

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 Position and Capital Requirements

We have incurred operating losses since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future.

We are a clinical stage biopharmaceutical company that develops orally bioavailable small molecule therapeutic products for the treatment of autoimmune-inflammatory, oncological and ophthalmic diseases. Since our incorporation in 1994, we have been focused on research and development activities with a view to developing our product candidates, CF101, CF102 and CF602. We have financed our operations primarily through the sale of equity securities (both in private placements and in public offerings on the Tel Aviv Stock Exchange, or TASE and NYSE MKT) and payments received under out-licensing agreements and have incurred losses in each year since our inception in 1994. We have historically incurred substantial net losses, including net losses of approximately NIS 20 million (approximately \$5 million) in 2015, NIS 25 million in 2014 (approximately \$6 million), and NIS 31 million in 2013 (approximately \$8 million). At December 31, 2015, we had an accumulated deficit of approximately NIS 323 million (approximately \$83 million). We do not know whether or when we will become profitable. To date, we have not commercialized any products or generated any revenues from product sales and accordingly we do not have a revenue stream to support our cost structure. Our losses have resulted principally from costs incurred in development and discovery activities. We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we:

- initiate and manage pre-clinical development and clinical trials for our current and new product candidates;
- seek regulatory approvals for our product candidates;
- implement internal systems and infrastructures;
- seek to license additional technologies to develop;
- hire management and other personnel; and
- move towards commercialization.

If our product candidates fail in clinical trials or do not gain regulatory clearance or approval, or if our product candidates do not achieve market acceptance, we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows. Moreover, our prospects must be considered in light of the risks and uncertainties encountered by an early-stage company and in highly regulated and competitive markets, such as the biopharmaceutical market, where regulatory approval and market acceptance of our products are uncertain. There can be no assurance that our efforts will ultimately be successful or result in revenues or profits.

We will need to raise additional capital to meet our business requirements in the future, and such capital raising may be costly or difficult to obtain and will dilute current shareholders' ownership interests.

As of December 31, 2015, we had cash and cash equivalents of approximately NIS 66 million (approximately \$17 million). During the first quarter of 2015, we received approximately NIS 5.1 million (approximately \$1.3 million) from Cipher Pharmaceuticals, or Cipher, as upfront payment for entering into the distribution agreement with Cipher and in September and October 2015, we raised approximately NIS 48.3 million (approximately \$12.5 million) in registered direct offerings. We believe that our existing financial resources will be sufficient to meet our requirements for the next twelve months. We have expended and believe that we will continue to expend substantial resources for the foreseeable future developing our product candidates. These expenditures will include costs associated with research and development, manufacturing, conducting preclinical experiments and clinical trials and obtaining regulatory approvals, as well as commercializing any products approved for sale. In addition, we have agreed to provide certain financial support to our subsidiary, OphthaliX Inc., or OphthaliX, for the foreseeable future. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. In addition, other unanticipated costs may arise. As a result of these and other factors currently unknown to us, we will require additional funds, through public or private equity or debt financings or other sources, such as strategic partnerships and alliances and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements will depend on many factors, including the progress and results of our clinical trials, the duration and cost of discovery and preclinical development, and laboratory testing and clinical trials for our product candidates, the timing and outcome of regulatory review of our product candidates, the number and development requirements of other product candidates that we pursue, and the costs of activities, such as product marketing, sales, and distribution. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our anticipated clinical trials.

Our future capital requirements depend on many factors, including:

- the failure to obtain regulatory approval or achieve commercial success of our product candidates, including CF101, CF102 and CF602;
- the results of our preclinical studies and clinical trials for our earlier stage product candidates, and any decisions to initiate clinical trials if supported by the preclinical results;
- the costs, timing and outcome of regulatory review of our product candidates that progress to clinical trials;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our issued patents and defending intellectual property-related claims;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates and any products we successfully commercialize;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any;
- the expenses needed to attract and retain skilled personnel;

- any product liability or other lawsuits related to our products;
- 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.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

We may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing shareholders will be diluted, and the terms may include liquidation or other preferences that adversely affect shareholder rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

If we fail to obtain necessary funds for our operations, we will be unable to maintain and improve our patented or licensed technology, and we will be unable to develop and commercialize our products and technologies.

Our present and future capital requirements depend on many factors, including:

- the level of research and development investment required to develop our product candidates, and maintain and improve our patented or licensed technology position;
- the costs of obtaining or manufacturing product candidates for research and development and testing;
- the results of preclinical and clinical testing, which can be unpredictable in product candidate development;
- changes in product candidate development plans needed to address any difficulties that may arise in manufacturing, preclinical activities or clinical studies;
- our ability and willingness to enter into new agreements with strategic partners and the terms of these agreements;

- our success rate in preclinical and clinical efforts associated with milestones and royalties;
- the costs of investigating patents that might block us from developing potential product candidates;
- the costs of recruiting and retaining qualified personnel;
- the time and costs involved in obtaining regulatory approvals;
- the number of product candidates we pursue;
- our revenues, if any;
- the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- our need or decision to acquire or license complementary technologies or new platform or product candidate targets.

If we are unable to obtain the funds necessary for our operations, we will be unable to maintain and improve our patented technology, and we will be unable to develop and commercialize our products and technologies, which would materially and adversely affect our business, liquidity and results of operations.

Risks Related to our Business and Regulatory Matters

We have not yet commercialized any products or technologies, and we may never become profitable.

We have not yet commercialized any products or technologies, and we may never be able to do so. We do not know when or if we will complete any of our product development efforts, obtain regulatory approval for any product candidates incorporating our technologies or successfully commercialize any approved products. Even if we are successful in developing products that are approved for marketing, we will not be successful unless these products gain market acceptance for appropriate indications at favorable reimbursement rates. The degree of market acceptance of these products will depend on a number of factors, including:

- the timing of regulatory approvals in the countries, and for the uses, we seek;
- the competitive environment;
- the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products;
- our ability to enter into strategic agreements with pharmaceutical and biotechnology companies with strong marketing and sales capabilities;
- the adequacy and success of distribution, sales and marketing efforts; and
- the pricing and reimbursement policies of government and third-party payors, such as insurance companies, health maintenance organizations and other plan administrators.

Physicians, patients, third-party payors or the medical community in general may be unwilling to accept, utilize or recommend, and in the case of third-party payors, cover any of our products or products incorporating our technologies. As a result, we are unable to predict the extent of future losses or the time required to achieve profitability, if at all. Even if we successfully develop one or more products that incorporate our technologies, we may not become profitable.

Our product candidates are at various stages of clinical and preclinical development and may never be commercialized.

Our product candidates are at various stages of clinical development and may never be commercialized. The progress and results of any future pre-clinical testing or future clinical trials are uncertain, and the failure of our product candidates to receive regulatory approvals will have a material adverse effect on our business, operating results and financial condition to the extent we are unable to commercialize any products. None of our product candidates has received regulatory approval for commercial sale. In addition, we face the risks of failure inherent in developing therapeutic products. Our product candidates are not expected to be commercially available for several years, if at all.

In addition, our product candidates must satisfy rigorous standards of safety and efficacy before they can be approved by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or EMA, and foreign regulatory authorities for commercial use. The FDA, EMA and foreign regulatory authorities have full discretion over this approval process. We will need to conduct significant additional research, involving testing in animals and in humans, before we can file applications for product approval. Typically, in the pharmaceutical industry, there is a high rate of attrition for product candidates in pre-clinical testing and clinical trials. Also, satisfying regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. In addition, delays or rejections may be encountered based upon additional government regulation, including any changes in FDA policy, during the process of product development, clinical trials and regulatory reviews.

In order to receive FDA approval or approval from foreign regulatory authorities to market a product candidate or to distribute our products, we must demonstrate thorough pre-clinical testing and thorough human clinical trials that the product candidate is safe and effective for its intended uses (e.g., treatment of a specific condition in a specific way subject to contradictions and other limitations). Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our new drug applications, or NDA, or grant approval for a narrowly intended use that is not commercially feasible. We might not obtain regulatory approval for our drug candidates in a timely manner, if at all. Failure to obtain FDA approval of any of our drug candidates in a timely manner or at all will severely undermine our business by reducing the number of salable products and, therefore, corresponding product revenues.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. For example, in December 2013, Ophthalix, our subsidiary, announced top-line results of a Phase III study with CF101 for dry-eye syndrome in which CF101 did not meet the primary efficacy endpoint of complete clearing of corneal staining, nor the secondary efficacy endpoints. In addition, two Phase IIb studies in rheumatoid arthritis, or RA, utilizing CF101 in combination with methotrexate, a generic drug commonly used for treating RA patients, or MTX, failed to reach their primary endpoints. We believe that this may have been due to low A3AR expression in the subpopulation of RA patients that did not respond well to treatment with MTX. Because of their low A3AR expression, such patients also did not respond well to treatment with CF101. We were not aware of this when we designed the studies. As such, we conducted an additional Phase IIb RA trial of CF101 as a standalone therapy in patients with A3AR expression levels above a certain threshold, and positive results from this study were announced in December 2013. Furthermore, a Phase II/III study of CF101 for psoriasis did not meet its primary endpoint although positive data from further analysis of the Phase II/III study suggests CF101 as a potential systemic therapy for patients with moderate-severe psoriasis.

Many companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Any delay in, or termination or suspension of, our clinical trials will delay the requisite filings with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. If the clinical trials do not support our product claims, the completion of development of such product candidates may be significantly delayed or abandoned, which will significantly impair our ability to generate product revenues and will materially adversely affect our results of operations.

This drug candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed from preclinical through early to late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late stage clinical trials, approval and commercialization, such changes do carry the risk that they will not achieve these intended objectives.

Changes in our planned clinical trials or future clinical trials could cause our product candidates to perform differently, including causing toxicities, which could delay completion of our clinical trials, delay approval of our product candidates, and/or jeopardize our ability to commence product sales and generate revenues.

We might be unable to develop product candidates that will achieve commercial success in a timely and cost-effective manner, or ever.

Even if regulatory authorities approve our product candidates, they may not be commercially successful. Our product candidates may not be commercially successful because government agencies and other third-party payors may not cover the product or the coverage may be too limited to be commercially successful; physicians and others may not use or recommend our products, even following regulatory approval. A product approval, assuming one issues, may limit the uses for which the product may be distributed thereby adversely affecting the commercial viability of the product. Third parties may develop superior products or have proprietary rights that preclude us from marketing our products. We also expect that at least some of our product candidates will be expensive, if approved. Patient acceptance of and demand for any product candidates for which we obtain regulatory approval or license will depend largely on many factors, including but not limited to the extent, if any, of reimbursement of costs by government agencies and other third-party payors, pricing, the effectiveness of our marketing and distribution efforts, the safety and effectiveness of alternative products, and the prevalence and severity of side effects associated with our products. If physicians, government agencies and other third-party payors do not accept our products, we will not be able to generate significant revenue.

Our current pipeline is based on our platform technology utilizing the Gi protein associated A3 adenosine receptor, or A3AR, as a potent therapeutic target and currently includes three molecules, the CF101, CF102 and CF602 product candidates, of which CF 101 is the most advanced. Failure to develop these molecules will have a material adverse effect on us.

Our current pipeline is based on a platform technology where we target the A3AR with highly selective ligands, or small signal triggering molecules that bind to specific cell surface receptors, such as the A3AR, including CF101, CF102 and CF602, currently developed for the treatment of autoimmune-inflammatory, oncological and ophthalmic disorders. A3ARs are structures found in cell surfaces that record and transfer messages from small molecules or ligands, such as CF101, CF102 and CF602 to the rest of the cell. CF101 is the most advanced of our drug candidates. As such, we are currently dependent on only three molecules for our potential commercial success, and any safety or efficacy concerns related to such molecules would have a significant impact on our business. Failure to develop our drug candidates, in whole or in part, will have a material adverse effect on us.

Clinical trials are very expensive, time-consuming and difficult to design and implement, and, as a result, we may suffer delays or suspensions in future trials which would have a material adverse effect on our ability to generate revenues.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Regulatory authorities, such as the FDA, may preclude clinical trials from proceeding. Additionally, the clinical trial process is time-consuming, failure can occur at any stage of the trials, and we may encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;

- lack of effectiveness or efficacy during clinical trials;
- failure of third party suppliers to perform final manufacturing steps for the drug substance;
- slower than expected rates of patient recruitment and enrollment;
- lack of healthy volunteers and patients to conduct trials;
- inability to monitor patients adequately during or after treatment;
- failure of third party contract research organizations to properly implement or monitor the clinical trial protocols;
- failure of institutional review boards to approve our clinical trial protocols;
- inability or unwillingness of medical investigators and institutional review boards to follow our clinical trial protocols; and
- lack of sufficient funding to finance the clinical trials.

We have experienced the risks involved with conducting clinical trials, including but not limited to, increased expense and delay and failure to meet end points of the trial. For example, in December 2013, Ophthalix, our subsidiary, announced top-line results of a Phase III study with CF 101 for dry-eye syndrome in which CF101 did not meet the primary efficacy endpoint of complete clearing of corneal staining, nor the secondary efficacy endpoints. In addition, two Phase IIb studies in RA, utilizing CF101 in combination with methotrexate, a generic drug commonly used for treating RA patients, or MTX, failed to reach their primary end points. We believe that this may have been due to low A3AR expression in the subpopulation of RA patients that did not respond well to treatment with MTX. Because of their low A3AR expression, such patients also did not respond well to treatment with CF101. We were not aware of this when it designed the studies. As such, we conducted an additional Phase IIb RA trial of CF101 as a standalone therapy in patients with A3AR expression levels above a certain threshold, and positive results from this study were announced in December 2013. Furthermore, a Phase II/III study of CF101 for psoriasis did not meet its primary endpoint although positive data from further analysis of the Phase II/III study suggests CF101 as a potential systemic therapy for patients with moderate-severe psoriasis.

In addition, we or regulatory authorities may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the regulatory authorities find deficiencies in our regulatory submissions or the conduct of these trials. Any suspension of clinical trials will delay possible regulatory approval, if any, and adversely impact our ability to develop products and generate revenue.

If we acquire or license additional technology or product candidates, we may incur a number of costs, may have integration difficulties and may experience other risks that could harm our business and results of operations.

We may acquire and license additional product candidates and technologies. Any product candidate or technology we license from others or acquire will likely require additional development efforts prior to commercial sale, including extensive pre-clinical or clinical testing, or both, and approval by the FDA and applicable foreign regulatory authorities, if any. All product candidates are prone to risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate or product developed based on licensed technology will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any product candidate that we develop based on acquired or licensed technology that is granted regulatory approval will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace. Moreover, integrating any newly acquired product candidates could be expensive and time-consuming. If we cannot effectively manage these aspects of our business strategy, our business may not succeed.

The manufacture of our product candidates is a chemical synthesis process and if one of our materials suppliers encounters problems manufacturing our products, our business could suffer.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with requirements that the FDA or foreign regulators establish. We do not intend to engage in the manufacture of our products other than for pre-clinical and clinical studies, but we or our materials suppliers may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA's or foreign regulators' requirements necessary to continue manufacturing our drug substance. Drug manufacturers are subject to ongoing periodic unannounced inspections by the FDA, the U.S. Drug Enforcement Agency, or DEA, and corresponding foreign regulators to ensure strict compliance with requirements and other governmental regulations and corresponding foreign standards. Any failure to comply with DEA requirements or FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our product candidates.

We do not currently have sales, marketing or distribution capabilities or experience, and we are unable to effectively sell, market or distribute our product candidates now and we do not expect to be able to do so in the future. The failure to enter into agreements with third parties that are capable of performing these functions would have a material adverse effect on our business and results of operations.

We do not currently have and we do not expect to develop sales, marketing and distribution capabilities. If we are unable to enter into agreements with third parties to perform these functions, we will not be able to successfully market any of our platforms or product candidates. In order to successfully market any of our platform or product candidates, we must make arrangements with third parties to perform these services.

As we do not intend to develop a marketing and sales force with technical expertise and supporting distribution capabilities, we will be unable to market any of our product candidates directly. To promote any of our potential products through third parties, we will have to locate acceptable third parties for these functions and enter into agreements with them on acceptable terms, and we may not be able to do so. Any third-party arrangements we are able to enter into may result in lower revenues than we could achieve by directly marketing and selling our potential products. In addition, to the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, as well as the terms of our agreements with such third parties, which cannot be predicted in most cases at this time. As a result, we might not be able to market and sell our products in the United States or overseas, which would have a material adverse effect on us.

We will to some extent rely on third parties to implement our manufacturing and supply strategies. Failure of these third parties in any respect could have a material adverse effect on our business, results of operations and financial condition.

If our current and future manufacturing and supply strategies are unsuccessful, then we may be unable to conduct and complete any future pre-clinical or clinical trials or commercialize our product candidates in a timely manner, if at all. Completion of any potential future pre-clinical or clinical trials and commercialization of our product candidates will require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. We do not have the resources, facilities or experience to manufacture our product candidates for commercial purposes on our own and do not intend to develop or acquire facilities for the manufacture of product candidates for commercial purposes in the foreseeable future. We may rely on contract manufacturers to produce sufficient quantities of our product candidates necessary for any pre-clinical or clinical testing we undertake in the future. Such contract manufacturers may be the sole source of production and they may have limited experience at manufacturing, formulating, analyzing, filling and finishing our types of product candidates.

We also intend to rely on third parties to supply the requisite materials needed for the manufacturing of our active pharmaceutical ingredients, or API. There may be a limited supply of these requisite materials. We might not be able to enter into agreements that provide us assurance of availability of such components in the future from any supplier. Our potential suppliers may not be able to adequately supply us with the components necessary to successfully conduct our pre-clinical and clinical trials or to commercialize our product candidates. If we cannot acquire an acceptable supply of the requisite materials to produce our product candidates, we will not be able to complete pre-clinical and clinical trials and will not be able to market or commercialize our product candidates.

We depend on key members of our management and key consultants and will need to add and retain additional leading experts. Failure to retain our management and consulting team and add additional leading experts could have a material adverse effect on our business, results of operations or financial condition.

We are highly dependent on our executive officers and other key management and technical personnel. Our failure to retain our Chief Executive Officer, Pnina Fishman, Ph.D., who has developed much of the technology we utilize today, or any other key management and technical personnel, could have a material adverse effect on our future operations. Our success is also dependent on our ability to attract, retain and motivate highly trained technical, and management personnel, among others, to continue the development and commercialization of our current and future products. We presently maintain a life insurance policy on our Chief Executive Officer, Pnina Fishman.

Our success also depends on our ability to attract, retain and motivate personnel required for the development, maintenance and expansion of our activities. There can be no assurance that we will be able to retain our existing personnel or attract additional qualified employees or consultants. The loss of key personnel or the inability to hire and retain additional qualified personnel in the future could have a material adverse effect on our business, financial condition and results of operation.

We face significant competition and continuous technological change, and developments by competitors may render our products or technologies obsolete or non-competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever be profitable.

We will compete against fully integrated pharmaceutical and biotechnology companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs than we do, and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking pre-clinical testing and human clinical trials;
- obtaining FDA, addressing various regulatory matters and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

If our competitors develop and commercialize products faster than we do, or develop and commercialize products that are superior to our product candidates, our commercial opportunities will be reduced or eliminated. The extent to which any of our product candidates achieve market acceptance will depend on competitive factors, many of which are beyond our control. Competition in the biotechnology and biopharmaceutical industry is intense and has been accentuated by the rapid pace of technology development. Our competitors include large integrated pharmaceutical companies, biotechnology companies that currently have drug and target discovery efforts, universities, and public and private research institutions. Almost all of these entities have substantially greater research and development capabilities and financial, scientific, manufacturing, marketing and sales resources than we do. These organizations also compete with us to:

- attract parties for acquisitions, joint ventures or other collaborations;
- license proprietary technology that is competitive with the technology we are developing;

- attract funding; and
- attract and hire scientific talent and other qualified personnel.

Our competitors may succeed in developing and commercializing products earlier and obtaining regulatory approvals from the FDA more rapidly than we do. Our competitors may also develop products or technologies that are superior to those we are developing, and render our product candidates or technologies obsolete or non-competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever be profitable.

Our competitors currently include companies with marketed products and/or an advanced research and development pipeline. The major competitors in the arthritis and psoriasis therapeutic field include Amgen, Centocor, Pfizer, Novartis, Abbvie, Celgene, Eli Lilly, Janssen and more. The competitive landscape in the ophthalmic therapeutics field includes Alcon, a Novartis company, Allergan, Pfizer, Akorn, Merck and more. Competitors in the hepatocellular carcinoma, also known as primary liver cancer, or HCC field include companies such as Bayer. Competitors in the NASH field include companies such as Gilead, Genfit, Regado, Galmed, Raptor and Intercept. Competitors in the erectile dysfunction field include Pfizer, Eli Lilly and Bayer. See “Item 4. Information on the Company–B. Business Overview–Competition.”

Moreover, several companies have reported the commencement of research projects related to the A3AR. Such companies include CV Therapeutics Inc. (which was acquired by Gilead), King Pharmaceuticals R&D Inv. (which was acquired by Pfizer), Hoechst Marion Roussel Inc., Novo Nordisk A/S and Inotek Pharmaceuticals. However, to the best of our knowledge, there is no approved drug currently on the market which is similar to our A3AR agonists, nor are we aware of any allosteric modulator in the A3AR product pipeline similar to our allosteric modulator with respect to chemical profile and mechanism of action.

We are subject to a purported class action lawsuit. This litigation could result in substantial damages and may divert management’s time and attention from our business.

On June 29, 2015, we received a lawsuit, filed with the District Court of Tel-Aviv, requesting recognition of this lawsuit as a class action. The lawsuit named the Company, its Chief Executive Officer and directors as defendants. The lawsuit alleges, among other things, that we misled the public with regard to disclosures concerning the efficacy of our drug candidate, CF101. The claimant alleges that he suffered personal damages of over NIS 73,000, while also claiming that our shareholders suffered damages of approximately NIS 125 million. On November 27, 2015 and December 1, 2015, we filed a motion to dismiss the action in part and on March 31, 2016, we filed a response to the lawsuit. While we strongly believe the lawsuit and its allegations to be baseless and without merit and will vigorously defend this action, due to the inherent uncertainties that accompany litigation of this nature, there can be no assurance that we will be successful, and an adverse resolution of the lawsuit may result in damages beyond the Company’s insurance coverage for such cases, which could cause a risk of loss and expenditures that may adversely affect its financial condition and results of operations. Furthermore, this action may divert management’s time and attention from our business, and we could be forced to expend significant resources and pay significant costs and expenses, including legal fees, in connection with defending this lawsuit.

We may suffer losses from product liability claims if our product candidates cause harm to patients.

Any of our product candidates could cause adverse events. Although data from a pooled analysis of approximately 1,000 patients treated with CF101, indicates that CF101 is safe and well tolerated at doses up to 4.0 mg administered twice daily for up to 32 weeks, there were incidences (albeit less than or equal to 5%) of adverse events in eight completed and fully analyzed trials in inflammatory disease. Such adverse events included nausea, diarrhea, constipation, common bacterial and viral syndromes (such as tonsillitis, otitis and respiratory and urinary tract infections), myalgia, arthralgia, dizziness, headache, palpitations and pruritus. We observed an even lower incidence (less than or equal to 2%) of serious adverse events, including pancytopenia (although extensive evaluation suggests that such adverse event was associated with an inadvertent overdose of MTX), exacerbation of chronic obstructive lung disease and exacerbation of Parkinson’s Disease. Notwithstanding the foregoing, the placebo group in such studies had a higher incidence of overall adverse events than the pooled CF101 groups. No new safety concerns have been identified and no novel or unexpected safety concerns have appeared over 32 weeks of treatment in more recent trials.

There is also a risk that certain adverse events may not be observed in clinical trials, but may nonetheless occur in the future. If any of these adverse events occur, they may render our product candidates ineffective or harmful in some patients, and our sales would suffer, materially adversely affecting our business, financial condition and results of operations.

In addition, potential adverse events caused by our product candidates could lead to product liability lawsuits. If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit the marketing and commercialization of our product candidates. Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We may not be able to avoid product liability claims. Product liability insurance for the pharmaceutical and biotechnology industries is generally expensive, if available at all. If, at any time, we are unable to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims, we may be unable to clinically test, market or commercialize our product candidates. A successful product liability claim brought against us in excess of our insurance coverage, if any, may cause us to incur substantial liabilities, and, as a result, our business, liquidity and results of operations would be materially adversely affected.

Our product candidates will remain subject to ongoing regulatory requirements even if they receive marketing approval, and if we fail to comply with these requirements, we could lose these approvals, and the sales of any approved commercial products could be suspended.

Even if we receive regulatory approval to market a particular product candidate, the product will remain subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and recordkeeping. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the uses for which the product may be marketed or the conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, which could negatively impact us or our collaboration partners by reducing revenues or increasing expenses, and cause the approved product candidate not to be commercially viable. In addition, as clinical experience with a drug expands after approval, typically because it is used by a greater number and more diverse group of patients after approval than during clinical trials, side effects and other problems may be observed after approval that were not seen or anticipated during pre-approval clinical trials or other studies. Any adverse effects observed after the approval and marketing of a product candidate could result in limitations on the use of or withdrawal of any approved products from the marketplace. Absence of long-term safety data may also limit the approved uses of our products, if any. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks, including the following:

- Restrictions on the products, manufacturers or manufacturing process;
- Warning letters;
- Civil or criminal penalties, fines and injunctions;
- Product seizures or detentions;
- Import or export bans or restrictions;
- Voluntary or mandatory product recalls and related publicity requirements;
- Suspension or withdrawal of regulatory approvals;
- Total or partial suspension of production, and
- Refusal to approve pending applications for marketing approval of new products or supplements to approved applications.

If we or our collaborators are slow or unable to adapt to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, marketing approval for our product candidates may be lost or cease to be achievable, resulting in decreased revenue from milestones, product sales or royalties, which would have a material adverse effect on our results of operations.

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 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.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our research and development programs and the development of our product candidates could be delayed.

We may not be able to successfully grow and expand our business. Failure to manage our growth effectively will have a material adverse effect on our business, results of operations and financial condition.

We may not be able to successfully grow and expand. Successful implementation of our business plan will require management of growth, including potentially rapid and substantial growth, which will result in an increase in the level of responsibility for management personnel and place a strain on our human and capital resources. To manage growth effectively, we will be required to continue to implement and improve our operating and financial systems and controls to expand, train and manage our employee base. Our ability to manage our operations and growth effectively requires us to continue to expend funds to enhance our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented personnel. If we are unable to scale up and implement improvements to our control systems in an efficient or timely manner, or if we encounter deficiencies in existing systems and controls, then we will not be able to make available the products required to successfully commercialize our technology. Failure to attract and retain sufficient numbers of talented personnel will further strain our human resources and could impede our growth or result in ineffective growth. Moreover, the management, systems and controls currently in place or to be implemented may not be adequate for such growth, and the steps taken to hire personnel and to improve such systems and controls might not be sufficient. If we are unable to manage our growth effectively, it will have a material adverse effect on our business, results of operations and financial condition.

If we are unable to obtain adequate insurance, our financial condition could be adversely affected in the event of uninsured or inadequately insured loss or damage. Our ability to effectively recruit and retain qualified officers and directors could also be adversely affected if we experience difficulty in obtaining adequate directors' and officers' liability insurance.

We may not be able to obtain insurance policies on terms affordable to us that would adequately insure our business and property against damage, loss or claims by third parties. To the extent our business or property suffers any damages, losses or claims by third parties, which are not covered or adequately covered by insurance, our financial condition may be materially adversely affected.

We may be unable to maintain sufficient insurance as a public company to cover liability claims made against our officers and directors. If we are unable to adequately insure our officers and directors, we may not be able to retain or recruit qualified officers and directors to manage us.

Risks Related to Our Intellectual Property

The termination of the National Institute of Health, or NIH, license agreement between us and NIH due to patent expiration may diminish our proprietary position.

As a result of the termination of the NIH license agreement between us and the NIH in June 2015 due to patent expiration, we no longer hold rights to a family of composition of matter patents relating to CF101 that were licensed from NIH. Nevertheless, because CF101 may be a new chemical entity, or NCE, following approval of an NDA, we, if we are the first applicant to obtain NDA approval, may be entitled to five years of data exclusivity in the United States with respect to such NCEs. Analogous data and market exclusivity provisions, of varying duration, may be available in Europe and other foreign jurisdictions. We also have rights under our pharmaceutical use issued patents with respect to CF101 and CF102, which provide patent exclusivity within our field of activity until the mid- to late-2020s. While we believe that we may be able to protect our exclusivity through such use patent portfolio and such period of exclusivity, the lack of composition of matter patent protection may diminish our ability to maintain a proprietary position for our intended uses of CF101. Moreover, we cannot be certain that we will be the first applicant to obtain an FDA approval for any indication of CF101 and we cannot be certain that we will be entitled to NCE exclusivity. In addition, we have discontinued the prosecution of a family of pending patent applications under joint ownership of us and NIH pertaining to the use of A3AR agonists for the treatment of uveitis. Such diminution of our proprietary position could have a material adverse effect on our business, results of operation and financial condition.

We license from Leiden University intellectual property which protects certain small molecules which target the A3AR, in furtherance of our platform technology, and we could lose our rights to this license if a dispute with Leiden University arises or if we fail to comply with the financial and other terms of the license.

We have licensed intellectual property from Leiden University pursuant to a license agreement. The license agreement imposes certain payment, reporting, confidentiality and other obligations on us. In the event that we were to breach any of the obligations and fail to cure, Leiden University would have the right to terminate the license agreement. In addition, Leiden University has the right to terminate the license agreement upon our bankruptcy, insolvency, or receivership. If any dispute arises with respect to our arrangements with Leiden University, such dispute may disrupt our operations and may have a material adverse impact on us if resolved in a manner that is unfavorable to us.

The failure to obtain or maintain patents, licensing agreements, including our current licensing agreements, and other intellectual property could impact our ability to compete effectively.

To compete effectively, we need to develop and maintain a proprietary position with regard to our own technologies, intellectual property, licensing agreements, product candidates and business. Legal standards relating to the validity and scope of claims in the biotechnology and biopharmaceutical fields are still evolving. Therefore, the degree of future protection for our proprietary rights in our core technologies and any products that might be made using these technologies is also uncertain. The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- while the patents we license have been issued, the pending patent applications we have filed may not result in issued patents or may take longer than we expect to result in issued patents;
- we may be subject to interference proceedings;

- we may be subject to opposition proceedings in foreign countries;
- any patents that are issued may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- other companies may challenge patents licensed or issued to us or our customers;
- other companies may independently develop similar or alternative technologies, or duplicate our technologies;
- other companies may design around technologies we have licensed or developed; and
- enforcement of patents is complex, uncertain and expensive.

If patent rights covering our products and methods are not sufficiently broad, they may not provide us with any protection against competitors with similar products and technologies. Furthermore, if the United States Patent and Trademark Office, or the USPTO, or foreign patent offices issue patents to us or our licensors, others may challenge the patents or design around the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against our competitors.

We cannot be certain that patents will be issued as a result of any pending applications, and we cannot be certain that any of our issued patents will give us adequate protection from competing products. For example, issued patents, including the patents licensed by us, may be circumvented or challenged, declared invalid or unenforceable, or narrowed in scope. In addition, since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make our inventions or to file patent applications covering those inventions.

It is also possible that others may obtain issued patents that could prevent us from commercializing our products or require us to obtain licenses requiring the payment of significant fees or royalties in order to enable us to conduct our business. As to those patents that we have licensed, our rights depend on maintaining our obligations to the licensor under the applicable license agreement, and we may be unable to do so.

In addition to patents and patent applications, we depend upon trade secrets and proprietary know-how to protect our proprietary technology. We require our employees, consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the disclosure of confidential information to any other parties. We require our employees and consultants to disclose and assign to us their ideas, developments, discoveries and inventions. These agreements may not, however, provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure.

Costly litigation may be necessary to protect our intellectual property rights and we may be subject to claims alleging the violation of the intellectual property rights of others.

We may face significant expense and liability as a result of litigation or other proceedings relating to patents and other intellectual property rights of others. In the event that another party has also filed a patent application or been issued a patent relating to an invention or technology claimed by us in pending applications, we may be required to participate in an interference proceeding declared by the USPTO to determine priority of invention, which could result in substantial uncertainties and costs for us, even if the eventual outcome were favorable to us. We, or our licensors, also could be required to participate in interference proceedings involving issued patents and pending applications of another entity. An adverse outcome in an interference proceeding could require us to cease using the technology or to license rights from prevailing third parties.

The cost to us of any patent litigation or other proceeding relating to our licensed patents or patent applications, even if resolved in our favor, could be substantial. Our ability to enforce our patent protection could be limited by our financial resources, and may be subject to lengthy delays. If we are unable to effectively enforce our proprietary rights, or if we are found to infringe the rights of others, we may be in breach of our License Agreement.

A third party may claim that we are using inventions claimed by their patents and may go to court to stop us from engaging in our normal operations and activities, such as research, development and the sale of any future products. Such lawsuits are expensive and would consume time and other resources. There is a risk that the court will decide that we are infringing the third party's patents and will order us to stop the activities claimed by the patents, redesign our products or processes to avoid infringement or obtain licenses (which may not be available on commercially reasonable terms). In addition, there is a risk that a court will order us to pay the other party damages for having infringed their patents.

Moreover, there is no guarantee that any prevailing patent owner would offer us a license so that we could continue to engage in activities claimed by the patent, or that such a license, if made available to us, could be acquired on commercially acceptable terms. In addition, third parties may, in the future, assert other intellectual property infringement claims against us with respect to our product candidates, technologies or other matters.

We rely on confidentiality agreements that could be breached and may be difficult to enforce, which could result in third parties using our intellectual property to compete against us.

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to obtain these types of agreements from our contractors, consultants, advisors and research collaborators, to the extent that employees and consultants utilize or independently develop intellectual property in connection with any of our projects, disputes may arise as to the intellectual property rights associated with our products. If a dispute arises, a court may determine that the right belongs to a third party. In addition, enforcement of our rights can be costly and unpredictable. We also rely on trade secrets and proprietary know-how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

- these agreements may be breached;
- these agreements may not provide adequate remedies for the applicable type of breach;
- our trade secrets or proprietary know-how will otherwise become known; or
- our competitors will independently develop similar technology or proprietary information.

International patent protection is particularly uncertain, and if we are involved in opposition proceedings in foreign countries, we may have to expend substantial sums and management resources.

Patent law outside the United States is different than in the United States. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, if at all. A failure to obtain sufficient intellectual property protection in any foreign country could materially and adversely affect our business, results of operations and future prospects. Moreover, we may participate in opposition proceedings to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and divert management's resources and attention.

Although most jurisdictions in which we have applied for, intend to apply for, or have been issued patents have patent protection laws similar to those of the United States, some of them do not. For example, we expect to do business in Brazil and India in the future. However, the Brazilian drug regulatory agency, ENVISA, has the authority to nullify patents on the basis of its perceived public interest and the Indian patent law does not allow patent protection for new uses of pharmaceuticals (many of our current patent applications are of such nature). Additionally, due to uncertainty in patent protection law, we have not filed applications in many countries where significant markets exist, including Indonesia, Pakistan, Russia, African countries and Taiwan.

We may be unable to protect the intellectual property rights of the third parties from whom we license certain of our intellectual property or with whom we have entered into other strategic relationships.

Certain of our intellectual property rights are currently licensed from Leiden University, and, in the future, we intend to continue to license intellectual property from Leiden University and/or other universities and/or strategic partners. Such third parties may determine not to protect the intellectual property rights that we license from them and we may be unable defend such intellectual property rights on our own or we may have to undertake costly litigation to defend the intellectual property rights of such third parties. There can be no assurances that we will continue to have proprietary rights to any of the intellectual property that we license from such third parties or otherwise have the right to use through similar strategic relationships. Any loss or limitations on use with respect to our right to use such intellectual property licensed from third parties or otherwise obtained from third parties with whom we have entered into strategic relationships could have a material adverse effect on our business, results of operations and financial condition.

Under current U.S. and Israeli law, we may not be able to enforce employees' covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

We have entered into non-competition agreements with our key employees, in most cases within the framework of their employment agreements. These agreements prohibit our key employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. Under applicable U.S. and Israeli law, we may be unable to enforce these agreements. If we cannot enforce our non-competition agreements with our employees, then we may be unable to prevent our competitors from benefiting from the expertise of our former employees, which could materially adversely affect our business, results of operations and ability to capitalize on our proprietary information.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- We or our licensors or any future strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- We or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- It is possible that our pending patent applications will not lead to issued patents;
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop additional proprietary technologies that are patentable; and
- The patents of others may have an adverse effect on our business.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks Related to Our Industry

We are subject to government regulations and we may experience delays in obtaining required regulatory approvals in the United States to market our proposed product candidates.

Various aspects of our operations are subject to federal, state or local laws, rules and regulations, any of which may change from time to time. Costs arising out of any regulatory developments could be time-consuming and expensive and could divert management resources and attention and, consequently, could adversely affect our business operations and financial performance.

Delays in regulatory approval, limitations in regulatory approval and withdrawals of regulatory approval may have a material adverse effect on us. If we experience significant delays in testing or receiving approvals or sign-offs to conduct clinical trials, our product development costs, or our ability to license product candidates, will increase. If the FDA grants regulatory approval to market a product, this approval will be limited to those disease states and conditions for which the product has demonstrated, through clinical trials, to be safe and effective. Any product approvals that we receive in the future could also include significant restrictions on the use or marketing of our products. Product approvals, if granted, can be withdrawn for failure to comply with regulatory requirements or upon the occurrence of adverse events following commercial introduction of the products. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other regulatory action against our product candidates or us. If approval is withdrawn for a product, or if a product were seized or recalled, we would be unable to sell or license that product and our revenues would suffer. In addition, outside the United States, our ability to market any of our potential products is contingent upon receiving market application authorizations from the appropriate regulatory authorities and these foreign regulatory approval processes include all of the risks associated with the FDA approval process described above.

We expect the healthcare industry to face increased limitations on reimbursement as a result of healthcare reform, which could adversely affect third-party coverage of our products and how much or under what circumstances healthcare providers will prescribe or administer our products.

In both the United States and other countries, sales of our products will depend in part upon the availability of reimbursement from third-party payors, which include governmental authorities, managed care organizations and other private health insurers. Third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services.

Increasing expenditures for healthcare have been the subject of considerable public attention in the United States. Both private and government entities are seeking ways to reduce or contain healthcare costs. Numerous proposals that would effect changes in the U.S. healthcare system have been introduced or proposed in Congress and in some state legislatures, including reducing reimbursement for prescription products and reducing the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products.

In 2010, the United States Congress enacted the Patient Protection and Affordable Care Act of 2010 or, Affordable Care Act. The Affordable Care Act seeks to reduce the federal deficit and the rate of growth in health care spending through, among other things, stronger prevention and wellness measures, increased access to primary care, changes in health care delivery systems and the creation of health insurance exchanges. Enrollment in the health insurance exchanges began in October 2013. The Affordable Care Act requires the pharmaceutical industry to share in the costs of reform, by, among other things, increasing Medicaid rebates and expanding Medicaid rebates to cover Medicaid managed care programs. Other components of healthcare reform include funding of pharmaceutical costs for Medicare patients in excess of the prescription drug coverage limit and below the catastrophic coverage threshold. Under the Affordable Care Act, pharmaceutical companies are now obligated to fund 50% of the patient obligation for branded prescription pharmaceuticals in this gap, or "donut hole." Additionally, commencing in 2011, an excise tax was levied against certain branded pharmaceutical products. The tax is specified by statute to be approximately \$3 billion in 2012 through 2016, \$3.5 billion in 2017, \$4.2 billion in 2018, and \$2.8 billion each year thereafter. The tax is to be apportioned to qualifying pharmaceutical companies based on an allocation of their governmental programs as a portion of total pharmaceutical government programs.

Although we cannot predict the full effect on our business of the implementation of existing legislation, including the Affordable Care Act or the enactment of additional legislation, we believe that legislation or regulations that reduce reimbursement for or restrict coverage of our products could adversely affect how much or under what circumstances healthcare providers will prescribe or administer our products. This could materially and adversely affect our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our products. In addition, we believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

We are subject to federal anti-kickback laws and regulations. Our failure to comply with these laws and regulations could have adverse consequences to us.

There are extensive U.S. federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These federal laws include: the anti-kickback statute, which prohibits certain business practices and relationships, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other federal healthcare programs; the physician self-referral prohibition, commonly referred to as the Stark Law; the anti-inducement law, which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program; the False Claims Act, which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment by the federal government, including the Medicare and Medicaid programs; and the Civil Monetary Penalties Law, which authorizes the U.S. Department of Health and Human Services to impose civil penalties administratively for fraudulent or abusive acts.

Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, money penalties, imprisonment, denial of Medicare and Medicaid payments, or exclusion from the Medicare and Medicaid programs, or both, and debarment. As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to root out waste and to control fraud and abuse in governmental healthcare programs. Private enforcement of healthcare fraud has also increased, due in large part to amendments to the civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. A violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on our liquidity and financial condition. An investigation into the use by physicians of any of our products once commercialized may dissuade physicians from either purchasing or using them, and could have a material adverse effect on our ability to commercialize those products.

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 the 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 we may be a PFIC during 2015 and although we have not determined whether we will be a PFIC in 2016, or in any subsequent year, our operating results for any such years may cause us to be a PFIC. If we are a PFIC in 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 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. 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 that we control is a PFIC.

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

The stock market in general and the market price of our ordinary shares on the TASE and our ADSs on the NYSE MKT is subject to fluctuation, and changes in our share price may be unrelated to our operating performance. 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 strategic partnerships, out-licensing, in-licensing, joint ventures, acquisitions 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;
- success in clinical and preclinical studies;
- 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;
- 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 the ADSs and result in substantial losses by our investors.

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

Sales by us or our security-holders of substantial amounts of our ordinary shares or the 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 the ADSs. The issuance of any additional ordinary shares or ADSs, or any securities that are exercisable for or convertible into our ordinary shares or the ADSs, may have an adverse effect on the market price of our ordinary shares or the ADSs, as applicable, and will have a dilutive effect on our shareholders.

ADS holders are not shareholders and do not have shareholder rights.

The Bank of New York Mellon, as Depositary, delivers the ADSs. Each ADS represents two of our ordinary shares. ADS holders will not be treated as shareholders and do not have the rights of shareholders. The depositary will be the holder of the shares underlying the ADSs. Holders of ADSs will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and the beneficial owners of ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. Our shareholders have shareholder rights. Israeli law and our Articles of Association govern shareholder rights. ADS holders do not have the same voting rights as our shareholders. Shareholders are entitled to our notices of general meetings and to attend and vote at our general meetings of shareholders. At a general meeting, every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote. This is subject to any other rights or restrictions which may be attached to any shares. ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. *Otherwise you won't be able to exercise your right to vote unless you withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares.* The depositary will notify ADS holders of shareholders' meetings and arrange to deliver our voting materials to them if we ask it to. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of Israel and our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. The depositary will only vote or attempt to vote as instructed. We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the matter of carrying out voting instructions. *This means that you may not be able to exercise your right to vote and there may be nothing you can do if your shares are not voted as requested.*

ADS holders do not have the same rights to receive dividends or other distributions as our shareholders. Subject to any special rights or restrictions attached to a share, the directors may determine that a dividend will be payable on a share and fix the amount, the time for payment and the method for payment (although we have never declared or paid any cash dividends on our ordinary shares and we do not anticipate paying any cash dividends in the foreseeable future). Dividends and other distributions payable to our shareholders with respect to our ordinary shares generally will be payable directly to them. Any dividends or distributions payable with respect to ordinary shares deposited in the ADS facility will be paid to the depository, which has agreed to pay to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. ADS holders will receive these distributions in proportion to the number of ordinary shares their ADSs represent. In addition, there may be certain circumstances in which the depository may not pay ADS holders amounts distributed by us as a dividend or distribution.

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

Our ordinary shares have traded on the TASE since October 2005 and the ADSs have been listed on the NYSE MKT since November 2013. Trading on these markets will take place in different currencies (U.S. dollars on the NYSE MKT and NIS on the TASE), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Israel). The trading prices of our securities on these two markets may differ due to these and other factors. Any decrease in the price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

The ADSs have a limited prior trading history in the United States, and an active market may not develop, which may limit the ability of our investors to sell the ADSs in the United States.

There is a limited public market for the ADSs in the United States. The ADSs are thinly traded and an active trading market for the ADSs may never develop or may not be sustained if one develops. If an active market for the ADSs does not develop or is not sustained, it may be difficult to sell your ADSs.

We have incurred significant additional increased costs as a result of the listing of ADSs for trading on the NYSE MKT, and our management is required to devote substantial time to new compliance initiatives as well as to compliance with ongoing U.S. and Israeli reporting requirements.

As a public company in the United States, we incur additional significant accounting, legal and other expenses that we did not incur before becoming a reporting company in the United States. We also incur costs associated with corporate governance requirements of the SEC and the NYSE MKT Company Guide, as well as requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act as a result of ADSs being listed on the NYSE MKT. These rules and regulations have increased our legal and financial compliance costs, introduced new costs such as investor relations, stock exchange listing fees and shareholder reporting, and made some activities more time consuming and costly. The implementation and testing of such processes and systems may require us to hire outside consultants and incur other significant costs. Any future changes in the laws and regulations affecting public companies in the United States and Israel, including Section 404 and other provisions of the Sarbanes-Oxley Act, the rules and regulations adopted by the SEC and the NYSE MKT Company Guide, as well as applicable Israeli reporting requirements, for so long as they apply to us, may result in increased costs to us as we respond to such changes. These laws, rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our board committees or as executive officers.

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

As a foreign private issuer, we will be permitted to follow certain home country corporate governance practices instead of those otherwise required under the NYSE MKT Company Guide for domestic issuers. For instance, we may follow home country practice in Israel with regard to, among other things, composition and function of the audit committee and other committees of our Board of Directors and certain general corporate governance matters. In addition, in certain instances we will follow our home country law, instead of the NYSE MKT Company Guide, which requires that we obtain shareholder approval for certain dilutive events, such as 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. We comply with the director independence requirements of the NYSE MKT Company Guide, including the requirement that a majority of the Board of Directors be independent, and make the required affirmative determination thereunder upon filing the listing application with the NYSE MKT. Following our home country governance practices as opposed to the requirements that would otherwise apply to a United States company listed on the NYSE MKT may provide less protection than is accorded to investors under the NYSE MKT Company Guide applicable to domestic issuers.

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

Because we became a reporting company under the Exchange Act by means of filing a Form 20-F, we may have difficulty attract the attention of research analysts at major brokerage firms.

Because we did not become a reporting company by conducting an underwritten initial public offering in the U.S., we may have difficulty attracting the attention of security analysts at major brokerage firms in order for them to provide coverage of our company. The failure to receive research coverage or support in the market for our shares will have an adverse effect on our ability to develop a liquid market for the ADSs.

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 control over financial reporting is not effective, the reliability of our financial statements may be questioned and our share price and the ADS price may suffer.

We have become subject to the requirements of the Sarbanes-Oxley Act since the ADSs are listed on the NYSE MKT. Section 404 of the Sarbanes-Oxley Act requires companies subject to the reporting requirements of the U.S. securities laws to do a comprehensive evaluation of its and its subsidiaries' internal control over financial reporting. To comply with this statute, we must document and test our internal control procedures and our management and issue a report concerning our internal control over financial reporting. In addition, under the JOBS Act, emerging growth companies, like ourselves, are exempt from certain reporting requirements, including the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. Under this exemption, our auditor will not be required to attest to and report on our management's assessment of our internal control over financial reporting during a five-year transition period. We will need to prepare for compliance with Section 404 by strengthening, assessing and testing our system of internal controls to provide the basis for our report. However, 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 the testing, our management may identify material weaknesses or significant deficiencies, which may not be remedied in a timely manner to meet the deadline imposed by the Sarbanes-Oxley Act. If our management cannot favorably assess the effectiveness of our internal control over financial reporting, or our independent registered public accounting firm identifies material weaknesses in our internal controls, investor confidence in our financial results may weaken, and the market price of our securities may suffer.

As an “emerging growth company” under the JOBS Act, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements.

As an “emerging growth company” under the JOBS Act, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements. We are an emerging growth company until the earliest of: (i) the last day of the fiscal year during which we had total annual gross revenues of \$1 billion or more, (ii) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement, (iii) the date on which we have, during the previous three-year period, issued more than \$1 billion in non-convertible debt or (iv) the date on which we are deemed a “large accelerated issuer” as defined in Regulation S-K of the Securities Act. For so long as we remain an emerging growth company, we will not be required to:

- have an auditor report on our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- comply with any requirement that may be adopted by the Public Company Accounting Oversight Board, or the PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis);
- submit certain executive compensation matters to shareholders advisory votes pursuant to the “say on frequency” and “say on pay” provisions (requiring a non-binding shareholder vote to approve compensation of certain executive officers) and the “say on golden parachute” provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010; and
- include detailed compensation discussion and analysis in our filings under the Exchange Act, and instead may provide a reduced level of disclosure concerning executive compensation.

Although we intend to rely on the exemptions provided in the JOBS Act, the exact implications of the JOBS Act for us are still subject to interpretations and guidance by the SEC and other regulatory agencies. In addition, as our business grows, we may no longer satisfy the conditions of an emerging growth company. We are currently evaluating and monitoring developments with respect to these new rules and we cannot assure you that we will be able to take advantage of all of the benefits from the JOBS Act.

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 winter of 2008, winter of 2012 and the summer of 2014, Israel was engaged in an armed conflict with Hamas, a militia group and political party operating in the Gaza Strip, and during the summer of 2006, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party. Israel faces political tension with respect to its relationships with Turkey, Iran and certain Arab neighbor countries. In addition, recent conflicts involved missile strikes against civilian targets in various parts of Israel, and negatively affected business conditions in Israel. Recent political uprisings and social unrest in various countries in the Middle East and North Africa are affecting the political stability of those countries. This instability may lead to deterioration of the political relationships that exist between Israel and these countries, and have raised concerns regarding security in the region and the potential for armed conflict. 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 and service providers 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 such agreements. Any future deterioration in the political and security situation in Israel will negatively impact our business.

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 Israeli citizens to perform military service.

Many Israeli citizens, including Motti Farbstein, our Chief Operating and Financial Officer, are obligated to perform one month, and in some cases more, of annual military reserve duty until they reach the age of 45 (or older, for reservists with certain occupations) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists. It is possible that there will be military reserve duty call-ups in the future. Our operations could be disrupted by such call-ups, which may include the call-up of Motti Farbstein. 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. Part of our expenses are payable in U.S. dollars or in Euros as well as the revenues from our licensing arrangements that are payable in U.S. dollars and Canadian dollars, 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 not offset or compounded the effects caused by fluctuations between the NIS and the U.S. dollar or the Euro. To date, we have not engaged in hedging transactions. Although the Israeli rate of inflation has not had a material adverse effect on our financial condition during 2013, 2014, or 2015 to date, we may, in the future, decide to enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of the currencies mentioned above in relation to the NIS. These measures, however, may not adequately protect us from material adverse effects.

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

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, a majority of each class of securities of the target company must approve a merger. Moreover, a full tender offer can only be completed if the acquirer receives at least 95% of the issued share capital; provided that, pursuant to an amendment to the Israeli Companies Law, effective as of May 15, 2011, 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 our issued and outstanding share capital, in the aggregate, approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer), and the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition the court to alter the consideration for the acquisition (unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights).

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

These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders. See "Item 10. Additional Information – Memorandum and Articles of Association."

It may be difficult to enforce a U.S. judgment against us and our officers and directors named in this Annual Report on Form 20-F in Israel or the United States, or to serve process on our officers and directors.

We are incorporated in Israel. All of our executive officers and directors listed in this Annual Report on Form 20-F reside outside of the United States, and all of our assets and most of the assets of our executive officers and directors are located outside of the United States. Therefore, a judgment obtained against us or most of our executive officers and all of our directors in the United States, including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It also may be difficult for you to effect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel.

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

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