

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.

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

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

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

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

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

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

Risks Related to Our Financial Condition and Capital Requirements

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

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

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

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

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

Risks Related to Our Business and Regulatory Matters

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Industry

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property

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

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

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

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

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

Patent protection for our products is important and uncertain.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Ordinary Shares and ADSs

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Operations in Israel

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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