 per ADS. As of March 11, 2013 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.

B. Plan of Distribution

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable

B. Memorandum and Articles of Association

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

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

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

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

Dividends

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

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

Election of Directors

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

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

Shareholder Meetings

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

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

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

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

The Companies Law does not allow shareholders of publicly traded companies to approve corporate matters by written consent. Consequently, our Articles of Association does not allow shareholders to approve corporate matters by written consent.

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. A resolution for the voluntary winding up of the company requires the approval of holders of 75% of the voting rights represented at the meeting, in person, by proxy or by written ballot and voting on the resolution.

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

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 Amendment 20, 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, as set forth under Amendment 20.

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 rights that may be authorized in the future.

Access to Corporate Records

Under the Companies Law, all shareholders of a company generally have the right to review minutes of the company's general meetings, its shareholders register and principal shareholders register, articles of association, financial statements and any document it is required by law to file publicly with the Israeli Companies Registrar and the Israeli Securities Authority. 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. We may deny 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. In addition, the rules and regulations of the TASE also limit the terms permitted with respect to a new class of shares and prohibit any such new class of shares from having voting rights. Shareholders voting in such meeting will be subject to the restrictions provided in the Companies Law as described above.

C. Material Contracts

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

Incubator Agreement

We entered into an incubator agreement with the OCS in January 2005 to operate a biotechnology incubator. Our wholly-owned subsidiaries, BIJ Ltd. and BIJ L.P., operate the incubator. Under the arrangement, the OCS agreed to loan funds to the incubator in connection with in-licensing the rights to the therapeutic candidates. We in-license, through the incubator, certain, but not all, of the therapeutic candidates that we eventually incorporate into our pipeline. As of December 31, 2012, we received approximately $14.4 million of funding from the OCS under the incubator agreement, which does not include $5.9 million we have received from the OCS outside of the incubator agreement, as of that date. The OCS funds have been used to initiate 23 different development projects, 18 of which have been terminated. Three of our current development projects have been or will be funded under the incubator agreement: BL-1021, BL-1040 and BL-5040. Other projects may be funded by the OCS outside of the incubator agreement.

The incubator agreement had an initial six-year term ending on December 31, 2010. At the end of 2010, the OCS agreed to renew the agreement for an additional two years, with an option to renew for another one-year period at the same terms and conditions, subject to OCS approval. In 2012, the OCS approved our exercise of the option to extend the incubator agreement for the final one-year period through December 31, 2013. When the incubator agreement or expires, we will no longer be eligible for funding from the OCS through the incubator for new projects in the incubator, but projects and the terms of any outstanding funding at the time of expiration or termination will not be affected by the termination or expiration.

Under the incubator program, the Biotechnology Incubators Committee of the OCS is required to approve each project we intend to perform through the incubator and has broad discretionary powers with respect to approving equipment purchases and the general operation of the incubator. All of the restrictions placed on OCS-funded technology apply as well to all intellectual property derived from the incubator project. See “Item 4. Information on the Company — Business Overview — Government Funding for Development Programs — Israel Office of the Chief Scientist — Research and Development Grants.”

If we elect to terminate an incubator project for drug development, we are required to provide to the OCS the reasons that led to the termination of the project together with a financial and technical report relating to the drug development. We are also obligated to send notice to the entity that in-licensed to us the technology used for developing the drug. If the licensor is interested in continuing the development of the therapeutic candidate, the licensor is required to execute an agreement with the OCS and us to assume all rights and obligations relating to the funding received from the OCS. We expect that upon termination of a project and fulfillment of all OCS requirements for such termination, all loans associated with such project will be forgiven by the OCS.

The funding provided to us under the incubator agreement is in the form of a separate loan for each project, which is to be repaid solely out of the revenues generated by such project, with interest, until the full repayment of the loan. Revenue derived from a product developed in the incubator is subject to royalty payments at the same rates as set forth in the Research Law, as described in this annual report, and until the loans provided for that project are repaid. However, if a loan is not repaid within two years following the completion of the applicable incubator project the interest rate for that loan will be doubled for the third through fifth years after completion of the project. The loan and all accrued interest is repayable upon demand if we violate the terms of the incubator agreement, with accrued interest. We initially provided the OCS with a bank guarantee in the sum of approximately NIS 8.1 million to cover all of our undertakings made under the agreement. Following the expiration of the initial term of the incubator agreement, that guarantee expired as well and has now been replaced by two guarantees. The first guarantee (associated with the first renewal of the incubator agreement) is in the amount of NIS 1.5 million and will expire on March 31, 2013. The second guarantee (associated with the second renewal of the incubator agreement) is in the amount of approximately NIS 1.4 million and will expire on March 31, 2014. In addition, all intellectual property held or developed by the incubator in connection with the incubator program is pledged as security for our obligations under the agreement. The intellectual property rights pledged may be realized by the State of Israel eight years after the date of approval of the relevant incubator program, or earlier in the event of a breach of the incubator agreement by us, or in the event liquidation or dissolution of our biotechnology incubator.

Early Development Program Agreement

We entered into an agreement with our shareholder, Pan Atlantic Bank and Trust Limited, or Pan Atlantic, pursuant to which Pan Atlantic committed to provide us with up to $5.0 million to be used in connection with the in-licensing and development of early development stage therapeutic candidates, our Early Development Program. At least 70% of the research projects performed under the Early Development Program must originate inside Israel. We operate our Early Development Program independently from our biotechnology incubator. Pursuant to our Early Development Program, we were entitled to request from Pan Atlantic, twice a year, up to $625,000 for an aggregate of up to $1.25 million per year, unless otherwise agreed by Pan Atlantic, for our early development research projects, provided that we match the program funds at a rate of $0.20 per every dollar invested by Pan Atlantic. Pan Atlantic fulfilled its entire $5.0 million funding commitment under the program during 2012. As part of the agreement, Pan Atlantic has the right to invest up to $5.0 million in our first public offering outside of Israel. Currently, there is a liability on our balance sheet of approximately $0.7 million, representing cumulative amounts received from Pan Atlantic in excess of the cumulative amounts spent on our Early Development Program as of December 31, 2012.

The term of the Early Development Program Agreement continues through the earlier of (i) the completion of the disbursement of all of the funds provided in the agreement and the completion of all research programs funded thereby and (ii) the termination of the agreement by either party. Each party to the agreement may terminate the agreement due to the default of the other party with respect to a material term of the agreement, which default is not cured within 30 days of the defaulting party's receipt of notice of default, or to the occurrence of specified bankruptcy events with respect to the other party to the agreement or if the other party engages in a sale of all or substantially all of its assets as would cause that party to be unwilling to fulfill its obligations under the agreement.

Share Purchase Agreement with LPC

On September 21, 2012, we entered into a purchase agreement with LPC, pursuant to which LPC agreed to purchase from us up to $15 million of our ADSs (subject to certain limitations) from time to time over a 36-month period. Also on September 21, 2012, we entered into a registration rights agreement with LPC, pursuant to which we filed a registration statement on October 2, 2012 with the SEC for 4,198,598 of our ADSs, covering the ADSs that have been issued or may be issued to LPC under the purchase agreement. The registration statement was declared effective on October 12, 1012.

In consideration for entering into the purchase agreement, we issued to 98,598 ADSs to LPC upon execution of the purchase agreement as an initial commitment fee, and we will issue additional ADSs to LPC as an additional commitment fee in connection with each purchase by LPC under the purchase agreement equal to 2.5% of the amount of ADSs issued on each applicable purchase date. We will issue these additional commitment ADSs only when, and if, we elect to sell ADSs to LPC under the purchase agreement.

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

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

LPC may not assign or transfer its rights and obligations under the purchase agreement. We may at any time in our sole discretion terminate the purchase agreement without fee, penalty or cost. The purchase agreement will automatically terminate on November 1, 2015.

Cumulatively, as of March 5, 2013, we have issued 1,568,811 ADSs under the LPC agreement (including the initial and additional commitment fees), raising approximately $4.7 million in gross proceeds.

D. Exchange Controls

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

E. Taxation

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

Israeli Tax Considerations

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

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax at the rate of 25% of their taxable income for 2012 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 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 tax exemption for a period of ten years commencing in the first year in which we generate taxable income after setting off our losses for Israeli tax purposes from prior years in the amount of approximately $100 million. The ten-year period may not extend beyond 14 years from the beginning of the Benefited Enterprise's election year. We received Benefited Enterprise status with respect to the Eligible Projects beginning in the 2009 tax year, so depending on when the Benefited Enterprise programs begin to generate taxable income, the benefit period could continue through 2022. However, any distribution of income derived from our Benefited Enterprise programs will result in such income being subject to a rate of corporate tax no greater than 25%.

Beginning with tax year 2013, we have the option to transition to a "Preferred Enterprise" regime under the Investments Law, according to which all of our income which is eligible for benefits under the regime would be subject to flat corporate tax rates of 7% in 2013 and 2014 and 6% in 2015 and thereafter, whether or not distributed. If we were to move our operations to a different part of the country, these rates may be increased. A transition to a Preferred Enterprise regime may not be reversed.

In addition, the ITA approved 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 would be subject to Israeli corporate tax at the standard rate, which is currently set at 25% for 2012 and onwards. If these tax benefits are reduced or eliminated, the amount of taxes that we pay would likely increase, as all of our operations would consequently be subject to corporate tax at the standard rate, which could adversely affect our results of operations.

Taxation of Israeli Individual Shareholders on Receipt of Dividends. Israeli residents who are individuals are generally subject to Israeli income tax for dividends paid on our ordinary shares (other than bonus shares or share dividends) at a rate of 25%, or 30% 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.

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

However, in the case of both Israeli individual shareholders and Israeli resident corporations, under the Investments Law, dividends distributed from taxable income accrued during the period of benefit of a Benefited Enterprise and which are attributable to a Benefited Enterprise are subject to tax at the rate of 15%, if the dividend is distributed during the tax benefit period under the Investment Law or within 12 years after that period. A weighted average rate may be set if the dividend is distributed from mixed types of income (regular and Benefited Enterprise income). This 15% tax rate similarly applies to dividends sourced from profits attributable to a Preferred Enterprise which are paid to Israeli resident individual shareholders, while such dividends paid to Israeli resident corporations are generally tax-exempt.

Taxation of Non-Israeli Shareholders on Receipt of Dividends. Non-residents of Israel are generally subject to Israeli income tax on the receipt of dividends paid on our Shares at the rate of 25% (or 30% if such person is a "substantial shareholder" at the time receiving the dividend or on any date in the 12 months preceding such date), which tax will be withheld at the source, unless a different rate is provided in a tax treaty between Israel and the shareholder's country of residence. If the income out of which the dividend is being paid is sourced from profits attributable to a Benefited Enterprise under the Investments Law, the rate is generally not more than 15%.

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

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

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

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

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

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

U.S. Federal Income Tax Considerations

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

As used in this summary, the term "U.S. Investor" means a beneficial owner of Shares that is, for U.S. federal income tax purposes, (i) an individual citizen or resident of the United States, (ii) a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income tax regardless of its source or (iv) a trust with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions, or an electing trust that was in existence on August 19, 1996 and was treated as a domestic trust on that date.

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

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

Taxation of U.S. Investors

The discussions under "— Distributions" and under "— Sale, Exchange or Other Disposition of Ordinary Shares" below assumes that we will not be treated as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. However, we have not determined whether we will be a PFIC in 2013, and it is possible that we will be a PFIC in 2013 or in any subsequent year. For a discussion of the rules that would apply if we are treated as a PFIC, see the discussion under "— Passive Foreign Investment Company."

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

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

Since the rules governing foreign tax credits are complex, U.S. Investors should consult their own tax advisor regarding the availability of foreign tax credits in their particular circumstances. In addition, the U.S. Treasury Department has expressed concerns that parties to whom ADSs are pre-released may be taking actions that are inconsistent with the claiming of foreign tax credits by U.S. holders of ADSs. Accordingly, the creditability of Israeli taxes could be affected by future actions that may be taken by the U.S. Treasury Department or parties to whom ADSs are pre-released.

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

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

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

Medicare Tax. In addition, with respect to taxable years beginning after December 31, 2012, certain U.S. persons, including individuals, estates and trusts, will be subject to an additional 3.8% Medicare tax on unearned income. For individuals, the additional Medicare tax applies to the lesser of (i) "net investment income" or (ii) the excess of "modified adjusted gross income" over $200,000 ($250,000 if married and filing jointly or $125,000 if married and filing separately). "Net investment income" generally equals the taxpayer's gross investment income reduced by the deductions that are allocable to such income. Investment income generally includes passive income such as interest, dividends, annuities, royalties, rents, and capital gains. U.S. Investors are urged to consult their own tax advisors regarding the implications of the additional Medicare tax resulting from their ownership and disposition of Shares.

U.S. Investors should consult their own tax advisors regarding the U.S. federal income tax consequences of receiving currency other than U.S. dollars upon the disposition of Shares.

Passive Foreign Investment Company

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

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

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

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

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

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

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

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

A U.S. Investor makes a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. Upon request, we will annually furnish U.S. Investors with information needed in order to complete IRS Form 8621 (which form would be required to be filed with the IRS on an annual basis by the U.S. Investor) and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC. A QEF election will not apply to any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Each U.S. Investor is encouraged to consult its own tax advisor with respect to tax consequences of a QEF election with respect to us.

Mark-to-Market Election. Alternatively, if our Shares are treated as "marketable stock," a U.S. Investor would be allowed to make a "mark-to-market" election with respect to our Shares, provided the U.S. Investor completes and files IRS Form 8621 in accordance with the relevant instructions and related Treasury Regulations. If that election is made, the U.S. Investor generally would include as ordinary income in each taxable year the excess, if any, of the fair market value of the Shares at the end of the taxable year over such holder's adjusted tax basis in the Shares. The U.S. Investor would also be permitted an ordinary loss in respect of the excess, if any, of the U.S. Investor's adjusted tax basis in the Shares over their fair market value at the end of the taxable year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. A U.S. Investor's tax basis in the Shares would be adjusted to reflect any such income or loss amount. Gain realized on the sale, exchange or other disposition of the Shares would be treated as ordinary income, and any loss realized on the sale, exchange or other disposition of the Shares would be treated as ordinary loss to the extent that such loss does not exceed the net mark-to-market gains previously included in income by the U.S. Investor, and any loss in excess of such amount will be treated as capital loss. Amounts treated as ordinary income will not be eligible for the favorable tax rates applicable to qualified dividend income or long-term capital gains.

Generally, stock will be considered marketable stock if it is "regularly traded" on a "qualified exchange" within the meaning of applicable Treasury regulations. A class of stock is regularly traded on an exchange during any calendar year during which such class of stock is traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter. Our ADSs will be marketable stock as long as they remain listed on the Nasdaq Capital Market and are regularly traded. A mark-to-market election will not apply to our ADSs held by a U.S. Investor for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election will not apply to any PFIC subsidiary that we own. Each U.S. Investor is encouraged to consult its own tax advisor with respect to the availability and tax consequences of a mark-to-market election with respect to our ADSs.

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

- the excess distribution or gain would be allocated ratably over the Non-Electing U.S. Investor's holding period for the Shares;
- the amount allocated to the current taxable year and any year prior to us becoming a PFIC would be taxed as ordinary income; and
- the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year.

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

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

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

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

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

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

Certain Reporting Requirements

Certain U.S. Investors are required to file IRS Form 926, Return by U.S. Transferor of Property to a Foreign Corporation, and certain U.S. Investors may be required to file IRS Form 5471, Information Return of U.S. Persons With Respect to Certain Foreign Corporations, reporting transfers of cash or other property to us and information relating to the U.S. Investor and us. Substantial penalties may be imposed upon a U.S. Investor that fails to comply. Each U.S. Investor should consult its own tax advisor regarding these requirements.

In addition, recently enacted legislation imposes new reporting requirements for the holder of certain foreign financial assets, including equity of foreign entities, if the aggregate value of all of these assets exceeds $50,000. The Shares are expected to be subject to these new reporting requirements unless the Shares are held in an account at a domestic financial institution. The requirement to file a report is effective for taxable years beginning after March 18, 2010. Penalties apply to any failure to file a required report. U.S. Investors should consult their own tax advisors regarding the application of this legislation.

Backup Withholding Tax and Information Reporting Requirements

Generally, information reporting requirements will apply to distributions on our Shares or proceeds on the disposition of our Shares paid within the United States (and, in certain cases, outside the United States) to U.S. Investors other than certain exempt recipients, such as corporations. Furthermore, backup withholding (currently at 28%) may apply to such amounts if the U.S. Investor fails to (i) provide a correct taxpayer identification number, (ii) report interest and dividends required to be shown on its U.S. federal income tax return, or (iii) make other appropriate certifications in the required manner. U.S. Investors who are required to establish their exempt status generally must provide such certification on IRS Form W-9.

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

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

F. Dividends and Paying Agents

Not applicable

G. Statement by Experts

Not applicable.

H. Documents on Display

We are currently subject to the information and periodic reporting requirements of the Exchange Act, and file periodic reports and other information with the SEC through its electronic data gathering, analysis and retrieval (EDGAR) system. Our securities filings, including this Annual Report and the exhibits thereto, are available for inspection and copying at the public reference facilities of the SEC located at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains a website at *http://www.sec.gov* from which certain filings may be accessed.

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

In addition, since our ordinary shares are traded on the TASE, we have filed Hebrew language periodic and immediate reports with, and furnish information to, the TASE and the Israel Securities Authority, or the ISA, as required under Chapter Six of the Israel Securities Law, 1968. Copies of our filings with the Israeli Securities Authority can be retrieved electronically through the MAGNA distribution site of the Israeli Securities Authority (*www.magna.isa.gov.il*) and the TASE website (*www.maya.tase.co.il*).

We maintain a corporate website at *www.biolinerx.com.* Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report on Form 20-F. We have included our website address in this Annual Report on Form 20-F solely as an inactive textual reference.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURE ON MARKET RISK

Market risk is the risk of loss related to changes in market prices, including interest rates and foreign exchange rates, of financial instruments that may adversely impact our consolidated financial position, results of operations or cash flows. We do not use derivative financial instruments for trading purposes. Accordingly, we have concluded that there is no material market risk exposure of the type contemplated by Item 11, and that no quantitative tabular disclosures are required. We are exposed to certain other types of market risks, as described below.

Risk of Interest Rate Fluctuation

Our investments consist primarily of cash, cash equivalents and short-term bank deposits. We may also invest in investment-grade marketable securities with maturities of up to three years, including commercial paper, money market funds, and government/non-government debt securities. The primary objective of our investment activities is to preserve principal while maximizing the income that we receive from our investments without significantly increasing risk and loss. Our investments are exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments. We manage this exposure by performing ongoing evaluations of our investments. Due to the short-term maturities of our investments to date, their carrying value has always approximated their fair value. It will be our policy to hold investments to maturity in order to limit our exposure to interest rate fluctuations.

Foreign Currency Exchange Risk

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the NIS, our functional and reporting currency, mainly against the dollar and the euro. Although the NIS is our functional currency, a significant portion of our expenses are denominated in both dollars and euros and our revenues have been, and can be expected in the future to be, denominated in either dollars or euros, or both. Our dollar and euro expenses consist principally of payments made to sub-contractors and consultants for preclinical studies, clinical trials and other research and development activities. We anticipate that a sizable portion of our expenses will continue to be denominated in currencies other than the NIS. If the NIS fluctuates significantly against either the dollar or the euro, it may have a negative impact on our results of operations. To date, fluctuations in the exchange rates have not materially affected our results of operations or financial condition for the periods under review.

To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Set forth below is a summary of the material terms of the deposit agreement, as amended, among our company, The Bank of New York Mellon as depositary, or the Depositary, and the owners and holders from time to time of our ADSs.

Description of the ADSs

Each of our ADSs represents 10 of our ordinary shares. Our ADSs trade on the Nasdaq Capital Market.

The form of the deposit agreement for the ADS and the form of American Depositary Receipt (ADR) that represents an ADS have been incorporated by reference as exhibits to this Annual Report on Form 20-F. Copies of the deposit agreement are available for inspection at the principal office of The Bank of New York Mellon, located at 101 Barclay Street, New York, New York 10286, and at the principal office of our custodians, Bank Leumi Le-Israel, 34 Yehuda Halevi St., Tel-Aviv 65546, Israel and Bank Hapoalim B.M., 104 Hayarkon Street, Tel Aviv 63432, Israel.

Dividends, Other Distributions and Rights

Amounts distributed to ADS holders will be reduced by any taxes or other governmental charges required to be withheld by the custodian or the Depositary. If the Depositary determines that any distribution in cash or property is subject to any tax or governmental charges that the Depositary or the custodian is obligated to withhold, the Depositary may use the cash or sell or otherwise dispose of all or a portion of that property to pay the taxes or governmental charges. The Depositary will then distribute the balance of the cash and/or property to the ADS holders entitled to the distribution, in proportion to their holdings.

Cash dividends and cash distributions. The Depositary will convert into dollars all cash dividends and other cash distributions that it or the custodian receives in a foreign currency. The Depositary will distribute to the ADS holders the amount it receives, after deducting any currency conversion expenses. If the Depositary determines that any foreign currency it receives cannot be converted and transferred on a reasonable basis, it may distribute the foreign currency (or an appropriate document evidencing the right to receive the currency), or hold that foreign currency uninvested, without liability for interest, for the accounts of the ADS holders entitled to receive it.

Distributions of ordinary shares. If we distribute ordinary shares as a dividend or free distribution, the Depositary may, with our approval, and will, at our request, distribute to ADS holders new ADSs representing the ordinary shares. The Depositary will distribute only whole ADSs. It will sell the ordinary shares that would have required it to use fractional ADSs and then distribute the proceeds in the same way it distributes cash. If the Depositary deposits the ordinary shares but does not distribute additional ADSs, the existing ADSs will also represent the new ordinary shares.

If holders of ordinary shares have the option of receiving a dividend in cash or in shares, we may also grant that option to ADS holders.

Other distributions. If the Depositary or the custodian receives a distribution of anything other than cash or shares, the Depositary will distribute the property or securities to the ADS holder, in proportion to such holder's holdings upon payment of its fees. If the Depositary determines that it cannot distribute the property or securities in this manner or that it is not feasible to do so, then, after consultation with us, it may distribute the property or securities by any means it thinks is equitable and practical, or it may sell the property or securities and distribute the net proceeds of the sale to the ADS holders. The Depositary may sell a portion of any distributed property that is sufficient to pay its fees.

Rights to subscribe for additional ordinary shares and other rights. If we offer our holders of ordinary shares any rights to subscribe for additional ordinary shares or any other rights, the Depositary will, if requested by us:

- make the rights available to all or certain holders of ADSs, by means of warrants or otherwise, if lawful and practically feasible; or
- if it is not lawful or practically feasible to make the rights available, attempt to sell those rights or warrants or other instruments.

In that case, the Depositary will allocate the net proceeds of the sales to the account of the ADS holders entitled to the rights. The allocation will be made on an averaged or other practicable basis without regard to any distinctions among holders.

If registration under the Securities Act of 1933, as amended, is required in order to offer or sell to the ADS holders the securities represented by any rights, the Depositary will not make the rights available to ADS holders unless a registration statement is in effect or such securities are exempt from registration. We do not, however, have any obligation to file a registration statement or to have a registration statement declared effective. If the Depositary cannot make any rights available to ADS holders and cannot dispose of the rights and make the net proceeds available to ADS holders, then it will allow the rights to lapse, and the ADS holders will not receive any value for them.

Voting of the underlying shares. Under the deposit agreement, an ADS holder is entitled, subject to any applicable provisions of Israeli law, our Articles of Association and bylaws and the deposited securities, to exercise voting rights pertaining to the shares represented by its ADSs. If we so request, the Depositary will send to ADS holders such information as is contained in the notice of meeting that the Depositary receives from us, as well as a statement that holders of as the close of business on the specified record date will be entitled to instruct the Depositary as to the exercise of voting rights and a statement as to the manner in which the such instructions may be given.

Changes affecting deposited securities. If there is any change in nominal value or any split-up, consolidation, cancellation or other reclassification of deposited securities, or any recapitalization, reorganization, business combination or consolidation or sale of assets involving us, then any securities that the Depositary receives in respect of deposited securities will become new deposited securities. Each ADS will automatically represent its share of the new deposited securities, unless the Depositary delivers new ADSs as described in the following sentence. The Depositary may distribute new ADSs or ask ADS holders to surrender their outstanding ADRs in exchange for new ADRs describing the new deposited securities.

Amendment of the deposit agreement. The Depositary and we may agree to amend the form of the ADSs and the deposit agreement at any time, without the consent of the ADS holders. If the amendment adds or increases any fees or charges (other than taxes or other governmental charges) or prejudices an important right of ADS holders, it will not take effect as to outstanding ADSs until 30 days after the Depositary has sent the ADS holders a notice of the amendment. At the expiration of that 30-day period, each ADS holder will be considered by continuing to hold its ADSs to agree to the amendment and to be bound by the deposit agreement as so amended. The Depositary and we may not amend the deposit agreement or the form of ADRs to impair the ADS holder's right to surrender its ADSs and receive the ordinary shares and any other property represented by the ADRs, except to comply with mandatory provisions of applicable law.

Termination of the deposit agreement. The Depositary will terminate the deposit agreement if we ask it to do so and will notify the ADS holders at least 30 days before the date of termination. The Depositary may also terminate the deposit agreement if it resigns and a successor depositary has not been appointed by us and accepted its appointment within 60 days after the Depositary has given us notice of its resignation. After termination of the deposit agreement, the Depositary will no longer register transfers of ADSs, distribute dividends to the ADS holders, accept deposits of ordinary shares, give any notices, or perform any other acts under the deposit agreement whatsoever, except that the Depositary will continue to:

- collect dividends and other distributions pertaining to deposited securities;
- sell rights as described under the heading "Dividends, other distributions and rights — Rights to subscribe for additional shares and other rights" above; and
- deliver deposited securities, together with any dividends or other distributions received with respect thereto and the net proceeds of the sale of any rights or other property, in exchange for surrendered ADRs.

Four months after termination, the Depositary may sell the deposited securities and hold the proceeds of the sale, together with any other cash then held by it, for the pro rata benefit of ADS holders that have not surrendered their ADSs. The Depositary will not have liability for interest on the sale proceeds or any cash it holds.

Charges of Depositary

We will pay the fees, reasonable expenses and out-of-pocket charges of the Depositary and those of any registrar only in accordance with agreements in writing entered into between us and the Depositary from time to time. The following charges shall be incurred by any party depositing or withdrawing ordinary shares or by any party surrendering ADRs or to whom ADRs are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADRs or deposited ordinary shares or a distribution of ADRs pursuant to the terms of the deposit agreement):

- taxes and other governmental charges;
- any applicable transfer or registration fees;
- certain cable, telex and facsimile transmission charges as provided in the Deposit Agreement;
- any expenses incurred in the conversion of foreign currency;
- a fee of $5.00 or less per 100 ADSs (or a portion thereof) for the execution and delivery of ADRs and the surrender of ADRs;

- a fee of $.05 or less per ADS (or portion thereof) for any cash distribution made pursuant to the Deposit Agreement;
- a fee for the distribution of securities pursuant to the Deposit Agreement;
- in addition to any fee charged for a cash distribution, a fee of $.05 or less per ADS (or portion thereof) per annum for depositary services;
- a fee for the distribution of proceeds of rights that the Depositary sells pursuant to the Deposit Agreement; and
- any other charges payable by the Depositary, any of the Depositary's agents, or the agents of the Depositary's agents in connection with the servicing of Shares or other Deposited Securities.

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

Liability of Holders for Taxes, Duties or Other Charges

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

ITEM 13. DEFAULTS, DIVIDENDS AND DELINQUENCIES

Not applicable.

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

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

(a) **Disclosure Controls and Procedures**

We have performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that the material financial and non-financial information required to be disclosed to the SEC is recorded, processed, summarized and reported timely. Based on our evaluation, our management, including the CEO and CFO, has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report are effective. Notwithstanding the foregoing, there can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within the Company to disclose material information otherwise required to be set forth in our reports.

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

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

Our management, including the CEO and CFO, conducted an evaluation, pursuant to Rule 13a-15(c) promulgated under the Exchange Act, of the effectiveness, as of the end of the period covered by this Annual Report, of its internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2012.

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

Not applicable.

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

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERTS

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

ITEM 16B. CODE OF ETHICS

In July 2011, our Board of Directors adopted a Code of Business Conduct and Ethics (the "Code") that applies to all our employees, including without limitation our chief executive officer, chief financial officer and controller. Our Code may be viewed on our website at *www.biolinerx.com*. A copy of our Code may be obtained, without charge, upon a written request addressed to our investor relations department, P.O. Box 45158, 19 Hartum Street, Jerusalem 9777518, Israel (Telephone no. +972-2-548-9100) (e-mail: info@BioLineRx.com).

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Registered Public Accounting Firm

The following table sets forth, for each of the years indicated, the fees billed by our independent registered public accounting firm.

	Year Ended December 31,	
	2011	**2012**
Services Rendered	(in NIS 000's)	
Audit (1)	407	394
Audit related services (2)	16	40
Tax (3)	249	154
Total	672	588

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

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

Not applicable.

ITEM 16E. PURCHASE 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 we are not required to distribute annual and quarterly reports directly to shareholders and the generally accepted business practice in Israel is not to distribute such reports to shareholders but to make such reports publicly available through the website of the Israeli Securities Authority. In addition, we make our audited financial statements available to our shareholders at our offices and mail such reports to shareholders upon request. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules.

- *Quorum*. While the Marketplace Rules of the Nasdaq Stock Market require that the quorum for purposes of any meeting of the holders of a listed company's common voting stock, as specified in the company's bylaws, be no less than 33 1/3% of the company's outstanding common voting stock, under Israeli law, a company is entitled to determine in its articles of association the number of shareholders and percentage of holdings required for a quorum at a shareholders meeting. Our Articles of Association provide that a quorum of two or more shareholders holding at least 25% of the voting rights in person or by proxy is required for commencement of business at a general meeting. However, the quorum set forth in our Articles of Association with respect to an adjourned meeting consists of any number of shareholders present in person or by proxy.

- *Independent Directors*. Our Board of Directors includes two external directors in accordance with the provisions contained in Sections 239-249 of the Companies Law and Rule 10A-3 of the general rules and regulations promulgated under the Securities Act of 1933, rather than a majority of external directors. Israeli law does not require, nor do our independent directors conduct, regularly scheduled meetings at which only they are present. We are required, however, to ensure that all members of our Audit Committee are "independent" under the applicable Nasdaq and SEC criteria for independence (as a foreign private issuer we are not exempt from the SEC independence requirement), and we must also ensure that a majority of the members of our Audit Committee are unaffiliated directors as defined in the Companies Law. Furthermore, Israeli law does not require, nor do our independent directors conduct, regularly scheduled meetings at which only they are present, which the Marketplace Rules of the Nasdaq Stock Market otherwise require.

- *Audit Committee*. Our Audit Committee complies with all of the requirements under Israeli law, and is composed of two external directors, which are all of our external directors, and only one other director, who cannot be the chairman of the Board of Directors. Consistent with Israeli law, the independent auditors are elected at a meeting of shareholders instead of being appointed by the Audit Committee.

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

- *Compensation Committee and Compensation of Officers*. Our Compensation Committee complies with the requirements of the Companies Law and Amendment 20, and is composed of two external directors, which are all of our external directors, and one additional director, who is not the chairman of our Board of Directors or otherwise employed by the Company. Additionally, we comply with the requirements set forth under the Companies Law and Amendment 20, 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. 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.

- *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.

ITEM 17. FINANCIAL STATEMENTS

Not applicable.

ITEM 18. FINANCIAL STATEMENTS

See the financial statements beginning on page F-1. The following financial statements and financial statement schedules are filed as part of this Annual Report on Form 20-F together with the report of the independent registered public accounting firm:

ITEM 19. EXHIBITS

Exhibit Number	Exhibit Description
2.1[5]	Articles of Association of the Registrant, as amended May 15, 2012.
2.2[2]	Form of Deposit Agreement dated as of July 21, 2011 among BioLineRx, Ltd., The Bank of New York Mellon, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder.
2.3[2]	Form of American Depositary Receipt; the Form is Exhibit A of the Form of Depositary Agreement.
4.2[1]	Employment Agreement with Moshe Phillip, M.D., dated January 8, 2004.
4.3[1]	Employment Agreement with Kinneret Savitsky, Ph.D., dated October 13, 2004.
4.5[1]	Employment Agreement with Philip Serlin, dated May 24, 2009.
4.6†[1]	License Agreement entered into as of January 10, 2005, by and between BioLine Innovations Jerusalem L.P. and B.G. Negev Technologies and Applications Ltd.
4.7[1]	Assignment Agreement dated as of January 1, 2009 entered into by and between BioLine Innovations Jerusalem L.P. and BioLineRx Ltd.
4.8†[1]	Research and License Agreement entered into as of April 15, 2004 by and among BioLineRx Ltd., Bar Ilan Research and Development Company Ltd., and Ramot and Tel Aviv University.
4.9[1]	First Amendment, dated as of June 2004, of Research and License Agreement, dated April 15, 2004, by and among the Registrant, Ramot at Tel Aviv University Ltd. and Bar Ilan Research and Development Company Ltd.
4.10[1]	Amendment Agreement dated as of December 20, 2005 entered into by and between the Registrant, Bar Ilan Research and Development Company Ltd. and Ramot at Tel Aviv University Ltd.
4.11[1]	Amendment Agreement dated as of March 7, 2006, entered into by and between the Registrant, Bar Ilan Research and Development Company Ltd. and Ramot at Tel Aviv University Ltd.
4.12†[1]	Assignment Agreement dated as of July 2, 2006 entered into by and between BioLineRx Ltd., Bar Ilan Research and Development Company Ltd., and Ramot and Tel Aviv University.
4.13[1]	Incubator agreement with the Office of the Chief Scientist, January 2005.
4.14[1]	Bridge Loan Agreement with Pan Atlantic Investments Limited dated January 10, 2007.
4.15[1]	Early Development Program Agreement with Pan Atlantic Investments Limited, dated January 10, 2007.
4.16†[1]	License Agreement between Innovative Pharmaceutical Concepts, Inc. and BioLineRx Ltd. dated November 25, 2007.
4.17†[1]	Amended and Restated License and Commercialization Agreement by and among Ikaria Development Subsidiary One LLC and BioLineRx Ltd. and BioLine Innovations Jerusalem L.P. dated August 26, 2009.

Exhibit Number	Exhibit Description
4.18[1]	BioLineRx Ltd. 2003 Share Incentive Plan.
4.19[1]	Lease Agreement between Kaps-Pharma Ltd. and BioLine Innovations Jerusalem L.P., dated July 10, 2005, and Extension to Lease Agreement, dated December 4, 2008.
4.20[1]	Amendment to Employment Agreement with Kinneret Savitsky, Ph.D., dated January 2, 2004.
4.21[1]	Employment Agreement with Leah Klapper, Ph.D., dated January 27, 2005.
4.22[1]	Rights Reacquisition Agreement entered into on May 10, 2011 between Cypress Bioscience, Inc. and BioLineRx Ltd.
4.24†[1]	Amended and Restated License Agreement entered into on June 20, 2010 between Cypress Bioscience, Inc. and BioLineRx Ltd.
4.25†[1]	Payment Date Extension Amendment by and among Ikaria Development Subsidiary One LLC and BioLineRx Ltd. and BioLine Innovations Jerusalem L.P., dated April 21, 2010.
4.26[1]	Amendment to the Amended and Restated license and Commercialization Agreement by and among Ikaria Development Subsidiary One LLC and BioLineRx Ltd. and BioLine Innovations Jerusalem L.P., dated April 21, 2010.
4.27[1]	Extension agreement dated January 2, 2011 to the Incubator Agreement with the Office of the Chief Scientist.
4.28[1]	Sponsored Research Agreement entered into as of June 23, 2011 by and between Yissum Research Development Company of the Hebrew University of Jerusalem Ltd. and BioLineRx Ltd.
4.29[1]	License Agreement entered into as of June 23, 2011 by and between Yissum Research Development Company of the Hebrew University of Jerusalem Ltd. and BioLineRx Ltd.
4.30[4]	Employment Agreement with David Malek, dated August 8, 2011
4.31[3]	Form of Warrant to purchase American Depositary Shares
4.32[7]	Form of Warrant to purchase American Depositary Shares
4.33†[8]	License Agreement entered into as of September 2, 2012 by and among BioLineRx Ltd. and Biokine Therapeutics Ltd.
8.1[1]	List of subsidiaries of the Registrant.
12.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1	Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2	Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1[3]	Form of Purchase Agreement between BioLineRx Ltd. and the Purchasers named therein, dated February 15, 2012

15.2[6]	Purchase Agreement between BioLineRx Ltd. and Lincoln Park, LLC, dated September 21, 2012
15.3[6]	Registration Rights Agreement between BioLineRx Ltd. and Lincoln Park, LLC, dated September 21, 2012
15.4[7]	Subscription Agreement between BioLineRx Ltd. And OrbiMed Israel Partners Limited Partnership, dated February 6, 2013
15.5	Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Registrant.

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

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

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

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

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

(5) Incorporated by reference to the Registrant's Registration Statement on Form S-8 (No. 333-183976) filed on September 19, 2012.

(6) Incorporated by reference to the Registrant's Form 6-K filed on September 27, 2012.

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

(8) Incorporated by reference to the Registrant's Form 6-K filed on February 25, 2013.

SIGNATURES

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

BIOLINERX LTD.

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

Date: March 12, 2013

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Audited Consolidated Financial Statements at December 31, 2012 and 2011 and for each of the three years in the period ended December 31, 2012

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders of
BioLineRx Ltd.

We have audited the accompanying consolidated statements of financial position of BioLineRx Ltd. ("BioLineRx") and its consolidated entities as of December 31, 2012 and 2011 and the related consolidated statements of comprehensive income (loss), changes in equity and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of BioLineRx's Board of Directors and management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by BioLineRx's Board of Directors and management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of BioLineRx and its consolidated entities as of December 31, 2012 and 2011 and their results of operations, changes in equity and cash flows for each of the three years in the period ended December 31, 2012, in conformity with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB").

Tel Aviv, Israel
March 12, 2013

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

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 68125, Israel, P.O Box 452 Tel-Aviv 61003 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.co.il

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31,		Convenience translation into USD (Note 1b) December 31,
		2011	2012	2012
		NIS in thousands		In thousands
Assets				
CURRENT ASSETS				
Cash and cash equivalents	5a	33,061	68,339	18,307
Short-term bank deposits	5b	65,782	11,459	3,070
Prepaid expenses		687	804	215
Other receivables	14a	3,825	2,254	604
Total current assets		103,355	82,856	22,196
NON-CURRENT ASSETS				
Restricted deposits	12b	2,746	3,513	941
Long-term prepaid expenses	14b	204	204	54
Property and equipment, net	6	4,211	3,172	850
Intangible assets, net	7	1,144	1,063	285
Total non-current assets		8,305	7,952	2,130
Total assets		111,660	90,808	24,326
Liabilities and equity				
CURRENT LIABILITIES				
Current maturities of long-term bank loan	8	307	137	37
Accounts payable and accruals:				
Trade	14c(1)	11,275	12,283	3,290
OCS		6,233	6,148	1,647
Other	14c(2)	7,894	5,443	1,458
Total current liabilities		25,709	24,011	6,432
NON-CURRENT LIABILITIES				
Long-term bank loan, net of current maturities	8	110	-	-
Retirement benefit obligations		83	143	38
Warrants	9c(2)	-	10,725	2,873
Total non-current liabilities		193	10,868	2,911
COMMITMENTS AND CONTINGENT LIABILITIES	12			
Total liabilities		25,902	34,879	9,343
EQUITY	9			
Ordinary shares		1,236	1,837	491
Share premium		421,274	464,629	124,468
Capital reserve		31,317	33,802	9,055
Accumulated deficit		(368,069)	(444,339)	(119,031)
Total equity		85,758	55,929	14,983
Total liabilities and equity		111,660	90,808	24,326

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

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Note	Year ended December 31,			Convenience translation into USD (Note 1b)
		2010	2011	2012	2012
		NIS in thousands			In thousands
REVENUES	16	113,160	-	-	-
COST OF REVENUES	14d	(25,571)	-	-	-
GROSS PROFIT		87,589	-	-	-
RESEARCH AND DEVELOPMENT EXPENSES, NET	14e	(54,966)	(42,623)	(64,304)	(17,226)
SALES AND MARKETING EXPENSES	14f	(4,609)	(3,308)	(3,227)	(864)
GENERAL AND ADMINISTRATIVE EXPENSES	14g	(14,875)	(12,722)	(14,026)	(3,757)
OPERATING INCOME (LOSS)		13,139	(58,653)	(81,557)	(21,847)
NON-OPERATING INCOME, NET	14h	-	-	3,958	1,060
FINANCIAL INCOME	14i	3,056	12,730	8,819	2,362
FINANCIAL EXPENSES	14j	(8,755)	(4,263)	(7,490)	(2,007)
NET INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS)		7,440	(50,186)	(76,270)	(20,432)
			NIS		USD
EARNINGS (LOSS) PER ORDINARY SHARE - BASIC	11a	0.06	(0.41)	(0.45)	(0.12)
EARNINGS (LOSS) PER ORDINARY SHARE - DILUTED	11a	0.06	(0.41)	(0.45)	(0.12)

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

BioLineRx Ltd.

STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	Share premium	Warrants	Capital reserve	Accumulated deficit	Total
	NIS in thousands					
BALANCE AT JANUARY 1, 2010	1,235	412,513	6,549	22,963	(325,323)	117,937
CHANGES IN 2010:						
Employee stock options exercised	1	291	-	(266)	-	26
Employee stock options forfeited and expired	-	1,631	-	(1,631)	-	-
Share-based compensation	-	-	-	6,557	-	6,557
Comprehensive income for the year	-	-	-	-	7,440	7,440
BALANCE AT DECEMBER 31, 2010	1,236	414,435	6,549	27,623	(317,883)	131,960
CHANGES IN 2011:						
Employee stock options exercised	*	177	-	(176)	-	1
Employee stock options forfeited and expired	-	113	-	(113)	-	-
Expiration of warrants	-	6,549	(6,549)	-	-	-
Share-based compensation	-	-	-	3,983	-	3,983
Comprehensive loss for the year	-	-	-		(50,186)	(50,186)
BALANCE AT DECEMBER 31, 2011	1,236	421,274	-	31,317	(368,069)	85,758
CHANGES IN 2012:						
Issuance of share capital, net	601	42,700	-	-	-	43,301
Employee stock options exercised	*	272	-	(270)	-	2
Employee stock options forfeited and expired	-	383	-	(383)	-	-
Share-based compensation	-	-	-	3,138	-	3,138
Comprehensive loss for the year	-	-	-	-	(76,270)	(76,270)
BALANCE AT DECEMBER 31, 2012	1,837	464,629	-	33,802	(444,339)	55,929

* Represents an amount less than NIS 1,000.

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

BioLineRx Ltd.

STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	Share premium	Capital reserve	Accumulated deficit	Total
	Convenience translation into USD (Note 1b)				
BALANCE AT DECEMBER 31, 2011	331	112,851	8,389	(98,599)	22,972
CHANGES IN 2012:					
Issuance of share capital, net	160	11,441	-	-	11,601
Employee stock options exercised	*	73	(72)	-	1
Employee stock options forfeited and expired	-	103	(103)	-	-
Share-based compensation	-	-	841	-	841
Comprehensive loss for the year	-	-	-	(20,432)	(20,432)
BALANCE AT DECEMBER 31, 2012	491	124,468	9,055	(119,031)	14,983

* Represents an amount less than $1,000.

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

BioLineRx Ltd.

CONSOLIDATED CASH FLOW STATEMENTS

	Year ended December 31,			Convenience translation into USD (Note 1b)
	2010	2011	2012	2012
		NIS in thousands		In thousands
CASH FLOWS - OPERATING ACTIVITIES				
Net income (loss)	7,440	(50,186)	(76,270)	(20,432)
Adjustments required to reflect net cash provided by (used in) operating activities (see appendix below)	33,231	7,445	1,125	301
Net cash provided by (used in) operating activities	40,671	(42,711)	(75,145)	(20,131)
CASH FLOWS - INVESTING ACTIVITIES				
Investments in short-term deposits	(28,333)	(63,456)	(12,025)	(3,221)
Maturities of short-term deposits	-	27,308	64,801	17,359
Investments in restricted deposits	(206)	(1,000)	(775)	(208)
Maturities of restricted deposits	1,353	675	-	-
Purchase of property and equipment	(1,853)	(951)	(598)	(160)
Purchase of intangible assets	(492)	(133)	(61)	(16)
Net cash provided by (used in) investing activities	(29,531)	(37,557)	51,342	13,754
CASH FLOWS - FINANCING ACTIVITIES				
Issuance of share capital and warrants, net of issuance expenses	-	-	59,207	15,861
Proceeds of bank loan	1,020	-	-	-
Repayments of bank loan	(281)	(308)	(300)	(80)
Proceeds from exercise of employee stock options	26	1	2	1
Net cash provided by (used in) financing activities	765	(307)	58,909	15,782
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	11,905	(80,605)	35,106	9,405
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	105,890	111,746	33,061	8,856
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(6,049)	1,920	172	46
CASH AND CASH EQUIVALENTS - END OF YEAR	111,746	33,061	68,339	18,307

* Less than 1,000.

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

BioLineRx Ltd.

CONSOLIDATED CASH FLOW STATEMENTS

	Year ended December 31,			Convenience translation into USD (Note 1b)
	2010	2011	2012	2012
	NIS in thousands			In thousands
APPENDIX				
Adjustments required to reflect net cash provided by (used in) operating activities:				
Income and expenses not involving cash flows:				
Depreciation and amortization	1,814	1,563	1,524	409
Impairment of intangible assets	1,846	88	-	-
Retirement benefit obligations	79	53	60	16
Long-term prepaid expenses	954	(8)	-	-
Exchange differences on cash and cash equivalents	6,049	(1,920)	(172)	(46)
Warrant issuance costs	-	-	1,204	323
Gain on adjustment of warrants to fair value	-	-	(7,265)	(1,946)
Commitment fee paid by issuance of share capital	-	-	880	235
Share-based compensation	6,557	3,983	3,138	841
Interest and exchange differences on short-term deposits	296	(1,597)	1,547	414
Interest and linkage on bank loan	-	(14)	20	5
Interest and exchange differences on restricted deposits	143	(7)	8	2
	17,738	2,141	944	253
Changes in operating asset and liability items:				
Decrease in trade accounts receivable and other receivables	34,798	1,847	1,454	389
Increase (decrease) in accounts payable and accruals	(19,305)	3,457	(1,273)	(341)
	15,493	5,304	181	48
	33,231	7,445	1,125	301
Supplementary information on investing and financing activities not involving cash lows:				
Credit received in connection with purchase of property and equipment	104	265	10	3
Credit received in connection with purchase of intangible assets	100	-	-	-
Supplementary information on interest received in cash	1,013	1,825	1,720	461

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

NOTE 1 – GENERAL INFORMATION

a. General

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

Since incorporation, BioLineRx has been engaged, both independently and through its consolidated entities (collectively, the "Company"), in the development of therapeutics, from pre-clinical-stage development to advanced clinical trials, for a wide range of medical needs.

In December 2004, BioLineRx registered a limited partnership, BioLine Innovations Jerusalem L.P. ("BIJ LP"), which commenced operations in January 2005. BioLineRx holds a 99% interest in BIJ LP, with the remaining 1% held by a wholly owned subsidiary of BioLineRx, BioLine Innovations Ltd. ("BIJ Ltd."). BIJ LP was established to operate a biotechnology incubator located in Jerusalem (the "Incubator") under an agreement with the State of Israel. See Note 12a(1).

In February 2007, BioLineRx listed its securities on the Tel Aviv Stock Exchange ("TASE") and they have been traded on the TASE since that time. Since July 2011, BioLineRx's American Depositary Shares ("ADSs") are also traded on the NASDAQ Capital Market. See Note 9.

In January 2008, BioLineRx established a wholly owned subsidiary, BioLineRx USA Inc. ("BioLineRx USA"), which served as the Company's business development arm in the United States. During 2011, the Company transferred its business development activities to Israel, and BioLine USA is no longer active.

The Company has been engaged in drug development since its incorporation. Although the Company has generated revenues from two out-licensing transactions, the Company cannot determine with reasonable certainty when and if the Company will have sustainable profits.

b. Convenience translation into US dollars ("dollars", "USD" or "$")

For the convenience of the reader, the reported New Israeli Shekel (NIS) amounts as of December 31, 2012 have been translated into dollars at the representative rate of exchange on December 31, 2012 ($1 = NIS 3.733). The dollar amounts presented in these financial statements should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated.

c. Approval of consolidated financial statements

The consolidated financial statements of the Company for the year ended December 31, 2012 were approved by the Board of Directors on March 12, 2013, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer and the Chief Financial and Operating Officer.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation

The Company's consolidated financial statements as of December 31, 2012 and 2011, and for each of the three years in the period ended December 31, 2012, have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). The significant accounting policies described below have been applied on a consistent basis for all years presented, unless noted otherwise.

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

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

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

b. Consolidation of the financial statements

Consolidated entities are all entities over which BioLineRx has the power to govern their financial and operating policies. This generally involves the holding of more than 50% of the shares or interests conferring voting rights of the applicable entity. The existence and effect of potential voting rights that are currently exercisable or convertible are considered when assessing whether BioLineRx controls an 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. The purchase method of accounting is used to account for the acquisition of subsidiaries by the Company.

c. Functional and presentation currency

Items included in the financial statements of each of the Company's entities are measured using the currency of the primary economic environment in which each entity operates (the "functional currency"). The consolidated financial statements are presented in NIS, which is the Company's functional and presentation currency.

Transactions that are executed in currencies other than the Company's functional currency ("foreign currency transactions") are translated into the functional currency using the exchange rates prevailing at the date of each transaction. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in profit or loss within the relevant line items to which the gains and losses are related.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

d. Property and equipment

Property and equipment are stated at historical cost less depreciation and related grants received from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor (the "OCS") – see also 2g below. Historical cost includes expenditures that are directly attributable to the acquisition of the items. Assets are depreciated by the straight-line method over the estimated useful lives of the assets, provided that the Company's management believes the residual values of the assets to be negligible, as follows:

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

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

Leasehold improvements are amortized by the straight-line method over the term of the lease, which is shorter than the estimated useful life of the improvements.

e. Intangible assets

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

Intellectual property
The Company recognizes in its financial statements intangible assets developed by the Company to the extent that the conditions stipulated in q. below are met. Intellectual property acquired by the Company is initially measured at cost. Intellectual property acquired by the Company for development purposes is not amortized and is tested annually for impairment. See f. below.

Computer software
Acquired computer software licenses are capitalized on the basis of the costs incurred to acquire and bring to use the specific software. These costs are amortized over the estimated useful lives of the software (3-5 years).

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

f. Impairment of non-financial assets

Impairment testing of intellectual property is required when the Company decides to terminate or suspend the development of a project based on such intellectual property. The Company performs impairment reviews on an annual basis, or more frequently if events or changes in circumstances indicate a potential impairment. Property and equipment, as well as computer software, are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized equal to the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and the asset's value in use to the Company.

g. Government grants related to fixed assets

Government grants related to fixed assets are recorded as a reduction in the book value of the related assets, and are charged to profit and loss in accordance with the straight-line method.

h. Financial assets

1) Classification

The Company classifies its financial assets in the following categories: (i) at fair value through profit or loss and (ii) loans and receivables. The classification depends on the purpose for which each financial asset was acquired. The Company's management determines the classification of financial assets at initial recognition.

a) Financial assets at fair value through profit or loss

The Company's investment policy with regard to its excess cash, as adopted by its Board of Directors, is composed of the following objectives: (i) preserving investment principal, (ii) providing liquidity and (iii) providing optimum yields pursuant to the policy guidelines and market conditions. The policy provides detailed guidelines as to the securities and other financial instruments in which the Company is allowed to invest. In addition, in order to maintain liquidity, investments are structured to provide flexibility to liquidate at least 50% of all investments within 15 business days. Information about these assets, including details of the portfolio and income earned, is provided internally on 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 "accounts receivable," "cash and cash equivalents", "bank deposits" and "restricted deposits" in the balance sheet. See Notes 2i, 2j and 2k.

2) Recognition and measurement

Investments are initially recognized at fair value plus transaction costs for all financial assets not carried at fair value through profit or loss. Financial assets carried at fair value through profit or loss are initially recognized at fair value, and transaction costs are expensed in profit or loss. Financial assets are de-recognized when the rights to receive cash flows from the investments have expired or have been transferred and the Company has transferred substantially all risks and rewards of ownership. Loans and receivables are subsequently carried at amortized cost using the effective interest method.

3) Offsetting financial instruments

Financial assets and liabilities are offset and the net amount reported in the balance sheet when there is a legally enforceable right to offset the recognized amounts and there is an intention to settle on a net basis or realize the asset and settle the liability simultaneously.

i. Cash equivalents

Cash and cash equivalents include cash on hand and short-term bank deposits (up to three months from date of deposit) that are not restricted as to withdrawal or use, and are therefore considered to be cash equivalents.

j. Restricted deposits

The Company has placed a lien on NIS and dollar deposits in banks to secure its liabilities and commitments to various parties. Those deposits are presented separately as non-current assets, in accordance with the timing of the relevant restrictions. See Notes 12b(1) and 12b(2).

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

k. Trade receivables

Trade receivable balances relate to amounts receivable from customers of the Company in respect of sub-licenses granted, or services that have been provided, during the normal course of business. If collection of these amounts is expected within one year or less, they are classified in current assets; otherwise, they are reflected in non-current assets.

Trade receivables are initially recognized at their fair value. Thereafter, they are measured at amortized cost, based on the effective interest method, less any allowance for doubtful accounts.

l. 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 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 balance sheet 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.

m. Share capital

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

n. Trade payables

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

o. Deferred taxes

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

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

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

p. Revenue recognition

The Company recognizes revenue in accordance with International Accounting Standard ("IAS") 18 – "Revenue," including guidance regarding arrangements with multiple deliverables. Pursuant to this guidance, the Company applies revenue recognition criteria to the separately identifiable components of a single transaction. The consideration from the arrangement is allocated among the separately identifiable components by reference to their fair value.

Revenues incurred in connection with out-licensing of the Company's patents and other intellectual property are recognized when all of the following criteria have been met as of the balance sheet date:

- The Company has transferred to the buyer the significant risks and rewards of ownership of the patents and intellectual property.
- The Company does not retain either the continuing managerial involvement to the degree usually associated with ownership or the effective control over the patent and intellectual property.
- The amount of revenue can be measured reliably.
- It is probable that the economic benefits associated with the transaction will flow to the Company.
- The costs incurred or to be incurred in respect of the sale can be measured reliably.

Revenues in connection with rendering of services are recognized by reference to the stage of completion of the transaction as of the balance sheet date, if and when the outcome of the transaction can be estimated reliably.

Revenues from royalties are recognized on an accrual basis in accordance with the substance of the relevant agreement.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

q. 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:

- technical 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, 2012, the Company has not yet capitalized research and development expenses.

r. Government participation in research and development expenses

The Company receives participation in research and development expenses from the State of Israel through the OCS, both in the form of loans extended to the Incubator for research and development, as described in Note 12a(1), and in the form of grants, as described in Note 12a(2).

Despite the formal difference between the two types of support from the OCS, there is no material financial difference between them. Each loan and grant qualifies as a "forgivable loan" in accordance with IAS 20, "Accounting for Government Grants and Disclosure of Government Assistance," since the loans and grants are repayable only if the Company generates revenues related to the project that is the subject of the loan or grant.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

r. Government participation in research and development expenses (cont.)

The Company recognizes each forgivable loan on a systematic basis at the same time the Company records, as an expense, the related development costs for which the grant/loan is received, provided that there is reasonable assurance that (a) the Company complies with the conditions attached to the grant/loan, and (b) the grant/loan will be received. The amount of the forgivable loan is recognized based on the participation rate approved by the OCS.

The Company accounts for each forgivable loan as a liability unless it is more likely than not that the Company will meet the terms of forgiveness, in which case the forgivable loan is accounted for as a government grant and carried to income as a reduction of research and development expenses.

If forgivable loans are initially carried to income, as described above, and, in subsequent periods, it appears more likely than not that the project will be successful and that the loans will be repaid or royalties paid to the OCS, the Company recognizes a liability which is measured based on the Company's best estimate of the amount required to settle the Company's obligation at the end of each reporting period.

s. Employee benefits

1) Pension and severance pay obligations

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

The amounts recorded as an employee benefit expense in respect of defined contribution plans for the years 2010, 2011 and 2012 were NIS 1,982,000, NIS 1,988,000 and NIS 1,997,000, respectively.

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 balance sheet 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.

Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are charged to income.

Past-service costs are recognized immediately in income, unless the changes to the pension plan are conditional on the employees remaining in service for a specified period of time (the vesting period). In such cases, the past-service costs are amortized on a straight-line basis over the vesting period.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

s. Employee benefits (cont.)

2) Vacation days and recreation pay

Labor laws in Israel entitle every employee to vacation days and recreation pay, both of which are computed annually. The entitlement with respect to each employee is based on the employee's length of service at the Company. The Company recognizes a liability and an expense in respect of vacation and recreation pay based on the individual entitlement of each employee.

3) Share-based payments

The Company operates an equity-settled, share-based compensation plan, under which it receives services from employees as consideration for equity instruments (options) of the Company. The fair value of the employee services received in exchange for the grant of the options is recognized as an expense. The total amount to be expensed is determined by reference to the fair value of the options granted:

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

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

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

t. Earnings (loss) per share

1) Basic

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

2) Diluted

The diluted earnings (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 and options granted to employees and service providers. The dilutive potential shares were not taken into account in computing loss per share in 2011 and 2012, as their effect would not have been dilutive.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

u. Changes in accounting policy and disclosures

New standards and interpretations not yet adopted

A number of new standards and amendments to standards and interpretations are effective for annual periods beginning after January 1, 2012, and have not been applied in preparing these consolidated financial statements. None of these is expected to have a significant effect on the Company's consolidated financial statements, except the following set out below, for which the impact has not been fully assessed.

Amendment to IAS 1, "Financial Statement Presentation" – this amendment, regarding other comprehensive income, is effective for annual financial statement periods commencing on or after July 1, 2012. The main change resulting from this amendment is a requirement for entities to group items presented in other comprehensive income on the basis of whether they are potentially re-classifiable to profit or loss subsequently (reclassification adjustments).

IFRS 13, "Fair Value Measurement" – this standard, effective for financial statement periods commencing on or after January 1, 2013, aims to improve consistency and reduce complexity by providing a precise definition of fair value and a single source of fair value measurement and disclosure requirements for use across IFRSs. The requirements, which are largely aligned between IFRSs and U.S. GAAP, do not extend the use of fair value accounting, but provide guidance on how it should be applied where its use is already required or permitted by other standards within IFRSs or U.S. GAAP.

Amendment to IAS 19, "Employee Benefits" – this amendment, effective for financial statement periods commencing on or after January 1, 2013, changes the methodology for calculating long-term employee benefit liabilities. The impact on the Company will be to immediately recognize all past service costs, and to replace interest cost and expected return on plan assets with a net interest amount that is calculated by applying the discount rate to the net defined benefit liability (asset). Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are to be charged to equity.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

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

IFRS 9, "Financial instruments" – this standard, effective for financial statement periods commencing on or after January 1, 2015, addresses the classification, measurement and recognition of financial assets and financial liabilities. IFRS 9 was issued in November 2009 and October 2010. It replaces the parts of IAS 39 that relate to the classification and measurement of financial instruments. IFRS 9 requires financial assets to be classified into two measurement categories: those measured at fair value and those measured at amortized cost. The determination is made at initial recognition. The classification depends on the entity's business model for managing its financial instruments and the contractual cash flow characteristics of the instrument. For financial liabilities, the standard retains most of the IAS 39 requirements. The main change is that, in cases where the fair value option is taken for financial liabilities, the part of a fair value change due to an entity's own credit risk is recorded in other comprehensive income rather than the income statement, unless this creates an accounting mismatch. The Company has not yet assessed the full impact of IFRS 9. The Company will also consider the impact of the remaining phases of IFRS 9 when completed.

IFRS 10, "Consolidated Financial Statements" – this standard, effective for financial statement periods commencing on or after January 1, 2013, builds on existing principles by identifying the concept of control as the determining factor in whether an entity should be included within the consolidated financial statements of the parent company. The standard provides additional guidance to assist in the determination of control where this is difficult to assess. The Company has not yet assessed the full impact of IFRS 10.

There are no other IFRSs or IFRIC interpretations that are not yet effective that would be expected to have a material impact on the Company.

NOTE 3 – FINANCIAL RISK MANAGEMENT

Based on assessments by Company management, the Company's exposure to credit risk as of December 31, 2012 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.

NOTE 3 – FINANCIAL RISK MANAGEMENT (cont.)

a. Market risk

1) Concentration of currency risk

The Company's activities are partly denominated in foreign currency, which exposes the Company to risks resulting from changes in exchange rates (primarily the dollar).

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

	December 31, 2012				
	Income (loss)		Value on	Income (loss)	
Sensitive instrument	10% increase	5% increase	balance sheet	5% decrease	10% decrease
			NIS in thousands		
Dollar-linked balances:					
Cash and cash equivalents	5,025	2,512	50,247	(2,512)	(5,025)
Short-term bank deposits	1,146	573	11,459	(573)	(1,146)
Restricted deposits*	61	31	613	(31)	(61)
Trade payables	(878)	(439)	(8,780)	439	878
Total dollar-linked balances	5,354	2,677	53,539	(2,677)	(5,354)
Euro-linked trade payables	(41)	(20)	(409)	20	41
Total	5,313	2,657	53,130	(2,657)	(5,313)

* See also Note 12b(1).

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

The Company believes that the likelihood of a fluctuation in exchange rates of up to 10% in the 12-month period following the balance sheet date is reasonable.

	December 31, 2011				
	Income (loss)		Value on	Income (loss)	
Sensitive instrument	10% increase	5% increase	balance sheet	5% decrease	10% decrease
			NIS in thousands		
Dollar-linked balances:					
Cash and cash equivalents	1,218	609	12,176	(609)	(1,218)
Short-term bank deposits	6,578	3,289	65,782	(3,289)	(6,578)
Restricted deposits*	62	31	621	(31)	(62)
Trade payables	(814)	(407)	(8,142)	407	814
Total dollar-linked balances	7,044	3,522	70,437	(3,522)	(7,044)
Euro-linked trade payables	(23)	(12)	(233)	12	23
Total	7,021	3,510	70,204	(3,510)	(7,021)

* See also Note 12b(1).

NOTE 3 – FINANCIAL RISK MANAGEMENT (cont.)

a. Market risk (cont.)

1) Concentration of currency risk (cont.)

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

	Exchange rate of $1	Exchange rate of € 1	Israeli CPI*
	NIS	NIS	Points
As of December 31:			
2011	3.821	4.938	128.56
2012	3.733	4.921	130.66
Percentage increase (decrease) in:			
2011	7.7%	4.2%	2.2%
2012	(2.3)%	(0.3)%	1.6%

* Based on the CPI index for the month ending on each balance sheet date, on the basis that the average for year 2000 = 100.

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

	December 31, 2011			December 31, 2012		
	Dollar	Other currencies	NIS	Dollar	Other currencies	NIS
	NIS in thousands					
Assets:						
Current assets:						
Cash and cash equivalents	12,176	5	20,880	50,247	11	18,081
Short term bank deposits	65,782	-	-	11,459	-	-
Other receivables	-	-	3,825	-	-	2,254
Non-current assets:						
Restricted deposits	621	-	*2,125	613	-	*2,900
Total assets	78,579	5	26,830	62,319	11	23,235
Liabilities:						
Current liabilities:						
Current maturities of bank loan		-	*307	-	-	*137
Accounts payable and accruals:						
Trade	8,142	293	2,840	8,780	573	2,930
OCS	-	-	6,233	-	-	6,148
Other	-	-	3,252	-	-	2,889
Total liabilities	8,142	293	12,632	8,780	573	12,104
Net asset value	70,437	(288)	14,198	53,539	(562)	11,131

* Linked to the CPI

NOTE 3 – FINANCIAL RISK MANAGEMENT (cont.)

a. Market risk (cont.)

2) Fair value of financial instruments

As of December 31, 2012, the financial instruments of the Company consist of non-derivative assets and liabilities (primarily working capital items and restricted deposits), as well as a liability on account of warrants.

With regard to non-derivative assets and liabilities, in view of their nature, the fair value of the financial instruments included in working capital is generally close or identical to their carrying amount. The fair value of the restricted cash in long-term deposits also approximates the carrying amount, as these financial instruments bear interest at a rate approximating the prevailing interest rate.

With regard to warrants, see Note 9c(2).

3) Exposure to market risk and the management thereof

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

4) Interest rate risk

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

b. Credit risk

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

The Company's cash and cash equivalents at December 31, 2011 and 2012 were mainly deposited with major Israeli banks. In the Company's opinion, the credit risk in respect of these balances is remote.

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

	December 31,	
	2011	2012
	NIS in thousands	
Assets:		
Cash and cash equivalents	33,061	68,339
Short-term bank deposits	65,782	11,459
Other receivables	3,825	2,254
Restricted deposits	2,746	3,513
Total	105,414	85,565

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.)

As mentioned in Note 1, although the Company has succeeded in out-licensing two of its products, it cannot determine with reasonable certainty if and when it will become profitable on a current basis. Management believes that the Company's current cash and other resources, including the proceeds from the direct placement completed in February 2013 (see Note 17), will be sufficient to fund its projected cash requirements through the end of 2014. Accordingly, in the event that the Company does not continue to generate cash from its operating activities, the Company will need to raise additional capital in the future. Inability to raise additional capital would have a material adverse effect on the financial condition of the Company.

d. Financial instruments

As of December 31, 2011 and 2012, the Company's financial instruments consisted of loans and receivables, and a liability on account of warrants.

e. Fair value estimations

In February 2012, BioLineRx completed a private placement in which it issued ADSs and warrant to purchase additional ADSs – see Note 9c(2). The fair value of the warrants, which are not traded on an active market, is determined by using valuation techniques. These valuation techniques maximize the use of observable market data where it is available and rely as little as possible on entity specific estimates.

NOTE 4 – CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

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

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

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

a. Development expenses

Development expenses are capitalized in accordance with the accounting policy described in Note 2q. 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, 2012, the foregoing conditions have not been met and therefore development expenses have not been capitalized for any project.

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

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

b. Grants/loans from the OCS

In accordance with the accounting treatment prescribed in Note 2r, Company management is required to evaluate whether there is reasonable assurance that the grant/loan received will be paid or repaid. Additionally, whenever the grant/loan is initially recognized as income, management is required to evaluate whether the payment of royalties/repayment of loans to the OCS is considered more likely than not.

See Notes 12a(1) and 12a(2) with regard to the potential amount repayable to the OCS as of December 31, 2012.

c. Revenue recognition

In accordance with the accounting treatment prescribed in Note 2p, Company management is required to evaluate whether it is probable that the economic benefits related to the out-licensing agreement with Ikaria will flow to the Company and whether it is possible to reliably measure the amount of the revenues relating to the transaction.

As of December 31, 2012, receipt of additional economic benefits associated with such transactions was not considered probable. Accordingly, no revenues with respect to additional milestone payments were recorded in the 2012 financial statements.

NOTE 5 – CASH, CASH EQUIVALENTS AND SHORT-TERM BANK DEPOSITS

a. Cash and cash equivalents

	December 31,	
	2011	2012
	NIS in thousands	
Cash on hand and in bank	993	2,208
Short-term bank deposits	32,068	66,131
	33,061	68,339

The short-term bank deposits included in cash and cash equivalents bear interest at annual rates of between 0.60% and 2.65%. The carrying amount of cash and cash equivalents approximates their fair value, since they bear interest at rates similar to prevailing market interest rates.

b. Short-term bank deposit

The short-term bank deposit is linked to the dollar and bears interest at an annual rate of 0.76%.

NOTE 6 – 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	2009	2010
	NIS in thousands				NIS in thousands				NIS in thousands	
Composition in 2010										
Office furniture and equipment	696	28	-	724	169	42	-	211	527	513
Computers and communications equipment	1,549	372	(772)	1,149	1,251	234	(772)	713	298	436
Laboratory equipment, net*	3,136	1,510	-	4,646	1,300	611	-	1,911	1,836	2,735
Leasehold improvements	4,147	47	-	4,194	2,633	736	-	3,369	1,514	825
	9,528	1,957	(772)	10,713	5,353	1,623	(772)	6,204	4,175	4,509
*Item is net of OCS grants received - see 12a(1)d	2,250	-	-	2,250	1,150	338	-	1,488	1,100	762

	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	2010	2011
	NIS in thousands				NIS in thousands				NIS in thousands	
Composition in 2011										
Office furniture and equipment	724	155	-	879	211	43	-	254	513	625
Computers and communications equipment	1,149	420	-	1,569	713	248	-	961	436	608
Laboratory equipment, net*	4,646	465	-	5,111	1,911	737	-	2,648	2,735	2,463
Leasehold improvements	4,194	72	-	4,266	3,369	382	-	3,751	825	515
	10,713	1,112	-	11,825	6,204	1,410	-	7,614	4,509	4,211
*Item is net of OCS grants received – see 12a(1)d	2,250	-	-	2,250	1,488	338	-	1,826	762	424

NOTE 6 – 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, 2011	December 31, 2012
	NIS in thousands				NIS in thousands				NIS in thousands	
Composition in 2012										
Office furniture and equipment	879	27	-	906	254	52	-	306	625	600
Computers and communications equipment	1,569	111	-	1,680	961	310	-	1,271	608	409
Laboratory equipment, net*	5,111	198	-	5,309	2,648	689	-	3,337	2,463	1,972
Leasehold improvements	4,266	7	-	4,273	3,751	331	-	4,082	515	191
	11,825	343	-	12,168	7,614	1,382	-	8,996	4,211	3,172
*Item is net of OCS grants received – see 12a(1)d	2,250	-	-	2,250	1,826	311	-	2,137	424	113

NOTE 7 – INTANGIBLE ASSETS

	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	2009	2010
	NIS in thousands				NIS in thousands				NIS in thousands	
Composition in 2010										
Intellectual property	3,577	-	(1,846)	1,731	751	-	-	751	2,826	980
Computer software	760	347	-	1,107	544	191	-	735	216	372
	4,337	347	(1,846)	2,838	1,295	191	-	1,486	3,042	1,352

	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	2010	2011
	NIS in thousands				NIS in thousands				NIS in thousands	
Composition in 2011										
Intellectual property	1,731	-	(88)	1,643	751	-	-	751	980	892
Computer software	1,107	33	-	1,140	735	153	-	888	372	252
	2,838	33	(88)	2,783	1,486	153	-	1,639	1,352	1,144

	Balance at beginning of year	Additions during year	Deletions during year	Balance at end of year	Balance at beginning of year	Additions during year	Deletions during year	Balance at end of year	Net book value December 31,	
									2011	2012
	NIS in thousands				NIS in thousands				NIS in thousands	
Composition in 2012										
Intellectual property	1,643	-	-	1,643	751	-	-	751	892	892
Computer software	1,140	61	-	1,201	888	142	-	1,030	252	171
	2,783	61	-	2,844	1,639	142	-	1,781	1,144	1,063

During 2010, the Company wrote-off intellectual property in the total amount of NIS 1,846,000 in respect of three projects that were terminated – BL-2030, BL-4060 and BL-5020. During 2011, the Company wrote-off intellectual property in the total amount of NIS 88,000 in respect of the termination of BL-4040.

Depreciation in respect of computer software for all years presented, as well as the impairment of intellectual property for the years 2010 and 2011, was included in research and development expenses.

NOTE 8 – LONG-TERM BANK LOAN

	December 31,	
	2011	2012
	NIS in thousands	
Loan balance	417	137
Less current maturities	(307)	(137)
	110	-

The loan is denominated in NIS, linked to the CPI and bears interest at an annual rate of 2.4%. The book value of the loan approximates its fair value.

The loan is repayable in 36 monthly installments and is collateralized by a lien on the related equipment with a net book value of NIS 580,000.

NOTE 9 – EQUITY

a. Share capital

As of December 31, 2012 and 2011, share capital is composed of ordinary shares, as follows:

	Number of Ordinary Shares	
	December 31,	
	2011	2012
Authorized share capital	250,000,000	750,000,000
Issued share capital	123,603,141	183,713,197
Paid-up share capital	123,603,141	183,713,197

	In NIS	
	December 31,	
	2011	2012
Authorized share capital	2,500,000	7,500,000
Issued share capital	1,236,031	1,837,132
Paid-up share capital	1,236,031	1,837,132

In May 2012, BioLineRx's shareholders approved an increase in its registered share capital, from 250,000,000 ordinary shares of NIS 0.01 nominal value each to 750,000,000 ordinary shares of NIS 0.01 nominal value each.

As of December 31, 2012, the market price on NASDAQ of BioLineRx's ADSs was $2.53, and the market price on the Tel Aviv Stock Exchange of BioLineRx's ordinary shares was NIS 0.941. Each ADS represents 10 ordinary shares.

NOTE 9 – 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, 2012 and 2011, all outstanding share capital consisted of ordinary shares.

c. Changes in the Company's equity

1) In December 2009, BioLineRx issued 11,293,419 ordinary shares and 7,528,946 Series 2 warrants in a public offering. Each warrant was exercisable into one Ordinary Share at an exercise price of NIS 6.08 (not linked). The warrants expired in December 2011.

Total net proceeds from the offering amounted to NIS 45,700,000, after deducting NIS 1,400,000 of issuance costs. The issuance costs were allocated between share premium and the warrants based on the relative market value (as indicated on the TASE) of the shares and warrants on the date of the offering.

2) In February 2012, BioLineRx completed a private placement to healthcare-focused U.S. institutional investors, pursuant to which it issued an aggregate of 5,244,301 ADSs, at a purchase price of $2.86 per ADS, and warrants to purchase up to 2,622,157 additional ADSs, at an exercise price of $3.57 per ADS. The offering raised a total of $15,000,000, with net proceeds of approximately $14,100,000, after deducting fees and expenses.

The warrants are exercisable over a period of five years from the date of their issuance. Since the exercise price was not deemed to be fixed, the warrants are not qualified for classification as an equity instrument and have therefore been classified as a non-current financial liability.

The amount of the private placement consideration allocated to the warrants was approximately $4,800,000, as calculated on the basis of the Black-Scholes model, which reflected their fair value as of the issuance date. The portion of total issuance costs allocable to the warrants, in the amount of approximately $300,000, was recorded as non-operating expense on the statement of comprehensive income (loss). The change in fair value from the date of issuance through December 31, 2012, amounting to approximately $1,900,000, has been recorded as non-operating income on the statement of comprehensive loss.

d. Share purchase agreement

In September 2012, BioLineRx and Lincoln Park Capital Fund, LLC, an Illinois limited liability company ("LPC"), entered into a $15 million purchase agreement (the "Purchase Agreement"), together with a registration rights agreement, whereby LPC agreed to purchase, from time to time, up to $15 million of BioLineRx's ADSs, subject to certain limitations, during the 36-month term of the Purchase Agreement. BioLineRx has the right, in its sole discretion, over a 36-month period to sell up to $15 million of ADSs (subject to certain limitations) to LPC, depending on certain conditions as set forth in the Purchase Agreement.

NOTE 9 – EQUITY (cont.)

d. Share purchase agreement (cont.)

The purchase price of the ADSs purchased by LPC under the Purchase Agreement will be based on the prevailing market prices of BioLineRx's ADSs immediately preceding the time of sale without any fixed discount. BioLineRx will control the timing and amount of future sales, if any, of ADSs to LPC. LPC has no right to require BioLineRx to sell any ADSs to LPC, but LPC is obligated to make purchases as BioLineRx directs, subject to certain conditions.

In consideration for entering into the $15 million agreement, BioLineRx paid to LPC a commitment fee of $225,000, paid via the issuance of 98,598 ADSs, and will pay a further commitment fee of up to $375,500, pro rata, as the facility is used over time, which will be paid in ADSs valued based on the prevailing market prices of BioLineRx's ADSs at such time. The Purchase Agreement may be terminated by BioLineRx at any time, in its sole discretion, without any cost or penalty.

In connection with the Purchase Agreement, BioLineRx paid a finder's fee, in cash, to Oberon Securities, LLC of $150,000, and will pay an additional finder's fee of up to $300,000, pro rata, as the facility is used over time.

The initial commitment fee to LPC and the initial finder's fee to Oberon Securities, in the total aggregate amount of $375,000, as well as other one-time expenses associated with the initial set-up of the facility, were recorded as non-operating expense in the statement of comprehensive income (loss). Future commitment and finder's fees payable, if and when the facility is used over time, will be recorded as issuance expenses against share premium on the statement of financial position.

From the effective date of the Purchase Agreement through December 31, 2012, BioLineRx sold a total of 646,367 ADSs to LPC for aggregate gross proceeds of $1,800,000. In connection with these issuances, a total of 16,159 ADSs was issued to LPC as an additional commitment fee and a total of $36,000 was paid to Oberon Securities as an additional finder's fee.

On a cumulative basis, from the effective date of the Purchase Agreement through the approval date of these financial statements, BioLineRx has sold a total of 1,434,354 ADSs to LPC for aggregate gross proceeds of $4,690,000. In connection with these issuances, a total of 35,859 ADSs was issued to LPC as an additional commitment fee and a total of $94,000 was paid to Oberon Securities as an additional finder's fee.

NOTE 9 – EQUITY (cont.)

e. Share-based payments

1) Stock option plan – general

In 2003, BioLineRx adopted the 2003 Share Option Plan (the "Plan"). The Plan provides for the granting of options and ordinary shares to the Company's employees, directors, consultants and other service providers. Options are issued at the determination of the Board of Directors in accordance with applicable law. The options are generally exercisable for a seven-year period and the grants generally vest over a four-year period - 50% after the first two years of service, and 25% for each subsequent additional year of service. As of December 31, 2012, there were 13,575,811 ordinary shares issuable upon the exercise of outstanding options under the Plan.

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

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 2011, the Board of Directors approved the re-pricing of approximately 3,700,000 outstanding "underwater" employee stock options (out of a total of approximately 6,200,000 stock options outstanding at that time). The weighted average remaining vesting period of the options subject to re-pricing was 1.1 years, with a weighted average exercise price of NIS 4.07 per share. Terms of the re-pricing were as follows: (i) the exercise price of the options was reduced to NIS 1.80 per share and (ii) one additional year of vesting was added to the remaining vesting period of the options. The re-pricing was not applicable to options already vested, and it did not apply to options held by directors or consultants. The total compensation cost associated with the re-pricing was approximately NIS 900,000, and is being recorded as an expense over the new vesting period of the re-priced options.

In May 2012, the Company's Board of Directors approved an increase from 14 million to 30 million to the total pool of authorized but unissued ordinary shares reserved for purposes of the Plan and any other present or future share incentive plans of the Company, subject to adjustments as provided in Section 14 of the Plan. As of December 31, 2012, there were 8,921,178 remaining authorized but unissued ordinary shares in the pool reserved for future share-based incentive grants.

In November 2012, the Board of Directors approved a two-year extension to the exercise period for 3,867,910 previously issued and outstanding employee stock options. This extension brought the total exercise period of such options in line with the seven-year exercise period generally used for most employee stock options that were previously granted. The total compensation cost associated with this extension was approximately NIS 680,000, and is being recorded as an expense over the vesting period of the options.

NOTE 9 – EQUITY (cont.)

e. Share-based payments (cont.)

2) Employee stock options (cont.)

The following table contains additional information concerning options granted to employees and directors under the existing stock-option plans.

	Year ended December 31,					
	2010		2011		2012	
	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	2,053,551	2.44	6,461,975	3.56	5,557,720	1.87
Granted	4,905,400	4.11	462,200	1.33	8,122,000	1.07
Forfeited and expired	(443,873)	4.89	(1,336,974)	3.75	(687,895)	2.83
Exercised	(53,103)	0.46	(29,481)	0.04	(55,806)	0.04
Outstanding at end of year	6,461,975	3.56	5,557,720	1.87	12,936,019	1.32
Exercisable at end of year	1,120,270	1.69	1,362,970	1.96	1,526,437	2.04

The total consideration received from the exercise of stock options during 2010, 2011 and 2012 was NIS 26,000, NIS 1,000 and NIS 2,000, respectively.

The weighted average prices of BioLineRx's shares on the dates of exercise were NIS 3.53, NIS 1.97 and NIS 1.21 for 2010, 2011 and 2012, respectively.

See Note 9e(1) regarding the option re-pricing carried out in November 2011.

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

As of December 31,	Number of options outstanding	Range of exercise prices (in NIS)	Weighted average remaining contractual life (in years)
2010	6,461,975	0.04 - 5.04	4.69
2011	5,557,720	0.04 - 5.04	3.85
2012	12,936,019	0.04 - 5.04	5.90

NOTE 9 – EQUITY (cont.)

e. Share-based payments (cont.)

2) Employee stock options (cont.)

The fair value of all options granted to employees through December 31, 2012 has been determined using the Black-Scholes option-pricing model. These values are based on the following assumptions as of the applicable grant dates:

	2010	2011	2012
Expected dividend yield	0%	0%	0%
Expected volatility	66%	62%	68%
Risk-free interest rate	4%	3%	3%
Expected life of options (in years)	5	5	7

3) Stock options to consultants

From inception through December 31, 2006, the Company issued to consultants options for the purchase of 210,990 ordinary shares at an average exercise price of NIS 0.04 per share. In 2007, the Company issued options to consultants for the purchase of 144,242 ordinary shares at an average exercise price of NIS 2.13 per share. The options vest over four years and may be exercised for a period of ten years.

In 2010, the Company issued options to consultants for the purchase of 300,000 ordinary shares at an average exercise price of NIS 4.03 per share. The options vest over four years and may be exercised for a period of five years.

In 2012, the Company issued options to consultants for the purchase of 110,000 ordinary shares at an average exercise price of NIS 1.115 per share. The options vest over four years and may be exercised for a period of seven years.

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 2010, 2011 and 2012 amounted to NIS 1,054,000, NIS 1,005,000 and NIS 906,000, respectively.

NOTE 10 – TAXES ON INCOME

a. Corporate taxation in Israel

The income of BioLineRx and BIJ Ltd. is taxed at standard Israeli corporate tax rates. In July 2009, the Israeli Knesset passed a law, which provided for a gradual reduction in corporate tax rates as follows: 2009 - 26%, 2010 - 25%, 2011 - 24%, 2012 - 23%, 2013 - 22%, 2014 - 21%, 2015 - 20%, 2016 and thereafter -18%. These tax rate reductions were cancelled pursuant to a new law passed in December 2011, and the corporate tax rate applicable to 2012 and thereafter is 25%.

Capital gains recorded through December 31, 2011 are taxed at the standard corporate tax rate. Effective, January 1, 2012, all capital gains are subject to a tax rate of 25%.

BIJ LP is not subject to tax under Israeli tax law; rather, each of the partners thereof (BioLineRx and BIJ Ltd.) is liable for the tax applicable to the operations of BIJ LP in proportion to their respective share in BIJ LP's results.

b. Approved enterprise benefits

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

Subject to compliance with the applicable requirements, the portion of undistributed income derived from Benefited Enterprise programs will be entitled to a tax exemption for a period of ten years commencing in the first year in which BioLineRx generates taxable income after setting off losses for Israeli tax purposes from prior years (see c. below). The ten-year period may not extend beyond 14 years from the beginning of the Benefited Enterprise's election year. BioLineRx received Benefited Enterprise status with respect to Eligible Projects beginning in the 2009 tax year, so depending on when the Benefited Enterprise programs begin to generate taxable income, the benefit period could continue through 2022. However, any distribution of income derived from Benefited Enterprise programs will result in such income being subject to a rate of corporate tax of 25%.

Beginning with tax year 2013, BioLineRx has the option to transition to a "Preferred Enterprise" regime under the Investments Law, according to which all income which is eligible for benefits under the regime would be subject to flat corporate tax rates of 7% in 2013 and 2014 and 6% in 2015 and thereafter, whether or not distributed. If BioLineRx were to move its operations to a different part of Israel, these rates may be increased. A transition to a Preferred Enterprise regime may not be reversed.

In addition, the ITA approved BioLineRx's operations as an "Industrial Enterprise" under the Investments Law, meaning that BioLineRx is eligible for accelerated depreciation with respect to certain tangible assets belonging to its Benefited Enterprise. Should BioLineRx not meet the requirements for maintaining these benefits, they may be reduced or cancelled and, among other things, income deriving from the Eligible Projects would be subject to Israeli corporate tax at the standard rate of 25%.

NOTE 10 – TAXES ON INCOME (cont.)

c. Tax loss carryforwards

As of December 31, 2011 and 2012, the tax loss carryforwards of BioLineRx were approximately NIS 349,000,000 and NIS 414,000,000, respectively; and the tax loss carryforwards of BIJ Ltd. were approximately NIS 1,000,000 and 1,900,000 at both dates. The tax loss carryforwards of both BioLineRx and the BIJ Ltd. have no expiration date.

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

d. Tax assessments

In accordance with Israeli tax regulations, the tax assessments filed by BioLineRx and its Israeli subsidiaries through the 2007 tax year are considered final. BioLineRx USA has not yet been assessed for tax purposes.

e. Theoretical taxes

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

	Year ended December 31,					
	2010		2011		2012	
		NIS in thousands		NIS in thousands		NIS in thousands
Income (loss) before taxes	25%	7,440	24%	(50,186)	25%	(76,270)
Theoretical tax expense (tax benefit)		1,860		(12,045)		(19,068)
Disallowed deductions (tax exempt income):						
Gain on adjustment of warrants to fair value						(1,816)
Share-based compensation		1,639		967		785
Other		25		24		75
Utilization of tax losses carryforwards for which deferred taxes were not created		(3,652)		-		-
Increase in taxes for tax losses and timing differences incurred in the reporting year for which deferred taxes were not created		128		11,054		20,024
Taxes on income for the reported year		-		-		-

NOTE 10 – TAXES ON INCOME (cont.)

f. Value-added tax (VAT)

BioLineRx is jointly registered for VAT purposes together with its Israeli subsidiaries.

NOTE 11 – EARNINGS (LOSS) PER SHARE

a. The following table contains the data used in the computation of the basic earnings (loss) per share:

	Year ended December 31,		
	2010	**2011**	**2012**
		NIS in thousands	
Income (loss) attributed to ordinary shares	7,440	(50,186)	(76,270)
Number of shares used in basic calculation (in thousands)	123,512	123,587	169,405
Adjustment for incremental dilutive shares from the theoretical exercise of options and warrants	1,035	-	-
Number of shares used in diluted calculation (in thousands)	124,547	-	-
		NIS	
Basic earnings (loss) per ordinary share	0.06	(0.41)	(0.45)
Diluted earnings (loss) per ordinary share	0.06	(0.41)	(0.45)

NOTE 12 – COMMITMENTS AND CONTINGENT LIABILITIES

a. Commitments

1) Agreement with the State of Israel for operation of a biotechnology incubator

As part of the Incubator agreement between BIJ LP and the State of Israel, represented by the OCS (see principal provisions below), the State of Israel has agreed to grant loans to BIJ LP to partially finance projects approved by the OCS.

The loans bear interest in accordance with the Interest and Linkage Law, 1961 (as of December 31, 2011 and 2012 – 2.10% and 1.00%, respectively), and are repayable at the discretion of BIJ LP (but subject to the conditions described below concerning the sale of project assets or the realization of income from the project), as follows:

- In the first three years of a project's incubator stage, the loan principal is repayable, plus accrued interest.
- In the subsequent two years, the loan principal is repayable under the same terms, provided that the Incubator undertakes to maintain the advancement of the project at a rate similar to that of the preceding years.
- In the three following years, the loan principal is repayable with the addition of a double interest charge, provided that the Incubator undertakes to continue advancing the project at a rate similar to that of the preceding years.

If the Incubator sells assets or generates income from a project (including any intellectual property related thereto), at least 25% of the income from such sale must be used to repay the project loan, up to the original principal amount of the loan with the addition of interest as described herein. BIJ LP is required to repay the loan in full upon the sale of a project's intellectual property or the grant of an exclusive license to use the project's intellectual property. The total payments to the State of Israel from such income will not exceed the original principal amount of the applicable loan with the addition of interest and linkage to the CPI. In certain circumstances, if the intellectual property or manufacturing rights are transferred outside of Israel, the repayment amounts may be greater.

Pursuant to the Incubator agreement, the Incubator has undertaken to register a first-ranking pledge in favor of the OCS to cover the loans made to the Incubator. In accordance with the agreement, each pledge is specific to the loan for a specific project and includes a restriction on the transfer of, and/or licensing rights in, technologies that originate from the project, and on any equipment purchased for use in the project. The Company has signed and submitted pledge registration documents to the OCS.

The proceeds from the sale or use of project-related intellectual property serve as the exclusive source for repayment of OCS loans financing such projects, and the sole collateral for the repayment of project loans are pledges on project-related intellectual property and assets purchased with loan proceeds.

NOTE 12 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

1) Agreement with the State of Israel for the operation of a biotechnology incubator (cont.)

In 2010, 2011 and 2012, the Company received NIS 1,916,000, NIS 3,021,000 and NIS 2,661,000, respectively, from the OCS, of which NIS 842,000, NIS 257,000 and NIS 374,000, respectively, were related to discontinued projects. The Company has agreed with the OCS on a procedure for the discontinuation of projects by the Incubator and the action that should be taken to forgive loans received in respect of such discontinued projects.

The biotechnological incubator program is an initiative of the OCS that is designed to strengthen and promote the Israeli biotechnology industry, as well as biotechnology projects. This program was launched in 2001, following publication of Directive No. 8.4 of the Director-General of Israel's Ministry of Industry, Trade and Labor ("Directive 8.4"). This directive implements the recommendations of the "Monitor" report, which reviewed ways to promote the Israeli biotechnology industry and recommended the establishment of for-profit incubators to support commercially viable projects by providing physical, organizational, professional, marketing and business infrastructure to promote research and development by early-stage biotechnology enterprises.

Directive 8.4 was amended in May 2004, to prescribe two tracks for operating biotech incubators (see (e) below). Immediately after the amendment of Directive 8.4, the OCS issued a call for proposals to establish and operate incubators. BioLineRx's proposal was accepted by the OCS and subsequently, it entered into an agreement with the OCS, through BIJ LP, for the operation of a designated biotechnology incubator. The principal provisions of the incubator agreement are as follows:

(a) Period of the agreement

The incubator agreement originally had a six-year period expiring on December 31, 2010. However, in accordance with an approval certificate that was received from the OCS, the incubator agreement was extended for two additional periods, through December 31, 2013.

(b) Scope of Incubator operations

The Incubator is designed for the simultaneous operation of at least eight OCS-approved projects. The Company may operate additional projects within the Incubator's facilities that are not funded by the State or under the incubator program, provided that the operation of such additional projects does not interfere with OCS-approved projects.

NOTE 12 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

1) Agreement with the State of Israel for the operation of a biotechnology incubator (cont.)

(c) Summary of the Company's obligations

Within the framework of the incubator agreement, the Company has agreed to operate a biotechnology-designated incubator, to identify projects suitable for OCS approval, to make adequate premises and physical infrastructure available for at least eight projects and to provide administrative, organizational, professional and business support to the projects in order to facilitate research and development of commercially viable biotechnology projects. Among other things, some minimum requirements have been set for Incubator staff in terms of skills and employment levels. In addition, the Company has agreed to maintain a central laboratory for the use of all projects, equip the laboratory in accordance with the specifications provided in Directive 8.4 and in the Company's incubator proposal, and operate the Incubator using capable personnel. The Company is also required to make consulting and auditing services (accounting, legal, patent consulting, quality assurance, information science services, regulatory consulting and clinical trials) available to the projects at an acceptable scope and quality, from service providers approved by the OCS. The Company has undertaken to invest at least NIS 2,700,000 annually in the operation of the Incubator.

(d) Summary of OCS obligations

The OCS has undertaken to finance 50% of the cost of the equipment required for setting up the central laboratory and to make available State loans to each of the projects approved by the OCS at the rates of 85%, 80% and 75% of the project's approved budget in its first three years of operation, respectively, which are to be repaid to the State as described above. Each Incubator project is limited to a period of three years and a maximum budget of NIS 8,100,000, in respect of which the Company is responsible for obtaining the complementary financing (15% to 25%) for all three years, as described above.

In exchange for services provided by the Incubator, the Company is entitled to receive participation by the OCS in operating expenses of up to 20% of the personnel costs associated with each project's approved budget, and may not collect additional payments in respect of the basket of services required by the OCS. The participation limit also applies to the operating expenses of the central laboratory, but does not apply to the costs of consumable materials.

(e) The alternative incubator operating tracks

Directive 8.4 offers two alternative tracks for the operation of an incubator. Under the first track, each project is incorporated as a separate and independent company in which the incubator receives shares (the separate companies will allocate at least 30% of their share capital to the holder of the license/knowhow, up to 5% of the share capital for incubator services, and the remaining shares will be allotted to the incubator and other investors in proportion to their investments in the independent company, including the incubator's investments derived from State loans).

NOTE 12 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

1) Agreement with the State of Israel for the operation of a biotechnology incubator (cont.)

(e) The alternative incubator operating tracks (cont.)

Under the second track, the projects are directly run within the incubator by the concessioner, with the holder of the license/know-how being entitled to a fixed amount for the use of his know-how as well as to royalties upon the sale of the knowhow and in respect of the sales of a final product developed under the project. An incubator operating under the second track is allowed to operate additional specific projects under the guidelines of the first track, subject to fulfillment of the provisions in the guidelines. The Company has elected to operate the Incubator under the second track.

(f) Primary restrictions imposed on the Company and the Incubator

The agreement stipulates certain restrictions regarding operation of the Incubator and the projects, including, among others: maximum ownership of 15% in the Incubator by university research institutions; a limitation of subcontracting to no more than 40% of the approved budget; ownership by the Company (or the project company under the first track) of the intellectual property created in the project (it should be noted that an exception to this rule was carved out in a recent amendment to the R&D law from January 2011 regarding academic institutions); a prohibition on duplicate grants and participation or duplicity of projects; compliance with guidelines on investment of funds; restrictions on terms of the licensing agreements with the holders of the know-how, which mainly involves securing the rights of the OCS; compliance with the Israel R&D Law (the Encouragement of Research and Development in Industry Law) in terms of keeping in Israel the intellectual property and manufacturing rights relating to OCS-funded projects.

(g) Repayment of loans

Repayment of State loans is restricted to a project's own resources out of the proceeds received from the sale or licensing of a project (at least 25% of the proceeds). The sale or licensing of the technology is subject to payment of the aforementioned royalties, up to the amount of the loans received from the State for such project.

The State is entitled to foreclose on the collateral related to a given project to secure repayment of the related loan at the end of eight years from the date of project approval, or even earlier, in the event of a breach of the incubator agreement by the Company, liquidation, and other events as set forth in the agreement.

NOTE 12 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

1) Agreement with the State of Israel for the operation of a biotechnology incubator (cont.)

(h) Security

The Company initially provided a bank guarantee to the OCS in the amount of NIS 8,100,000 to secure its liabilities under the incubator agreement. After two years from the initial date of the incubator agreement, the amount of the guarantee is reduced every year by half the amount of the Incubator's reported approved expenses, subject to a minimum guarantee of NIS 1,500,000 (see Note 12b). Additionally, the rights in the various projects are pledged to the State to secure repayment of the loan out of project proceeds. With respect to incubators operating under the second track, a floating charge is placed on all intellectual property and all equipment purchased in connection with a project, including a restriction on the transfer or licensing of the technology created in the project. The collateral discussed in this paragraph may be forfeited even after the repayment period or upon breach of the incubator agreement.

(i) To the best knowledge of Company management, as of the date of approval of these financial statements, the Company is in compliance with its material obligations to the OCS under the incubator agreement.

With respect to the accounting treatment of State loans, see Note 2r.

2) Obligation to pay royalties to the Government of Israel

The Company is required to pay royalties to the Government of Israel, computed on the basis of proceeds from the sale or license of products whose development was supported by Government grants.

This obligation relates solely to the Government's financial participation in the development of products by the Company outside the framework of the Incubator operated by BIJ LP.

In accordance with the terms of the financial participation, the Government is entitled to royalties on the sale or license of any product whose development was supported with Government 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 $) received by the Company plus annual interest at the LIBOR rate. Under certain circumstances, the royalty rate is calculated according to a formula based on the ratio of the participation by the OCS in the project to the total project costs incurred by the Company. As of December 31, 2012, the contingent liability for potential royalties payable by the Company for grants received amounts to approximately NIS 2,000,000.

The Company's aggregate contingent liability to the OCS, both in respect of loans received in the framework of the biotechnology incubator (see paragraph (1) above), as well as the grants described herein, amounted to NIS 14,300,000 as of December 31, 2012.

NOTE 12 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

3) Licensing agreements

From time to time, the Company enters into in-licensing agreements with academic institutions, research institutions and companies in connection with development of certain technologies (the "licensors").

The objective of each engagement with a licensor is to obtain rights for one or more drugs in the preliminary stages of development by the licensors, to continue joint development of the drugs by the Company and the licensors until advanced stages of development and, consequently, to manufacture, distribute and market the drugs or to out-license the development, manufacture and commercialization rights to third parties. Such post-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 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 will work to register the various patents worldwide, and if the Company decides not to initiate or continue a patent registration proceeding in a given country, the Company is required to notify the applicable licensor to this effect and the licensor will be entitled to take action for registration of the patent in such country.

NOTE 12 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

3) 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 payment of up to $200,000 and/or periodic payments of up to $30,000 per year; (b) royalties on amounts the Company receives from an out-licensing transaction that generally range from 20% to 29.5% of net consideration, although in specific instances the royalty rate has been higher or lower than this range; (c) payments through the early stages of development (i.e. through the end of phase 2) of up to $150,000; (d) payments of up to $2,000,000 upon the achievement of milestones necessary for advancing to phase 3; (e) payments of up to $5,000,000 from the end of a successful phase 3 trial through approval of the therapeutic compound; and f) royalties on sales of the final product resulting from development under the license or including any component thereof, ranging between 3%-5% of the Company's net sales of the product, although in specific instances the royalty rate has been higher or lower than this range.

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

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

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

4) Lease agreements

a) The Company has entered into an operating lease agreement in connection with the lease of its premises. The agreement will expire on December 15, 2014. The Company has an option to extend the lease agreement for one additional two-year period. The annual lease fees are linked to the dollar and amount to approximately NIS 920,000. As to bank deposits pledged to secure the Company's liability under the lease agreement, see Note 12b(1).

b) The Company has entered into operating lease agreements in connection with a number of vehicles. The lease periods are generally for three years. The annual lease fees, linked to the CPI, are approximately NIS 1,330,000. To secure the terms of the lease agreements, the Company has made certain prepayments to the leasing companies, representing approximately two months of lease payments. These amounts have been recorded as prepaid expenses. See also Note 14b.

NOTE 12 – COMMITMENTS AND CONTINGENT LIABILITIES (cont.)

a. Commitments (cont.)

5) Early Development Program ("EDP") agreement

On the signature date of an investment agreement with Pan Atlantic Bank and Trust Limited ("Pan Atlantic") in 2007, BioLineRx also entered into an agreement with Pan Atlantic for the funding of an early development program (the "EDP Agreement"). According to the EDP Agreement, Pan Atlantic undertook to provide grants for the promotion of drug-development projects in the preliminary stages of research in an aggregate amount of up to $5,000,000, in semi-annual "calls" of up to $625,000 each. In parallel, for every dollar of EDP project funding provided by Pan Atlantic, BioLineRx committed to provide twenty cents of funding (i.e., a funding ratio of 5:1). Pan Atlantic's undertakings under the EDP agreement are not subject to Pan Atlantic being a lender to, or a shareholder of, BioLineRx. During 2012, Pan Atlantic fulfilled its entire $5,000,000 funding commitment under the EDP agreement.

In consideration for the EDP funding commitment, BioLineRx granted to Pan Atlantic the right to participate in a future public offering of BioLineRx outside of Israel, at the public offering price, in an amount of up to $5,000,000.

During 2010, 2011 and 2012, Pan Atlantic provided funding of NIS 3,877,000, NIS 4,455,000 and NIS 1,867,000, respectively, under the EDP Agreement. The amounts recognized as a reduction of research and development expenses in 2010, 2011 and 2012 were NIS 2,997,000, NIS 3,589,000 and NIS 3,955,000, respectively.

b. Contingent liabilities

Guarantees and liens:

1) As part of the Company's obligations under the Incubator agreement and to secure its liabilities to the OCS, the Company originally provided a NIS 8,100,000 bank guarantee (linked to the CPI) in favor of Israel's Ministry of Finance.

The guarantee is valid through March 2014. According to the Incubator agreement, after the two year anniversary of the initial date of the Incubator agreement, the amount of the guarantee has been reduced every year by half of the amount of the Incubator's reported approved expenses. As of December 31, 2012, the balance of the guarantee amounted to approximately NIS 2,900,000.

To secure the above guarantee, the Company has pledged to a bank a short-term deposit in the amount of NIS 2,900,000, which is presented under non-current assets.

2) To secure the Company's liability to the lessor of its premises, the Company has pledged several dollar-denominated bank deposits in the aggregate amount of $164,000 (NIS 613,000), which are presented under non-current assets.

NOTE 13 – TRANSACTIONS AND BALANCES WITH RELATED PARTIES

Transactions with related parties

Expenses (income):

	Year ended December 31,		
	2010	2011	2012
	NIS in thousands		
Participation in EDP project funding*	(2,997)	(3,589)	(3,713)
Benefits to related parties:			
Compensation and benefits to senior management, including benefit component of option grants	8,208	5,463	5,354
Number of individuals to which this benefit related	5	5	5
Compensation and benefits to directors, including benefit component of option grants	858	591	549
Number of individuals to which this benefit related	3	4	5

* This amount relates to a grant received from Pan Atlantic, in accordance with the EDP Agreement as detailed in Note 12a(5).

Key management compensation

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

	Year ended December 31,		
	2010	2011	2012
	NIS in thousands		
Salaries and other short-term employee benefits	5,609	4,409	4,448
Post-employment benefits	343	357	441
Other long-term benefits	42	45	57
Share-based compensation	3,072	1,243	957
	9,066	6,054	5,903

NOTE 14 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

a. Other receivables

	December 31,	
	2011	2012
	NIS in thousands	
Withholding tax	416	398
Institutions	1,123	1,553
Grants receivable from the OCS	2,286	-
Other	-	303
	3,825	2,254

b. Long-term prepaid expenses

The prepaid expenses relate to operating lease agreements in respect of the vehicles leased by the Company.

c. Accounts payable and accruals

	December 31,	
	2011	2012
	NIS in thousands	
1) Trade:		
Accounts payable:		
In Israel	2,574	2,922
Overseas	8,435	9,353
Checks payable	266	8
	11,275	12,283
2) Other:		
Payroll and related expenses	539	815
Accrual for vacation and recreationpay	1,049	965
Accrued expenses	1,655	980
Grants on account of EDP project development financing not yet recognized in income	4,642	2,554
Other	9	129
	7,894	5,443

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

NOTE 14 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (cont.)

d. Cost of revenues

	Year ended December 31,		
	2010	2011	2012
	NIS in thousands		
Payments to licensors*	25,571	-	-

* See Note 16.

e. Research and development expenses – net

	Year ended December 31,		
	2010	2011	2012
	NIS in thousands		
Payroll and related expenses, including vehicles	18,566	16,052	14,283
Depreciation and amortization	1,705	1,468	1,433
Impairment of intellectual property	1,846	88	-
Patent-related expenses	1,770	4,243	5,363
Research and development services	16,265	23,651	43,940
Professional fees	1,999	1,942	1,981
Materials	301	141	148
Overseas travel	215	167	115
Office supplies and telephone	2,682	3,055	3,457
Payments to OCS (see Note 16)	17,438	-	-
Other	360	891	338
	63,147	51,698	71,058
Less – OCS participation in research and development costs - see also Notes 12a(1) and (2)	(5,184)	(5,486)	(2,799)
Less – participation in research and development costs by a related party - see Note 13	(2,997)	(3,589)	(3,955)
	54,966	42,623	64,304

f. Sales and marketing expenses

	Year ended December 31,		
	2010	2011	2012
	NIS in thousands		
Payroll and related expenses, including vehicles	2,090	1,425	1,841
Marketing	2,258	1,428	1,044
Overseas travel	261	455	342
	4,609	3,308	3,227

NOTE 14 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (cont.)

g. General and administrative expenses

	Year ended December 31,		
	2010	**2011**	**2012**
	NIS in thousands		
Payroll and related expenses, including vehicles	6,205	6,380	6,664
Professional fees	6,540	4,283	4,708
Office supplies and telephone	111	105	79
Office maintenance	69	72	78
Insurance	271	433	618
Depreciation	109	95	91
Other	1,570	1,354	1,788
	14,875	12,722	14,026

h. Non-operating income, net

	Year ended December 31,		
	2010	**2011**	**2012**
	NIS in thousands		
Issuance costs allocated to warrants issued in private placement	-	-	(1,204)
Changes in fair value of warrants issued in private placement	-	-	7,265
Initial commitment and finder's fees associated with LPC agreement	-	-	(2,103)
	-	-	3,958

i. Financial income

	Year ended December 31,		
	2010	**2011**	**2012**
	NIS in thousands		
Income from interest and exchange differences on deposits	3,056	12,730	8,819
	3,056	12,730	8,819

j. Financial expenses

	Year ended December 31,		
	2010	**2011**	**2012**
	NIS in thousands		
Exchange differences	8,696	4,196	7,393
Bank commissions	59	67	97
	8,755	4,263	7,490

NOTE 15 – IKARIA AGREEMENT

During the third quarter of 2009, the Company entered into an out-licensing agreement with Ikaria, pursuant to which the Company granted Ikaria an exclusive, worldwide license to develop, manufacture and commercialize BL-1040 – a compound for the treatment of patients that have suffered an acute myocardial infarction ("AMI"). The agreement was signed in July 2009 and the transaction closed in September 2009, following receipt by the Company of OCS approval for the transaction, and transfer by the Company to Ikaria of all deliverables as stipulated under the agreement.

In accordance with the agreement, Ikaria is obligated to use commercially reasonable efforts to complete clinical development of and to commercialize BL-1040, and will bear all subsequent costs involved in the continued development of the product, the conduct and funding of its commercialization, and the prosecution and maintenance of patents.

Prior to execution of the agreement, the Company commenced a pilot phase 1/2 study designed to assess the safety and preliminary efficacy of BL-1040. According to the agreement, the Company was required to bear the costs related to completion of the study from that stage. Such costs, related to follow up and documentation of results, were accrued in 2009.

Total payments to the Company under the agreement (not including royalties) are up to $282,500,000, subject to the achievement of certain milestones. Upon the closing of the agreement, the Company became entitled to the first payment in the amount of $7,000,000, which was received in October 2009. In connection with this payment, the Company undertook to indemnify Ikaria for any obligations it may have had to withhold taxes on such payment. In April 2010, the first milestone payment of $10,000,000 was received, in respect of which withholding tax of 15% was deducted. The Company received a refund of the tax withheld in 2011. Approximately 50% of the remaining payments are subject to certain development and regulatory milestones and the rest are subject to commercialization milestones. The abovementioned first two payments were recognized as revenues in 2009, and future milestone payments will be recognized as revenues if and when their receipt will become probable and their amount can be reliably measured.

The Company is also entitled to royalties on the net sales of any product developed under the agreement, ranging from 11% to 15%, depending on annual net sales levels.

The out-licensing agreement with Ikaria terminates on the date that the last patent rights in respect of BL-1040 are still valid (through at least 2029).

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

NOTE 16 – CYPRESS AGREEMENT

In June 2010, the Company entered into an exclusive, royalty-bearing out-licensing agreement with Cypress Bioscience, Inc. for United States, Canada and Mexico (the "territories"), with regard to BL-1020, a therapeutic candidate for the treatment of schizophrenia. Under the agreement, Cypress Bioscience was obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and to commercialize BL-1020 in the territories, and was to bear all subsequent costs involved in the continued development of the product, the conduct and funding of its commercialization, and the prosecution and maintenance of patents in the territories. The agreement became effective in August 2010, upon receipt of the consent of the Office of the Chief Scientist of Israeli Ministry of Industry, Trade and Labor (“OCS”).

The Company received an upfront fee of $30,000,000 from Cypress Bioscience upon the effectiveness of the agreement.

The Company was required to pay 22.5% of all consideration received under the agreement to the licensors of BL-1020. As a result, $6,750,000 was charged to cost of revenues in 2010 in respect of the $30,000,000 upfront payment.

In addition, the Company is obligated to repay grants received from the OCS regarding the BL-1020 project, in accordance with the Israeli R&D Law and as agreed with the OCS. In this regard, during 2010, the Company recorded a liability to the OCS for the full amount of the grants received in respect of the project, in the total amount of $4,500,000. This amount was reflected in research and development expenses in the 2010 financial statements. The Company paid $3,000,000 of this liability to the OCS in August 2010, leaving a remaining balance of $1,500,000, reflected in current liabilities as of December 31, 2011 and 2012.

In May 2011, the Company signed an agreement, effective June 1, 2011, to reacquire all development and commercialization rights to BL-1020 granted to Cypress Bioscience pursuant to the license agreement signed in June 2010, as well as to terminate the license agreement. In consideration for the reacquisition of such rights, including substantially all materials required for timely commencement of the BL-1020 clinical trial that commenced in June 2011, the Company is obligated to pay Cypress Bioscience a 1% royalty on worldwide net sales of BL-1020 up to an aggregate cumulative amount of $80,000,000. In addition, the Company is obligated to pay Cypress Bioscience 10% of all future one-time payments received in respect of BL-1020, not to exceed an aggregate cumulative amount of $10,000,000, as reimbursement for costs that Cypress Bioscience incurred in developing the intellectual property portfolio, designing the clinical trial and conducting substantially all preparations to launch the trial.

NOTE 17 – EVENTS SUBSEQUENT TO THE BALANCE SHEET DATE

In February 2013, the Company completed a direct placement to leading healthcare investor, OrbiMed Israel Partners Limited Partnership, an affiliate of OrbiMed Advisors LLC. The placement consisted of 2,666,667 ADSs and 1,600,000 warrants to purchase an additional 1,600,000 ADSs, at a unit price of $3.00. The warrants have an exercise price of $3.94 per ADS and are exercisable for a term of five years. The offering raised a total of $8,000,000, with net proceeds of approximately $7,700,000, after deducting fees and expenses.

Exhibit 12.1

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

I, Kinneret Savitsky, certify that:

1. I have reviewed this annual report on Form 20-F of BioLineRx Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting;

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 12, 2013

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

Exhibit 12.2

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

I, Philip Serlin, certify that:

1. I have reviewed this annual report on Form 20-F of BioLineRx Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting;

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 12, 2013

/s/ Philip Serlin
Philip Serlin
Chief Financial and Operating Officer

Exhibit 13.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER UNDER SECTION 906 OF THE
SARBANES-OXLEY ACT

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of BioLineRx Ltd. (the "Company") hereby certifies, to such officer's knowledge that:

(i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2012 (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 12, 2013

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

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 13.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER UNDER SECTION 906 OF THE
SARBANES-OXLEY ACT

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of BioLineRx Ltd. (the "Company") hereby certifies, to such officer's knowledge that:

(i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2012 (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 12, 2013

/s/ Philip Serlin
Philip Serlin
Chief Financial and Operating Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 15.5

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-176419 and 333-183976) and on Form F-3 (Nos. 333-179792 and 333-1829976) of BIOLINERX LTD. (the "Company"), of our report dated March 12, 2013, relating to the financial statements, which appears in this Form 20-F.

Tel-Aviv, Israel
March 12, 2013

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

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