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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 20-F

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

For the fiscal year ended December 31, 2016

Commission File No.: 001-38041

THERAPIX BIOSCIENCES LTD.

(Exact name of registrant as specified in its charter)

Translation of registrant's name into English: Not applicable

State of Israel	**5 Azrieli Center (Square Tower)** **Tel-Aviv 6702501, Israel** **Tel: +972-3-6167055**
(Jurisdiction of incorporation or organization)	*(Address of principal executive offices)*

Dr. Elran Haber
Chief Executive Officer
Tel: +972-3-6167055
elran@therapixbio.com
5 Azrieli Center (Square Tower)
Tel-Aviv 6702501, Israel
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class to be registered	**Name of each exchange on which each class is to be registered**
American Depositary Shares, each representing forty (40) Ordinary Shares, NIS 0.1 par value per share	The Nasdaq Stock Market LLC

Ordinary Shares, NIS 0.1 par value per share* N/A

* Not for trading, but only in connection with the registration of the American Depositary Shares pursuant to requirements of the Securities and Exchange Commission.

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

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

40,998,471 Ordinary Shares, par value NIS 0.1 per share

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

Yes ☐ No ☒

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

Yes ☐ No ☒

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

Yes ☐ No ☒

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months.

Yes ☐ No ☐

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

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

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

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

U.S. GAAP ☐

International Financial Reporting Standards as issued by the International Accounting Standards Board ☒

Other ☐

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

☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company.

Yes ☐ No ☒

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INTRODUCTION

We are a specialty clinical-stage pharmaceutical company led by an experienced team of senior executives and scientists, focused on creating and enhancing a portfolio of technologies and assets based on cannabinoid pharmaceuticals. With this focus, we have initiated two internal drug development programs based on repurposing a U.S. Food and Drug Administration, or FDA, approved synthetic cannabinoid (dronabinol): Joint Pharma developing THX-TS01 targeted to the treatment of Tourette Syndrome, or TS, and BrainBright Pharma developing THX-ULD01 targeted to the high value and under-served market of mild cognitive impairments, or MCIs.

We were incorporated under the laws of the State of Israel on August 23, 2004. Our Ordinary Shares are listed on the Tel Aviv Stock Exchange, or TASE, under the symbol "THXBY." On March 22, 2017, our American Depositary Shares, or ADSs, each representing forty of our Ordinary Shares, commenced trading on the NASDAQ Capital Market under the symbol "TRPX".

Unless otherwise indicated, all references to the "Company," "we," "us, "our" and "Therapix" refer to Therapix Biosciences Ltd. and its wholly owned subsidiaries.

References to "U.S. dollars" and "$" are to currency of the United States of America, and references to "NIS" are to New Israeli Shekels. References to "Ordinary Shares" are to our Ordinary Shares, par value of NIS 0.1 per share. We report financial information under International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board and none of the financial statements were prepared in accordance with generally accepted accounting principles in the United States. Unless otherwise indicated, U.S. dollar convenience translations of NIS amounts presented in this annual report on Form 20-F for the year ended on December 31, 2016 are translated using the rate of NIS 3.845 to $1.00, the exchange rate reported by the Bank of Israel on December 31, 2016, U.S. dollar convenience translations of NIS amounts presented in this annual report on Form 20-F for the year ended on December 31,2015 are translated using the rate of NIS 3.902 to $1.00, the exchange rate reported by the Bank of Israel on December 31, 2015, and U.S. dollar convenience translations of NIS amounts presented in this annual report on Form 20-F for the year ended on December 31, 2014 are translated using the rate of NIS 3.889 to $1.00, the exchange rate reported by the Bank of Israel on December 31, 2014.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain information included or incorporated by reference in this annual report on Form 20-F may be deemed to be "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and other securities laws. Forward-looking statements are often characterized by the use of forward-looking terminology such as "may," "will," "expect," "anticipate," "estimate," "continue," "believe," "should," "intend," "project" or other similar words, but are not the only way these statements are identified.

Forward-looking statements include, but are not limited to, statements about:

- our timeline for our product candidate development path, including the anticipated starting and ending dates of our anticipated clinical trials;
- anticipated actions of the FDA or other regulatory bodies, including approval to conduct clinical trials, the scope of those trials and the prospects for regulatory approval of, or other regulatory action with respect to our product candidates, including the regulatory pathway to be designated to our product candidates;
- the commercial launch and future sales of our existing product candidates or any other future potential product candidates;
- our expectations regarding the commercial supply of our product candidates;
- our estimates regarding anticipated capital requirements and our needs for financing;
- the patient market size and market adoption of our product candidates by physicians and patients;
- the timing, cost or other aspects of the commercial launch of our product candidates;
- completion and receiving favorable results of our anticipated clinical trials;
- our expectations regarding when certain patents may be issued and the protection of our intellectual property;
- our expectations regarding licensing, acquisitions and strategic partnering; and
- those factors referred to in "Item 3. Key Information – D. Risk Factors," "Item 4. Information on the Company," and "Item 5. Operating and Financial Review and Prospects", as well as in this annual report on Form 20-F generally.

These statements are only current predictions and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements.

Readers are urged to carefully review and consider the various disclosures made throughout this annual report on Form 20-F which are designed to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

You should not put undue reliance on any forward-looking statements. Any forward-looking statements in this annual report on Form 20-F are made as of the date hereof, and we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

The selected consolidated financial data for the fiscal years set forth in the table below have been derived from our consolidated financial statements and notes thereto. We derived the selected data under the caption "Consolidated Statements of Operations Data" for the years ended December 31, 2016, 2015 and 2014 and the selected data under the caption "Consolidated Balance Sheet Data" for the years ended December 31, 2016, 2015 and 2014 from the audited consolidated financial statements included elsewhere in this annual report (and in the case of the selected data under the caption "Consolidated Balance Sheet Data" for the year ended December 31, 2014, from the audited consolidated financial statements included in our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on November 4, 2016). The selected financial data should be read in conjunction with our consolidated financial statements, and are qualified entirely by reference to such consolidated financial statements.

	December 31,			December 31,
	2014	2015	2016	2016
Consolidated Statements of Operations Data	(in thousands of NIS)			(in thousands of USD-convenience translation)
Revenues	-	-	-	
Research and development expenses, net	1,800	931	2,842	739
General and administrative expenses	5,238	5,297	4,870	1,267
Other expense (income), net	115	3,734	(30)	(7)
Operating loss	6,923	9,962	7,682	1,999
Finance expenses (income), net	26	15	26	6
Net comprehensive loss	7,282	10,164	7,728	2,010
Net loss per Ordinary Share	0.45	0.43	0.21	
Number of Ordinary Shares used in computing loss per Ordinary Share- thousands	16,071,577	23,853,196	37,457,538	37,457,538

	December 31,			December 31,
	2014	2015	2016	2016
Consolidated Balance Sheet Data	(in thousands of NIS)			(in thousands of USD-convenience translation)
Cash and cash equivalents	614	6,136	2,598	676
Total assets	1,017	6,501	4,788	1,245
Total non-current liabilities	156	-	-	-
Accumulated loss	103,591	113,468	121,124	31,502
Total equity (deficit)	(453)	5,114	2,203	573

EXCHANGE RATE INFORMATION

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

	NIS per U.S. dollars			
Annual	**High**	**Low**	**Average**	**Period End**
2016	3.983	3.746	3.841	3.845
2015	4.053	3.761	3.884	3.902
2014	3.994	3.402	3.577	3.889
2013	3.791	3.471	3.609	3.471
2012	4.084	3.700	3.856	3.733
Quarterly				
Fourth Quarter 2016	3.876	3.778	3.832	3.845
Third Quarter 2016	3.895	3.746	3.805	3.758
Second Quarter 2016	3.900	3.746	3.818	3.846
First Quarter 2016	3.983	3.766	3.908	3.766
Monthly				
March 2017	3.693	3.614	3.6493	3.632
February 2017	3.768	3.659	3.729	3.659
January 2017	3.860	3.769	3.818	3.769
December 2016	3.867	3.787	3.823	3.845
November 2016	3.876	3.799	3.843	3.839
October 2016	3.856	3.778	3.822	3.849

On April 26, 2017, the daily representative rate was $1.00 to NIS 3.634, as reported by the Bank of Israel.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should carefully consider the risks described below, together with all of the other information in this annual report on Form 20-F. The risks described below are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business operations. If any of these risks actually occurs, our business and financial condition could suffer and the price of our ADSs could decline.

Risks Related to Our Financial Condition and Capital Requirements

We are a specialty clinical-stage pharmaceutical company and have a limited operating history on which to assess the prospects for our business, have incurred significant losses since the date of our inception, and anticipate that we will continue to incur significant losses until we are able to successfully commercialize our product candidates.

Since our inception in 2004, we have been operating as a specialty pharmaceutical company and have a limited operating history on which to assess the prospects for our business, have incurred significant losses, and anticipate that we will continue to incur significant losses for the foreseeable future. We have only focused our business on the development of cannabinoid molecules since August 2015.

We have historically incurred substantial net losses; including net losses of approximately NIS 7.7 million (approximately $2 million) for the year ended December 31, 2016, net losses of approximately NIS 10.2 million in 2015 and approximately NIS 7.3 million in 2014. As of December 31, 2016 and December 31, 2015, we had an accumulated deficit of approximately NIS 121.1 million (approximately $31.5 million) and approximately NIS 113.5 million, respectively.

We have devoted substantially all of our financial resources to develop our product candidates. We have financed our operations primarily through the issuance of equity securities. The amount of our future net losses will depend, in part, on completing the development of our product candidates, the demand for our product candidates, the rate of our future expenditures and our ability to obtain funding through the issuance of our securities, strategic collaborations or grants. Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk and we have only focused our business on the development of cannabinoid molecules since August 2015. We are in the late stages of preclinical and at the early stages of clinical development for our product candidates, we have not yet commenced pivotal clinical studies for any product candidate, and it may be several years, if ever, before we complete pivotal clinical studies and have a product candidate approved for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of the markets for which our product candidates may receive approval and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors and adequate market share for our product candidates in those markets.

We expect to continue to incur significant losses until we are able to commercialize our product candidates, which we may not be successful in achieving. We anticipate that our expenses will increase substantially if and as we:

- continue the research and development of our product candidates;
- expand the scope of our current clinical studies for our product candidates;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical studies;
- establish a sales, marketing, and distribution infrastructure to commercialize our product candidates;
- seek to identify, assess, acquire, license, and/or develop other product candidates and subsequent generations of our current product candidates;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel; and
- create additional infrastructure to support our operations as a public company and our product candidate development and planned future commercialization efforts.

We were subject to administrative proceedings by the ISA that alleged certain violations of Israeli securities laws, that subjected us to monetary and other sanctions

In the past we were subject to an administrative inquiry relating to our reports (quality and scope of disclosure) to the ISA and the TASE with respect to the termination of a license agreement we had with Ramot for certain technology covering our previous immunotherapeutic Alzheimer's technology and program, or the BBS Technology, which was terminated in the beginning of 2014. In April 2017, we settled the administrative inquiry and admitted to the following breaches: (i) failure to submit an immediate report about a material event (the license agreement termination) in a timely and lawful manner; (ii) inclusion of a misleading detail in an immediate report; and (iii) misleading the ISA in connection with such actions. We were required to pay a monetary sanction of NIS 150,000 (approximately $40,000), and potentially an additional equal sum if we are found to have committed the same breaches in the next 24 months. In addition, our Chairman will be subject to a one year probationary condition, whereby if he is found to commit a similar violation, he will be prevented from serving as an officer or director of a public company. If we fail to comply with the applicable rules in the future, we may be subject again to administrative proceedings by the ISA that will subject us to monetary and other sanctions.

We have not generated any revenue from the sale of our current product candidates and may never be profitable.

We have not yet commercialized any of our product candidates and have not generated any revenue since the date of our inception. We do not know whether or when we will become profitable. Our ability to generate revenue and achieve profitability depends on our ability to successfully complete the development of, and to commercialize, our product candidates and on the demand for our product candidates. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our product candidates. Our ability to generate future revenue from product candidate sales depends heavily on our success in many areas, including but not limited to:

- completing research and preclinical and clinical development of our product candidates;
- obtaining regulatory and marketing approvals for product candidates for which we complete clinical studies;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate (in amount and quality) products to support market demand for our product candidates, if approved;
- launching and commercializing product candidates if and when we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing pharmaceutical or biotechnological and market developments;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency, or the EMA, or other regulatory agencies, domestic or foreign, to perform clinical, nonclinical or other types of studies in addition to those that we currently anticipate. In cases where we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product candidate, the ability to get reimbursement at an acceptable price and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably expected population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such product candidates, even if approved. Additionally, if we are not able to generate revenue from the sale of any approved product candidates, we may be forced to cease operations.

We expect that we will need to raise substantial additional funding before we can expect to become profitable from sales of our product candidates. This additional financing may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product candidate development efforts or other operations.

As of December 31, 2016, our cash and cash equivalents were approximately NIS 2.6 million (approximately $0.7 million), a working capital of NIS 0.5 million (approximately $130,000) and an accumulated deficit of NIS million 121.1 (approximately $31.5 million). Based upon our currently expected level of operating expenditures, we expect that our existing cash and cash equivalents will be sufficient to fund operations at least through June 30, 2018. We expect that we will require substantial additional capital to commercialize our product candidates. In addition, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including but not limited to:

- the scope, rate of progress, results and cost of product development, clinical studies, preclinical testing, and other related activities;

- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing, and distribution capabilities; and
- the terms and timing of any collaborative, licensing, and other arrangements that we may establish.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of holders of our securities and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our Ordinary Shares or ADSs to decline. The incurrence of indebtedness could result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable, and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Even if we believe that we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Raising additional capital would cause dilution to our existing shareholders, and may affect the rights of existing shareholders.

We may seek additional capital through a combination of private and public equity offerings, debt financings and collaborations and strategic and licensing arrangements. To the extent that we raise additional capital through the issuance of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of the ADSs.

Risks Related to the Discovery and Development of Our Product Candidates

We are heavily dependent on the success of our product candidates, which are in the late stages of pre-clinical development or early stages of clinical development. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

To date, we have invested substantially all of our efforts and financial resources to design and develop our product candidates, including conducting preclinical studies and providing general and administrative support for these operations. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize one or more product candidates. We currently generate no revenue from sales of any product candidate, and we may never be able to develop or commercialize a marketable product candidate.

Each of our product candidates is in the late stages of pre-clinical development or early stages of development and will require additional clinical development (and in some cases additional preclinical development), management of nonclinical, clinical and manufacturing activities, regulatory approval, obtaining adequate manufacturing supply, building of a commercial organization and significant marketing efforts before we generate any revenue from product candidate sales. It may be years before a pivotal study is initiated, if at all. Any clinical trials in the United States will require the approval of an Investigational New Drug, or IND, application by the FDA, and we cannot assure that we will obtain such approval in a timely manner, or at all. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

We as a company have never submitted marketing applications to the FDA or comparable foreign regulatory authorities. We cannot be certain that any of our product candidates will be successful in clinical studies or receive regulatory approval or what regulatory pathway the regulatory authorities shall designate for our product candidates. Further, our product candidates may not receive regulatory approval even if they are successful in clinical studies. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

We generally plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and in additional foreign countries. To obtain regulatory approvals we must comply with the numerous and varying regulatory requirements of such countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical studies, commercial sales, pricing and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations would be negatively affected.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical studies and depends upon numerous factors. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's safety-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical studies;
- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of a NDA in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical studies, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies and early clinical studies of our product candidates may not be predictive of the results of later-stage clinical studies. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent advanced clinical studies. There is a high failure rate for drugs proceeding through clinical studies, and product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having progressed satisfactorily through preclinical studies and initial clinical studies. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. We do not know whether any Phase I, Phase II, Phase III or other clinical studies we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain regulatory approval to market our product candidates.

We may find it difficult to enroll patients in our clinical studies. Difficulty in enrolling patients could delay or prevent clinical studies of our product candidates.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical studies if we encounter difficulties in enrollment.

Some of the conditions for which we plan to evaluate our current product candidates are for rare diseases. For example, based on a study conducted by the CDC, we estimate that approximately 138,000 children suffer from TS in the United States. Accordingly, there is a limited patient pool from which to draw for clinical studies. Further, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study.

Additionally, the process of finding patients may prove costly. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical studies, the proximity and availability of clinical study sites for prospective patients and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential product candidates will be delayed.

If we experience delays in the completion or termination of any clinical study of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product candidate revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical studies will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product candidate sales and generate revenue. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates.

If the FDA does not conclude that our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for our product candidates under Section 505(b)(2) are not as we expect, the approval pathway would likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated and in either case may not be successful.

We intend to seek FDA approval through the Section 505(b)(2) regulatory pathway for our product candidates. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the FDC Act, or Section 505(b)(2). Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval, and complications and risks associated with FDA approval, would substantially increase. We may need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing shareholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive product candidates reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of product candidates by the FDA under Section 505(b)(2) over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). For example, several companies have previously petitioned the FDA regarding the constitutionality of allowing others to rely upon FDA findings that are based on their proprietary data. If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its 505(b)(2) policies and practices, which could require that we generate full data regarding safety and effectiveness for previously approved active ingredients and delay or even prevent the FDA from approving any NDA that we submit under Section 505 (b)(2). Our product candidates are at early stages of development and are subject to uncertainty over what we must do on our development program in order to secure approval under Section 505(b)(2).

We may encounter substantial delays in our clinical studies, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, time consuming and uncertain as to outcome. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical studies;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical study site;
- imposition of a clinical hold by regulatory agencies, after review of an IND, application, or equivalent application, or an inspection of our clinical study operations or study sites;
- delays in recruiting suitable patients to participate in our clinical studies;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's Good Clinical Practices, or GCP, requirements, or applicable regulatory guidelines in other countries;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- patients dropping out of a study;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in us deciding, or regulators requiring us, to conduct additional clinical studies or abandon product candidate development programs; and
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. We may also be required to conduct additional safety, efficacy and comparability studies before we will be allowed to start clinical studies with our repurposed drugs. Clinical study delays could also shorten any periods during which our product candidates have patent protection and may allow our competitors to bring product candidates to market before we do, which could impair our ability to obtain orphan exclusivity and successfully commercialize our product candidates and may harm our business and results of operations.

In respect of our product candidates targeting rare indications, orphan drug exclusivity may afford limited protection, and if another party obtains orphan drug exclusivity for the drugs and indications we are targeting, we may be precluded from commercializing our product candidates in those indications during that period of exclusivity.

We are seeking to obtain an orphan designation for some of our product candidates in the United States and in Europe. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, defined, in part, as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products (COMP), grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union community. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug.

In the United States, the first NDA applicant with an orphan drug designation for a particular active moiety to treat a specific disease or condition that receives FDA approval is entitled to a seven-year exclusive marketing period in the United States for that product candidate, for that indication. In the European Union, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following drug approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

In June 2016, we submitted a request for orphan drug designation to the FDA for THX-TS01 for the treatment of TS. In a letter dated September 29, 2016, the FDA informed us that our request cannot be granted at this time, and is being held in abeyance until and subject to us providing additional information pertaining to the overall prevalence of TS in both children and adults, and further clinical data to support our scientific rationale for our request for orphan drug designation within 12 months. We intend to respond within the 12 month period, or during any extension thereof. There is no assurance that we will successfully obtain orphan drug designation for TS, any future rare indications or orphan exclusivity upon approval of any of our product candidates that have already obtained designation.

Even if we do obtain orphan exclusivity for any product candidate, the exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. Moreover, a drug product candidate with an active moiety that is a different cannabinoid from that in our drug candidate or, under limited circumstances, the same drug product candidate, may be approved by the FDA for the same indication during the period of marketing exclusivity. The limited circumstances include a showing that the second drug is clinically superior to the drug with marketing exclusivity through a demonstration of superior safety or efficacy or that it makes a major contribution to patient care. In addition, if a competitor obtains approval and marketing exclusivity for a drug product candidate with an active moiety that is the same as that in a product candidate we are pursuing for the same indication, approval of our product candidate would be blocked during the period of marketing exclusivity unless we could demonstrate that our product candidate is clinically superior to the approved product candidate. In addition, if a competitor obtains approval and marketing exclusivity for a drug product candidate with an active moiety that is the same as that in a product candidate we are pursuing for a different orphan indication, this may negatively impact the market opportunity for our product candidate.

There have been legal challenges to aspects of the FDA's regulations and policies concerning the exclusivity provisions of the Orphan Drug Act, and future challenges could lead to changes that affect the protections afforded our product candidates in ways that are difficult to predict. In a recent successful legal challenge, a court invalidated the FDA's denial of orphan exclusivity to a drug on the grounds that the drug was not proven to be clinically superior to a previously approved product candidate containing the same ingredient for the same orphan use. In response to the decision, the FDA released a policy statement stating that the court's decision is limited just to the facts of that particular case and that the FDA will continue to require the sponsor of a designated drug that is the "same" as a previously approved drug to demonstrate that its drug is clinically superior to that drug upon approval in order to be eligible for orphan drug exclusivity, or in some cases, to even be eligible for marketing approval. In the future, there is the potential for additional legal challenges to the FDA's orphan drug regulations and policies, and it is uncertain how such challenges might affect our business.

While orphan drug product candidates are typically sold at a high price relative to other medications, the market may not be receptive to high pricing of our product candidates.

We develop our product candidates to treat rare diseases, a space where medications are usually sold at high prices compared with other medications. However, our product candidates are repurposed drugs, which means, among other things, that they contain drug substances available in pharmacies for the purpose of treating indications that are different from the indications for which we plan to use. Accordingly, even if regulatory authorities approve our product candidates, the market may not be receptive to, and it may be difficult for us to achieve, a per-patient per-year price high enough to allow us to realize a return on our investment.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

The use of dronabinol has been associated with seizures, paranoia, rapid heart rate and unusual thoughts and behaviors. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive marketing label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Potential side effects of our cannabinoid-based treatments may include: asthenia, palpitations, tachycardia, vasodilation/facial flush, abdominal pain, nausea, vomiting, amnesia, anxiety/nervousness, ataxia, confusion, depersonalization, dizziness, euphoria, hallucinations, paranoid reaction, somnolence and abnormal thinking. Results of our studies may identify unacceptable severity and prevalence of these or other side effects. In such an event, our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications.

Drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the study or result in potential product candidate liability claims.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such product candidates, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Even if we obtain regulatory approval for a product candidate, our product candidates will remain subject to regulatory scrutiny.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States. In addition, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, regulations and Quality System Regulation, or QSR. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP, QSR and adherence to commitments made in any NDA. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. We will also be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotion for our product candidates. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product candidate's approved label. As such, we may not promote our product candidates for indications or uses for which they do not have FDA approval. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product candidate, product candidate labeling or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our product candidates in general or in specific patient subsets. If original marketing approval were obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical study to confirm clinical benefit for our product candidates. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. Furthermore, any new legislation addressing drug safety issues could result in delays in product candidate development or commercialization or increased costs to assure compliance. Foreign regulatory authorities impose similar requirements.

If a regulatory agency discovers previously unknown problems with a product candidate, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product candidate is manufactured, or disagrees with the promotion, marketing or labeling of a product candidate, such regulatory agency may impose restrictions on that product candidate or us, including requiring withdrawal of the product candidate from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain product candidates, or require a product candidate recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

We are subject to numerous complex regulations and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.

The research, testing, development, manufacturing, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, marketing, distribution, possession and use of our product candidates, among other things, are subject to regulation by numerous governmental authorities in the United States and elsewhere. The FDA regulates drugs under the FDC Act, and implementing regulations. Noncompliance with any applicable regulatory requirements can result in refusal to approve product candidates for marketing, warning letters, product candidate recalls or seizure of product candidates, total or partial suspension of production, prohibitions or limitations on the commercial sale of product candidates or refusal to allow the entering into of federal and state supply contracts, fines, civil penalties and/or criminal prosecution. Additionally, the FDA and comparable governmental authorities have the authority to withdraw product candidate approvals that have been previously granted. Moreover, the regulatory requirements relating to our product candidates may change from time to time and it is impossible to predict what the impact of any such changes may be.

We are developing product candidates that are controlled substances as defined in the Controlled Substances Act of 1970, or CSA, which establishes, among other things, certain registration, production quotas, security, recordkeeping, reporting, import, export and other requirements administered by the Drug Enforcement Administration, or the DEA. The active ingredient in our product candidates is dronabinol, which is a Schedule I controlled substance, meaning that any drug containing it cannot be marketed before it is rescheduled by the DEA as a Schedule II, III, IV or V substance. See Item 4.B. “Business Overview—Government Regulation—Controlled Substances” for additional information.

The manufacture, shipment, storage, sale and use, among other things, of controlled substances that are pharmaceutical product candidates are subject to a high degree of regulation. The DEA also conducts periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our product candidates as well. While some states automatically schedule a drug when the DEA does so, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product candidate for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product candidate. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with current cGMP, GCP, QSR and Good Laboratory Practices, or GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, the clinical data generated in our clinical studies may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical studies before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical studies comply with GCP regulations. In addition, our clinical studies must be conducted with product candidates which are produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical studies may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which could materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We will rely on third parties to manufacture our active pharmaceutical ingredient, or API, formulations. Our business could be harmed if those third parties fail to provide us with sufficient quantities of our needed supplies, or fail to do so at acceptable quality levels or prices.

We do not have the infrastructure or capability internally to manufacture the API formulations, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We plan to rely on third parties for such supplies. There are a limited number of manufacturers who have the ability to produce our API and there may be a need to identify alternate manufacturers to prevent a possible disruption of our clinical studies. Any significant delay or discontinuity in the supply of these components could considerably delay completion of our clinical studies, product candidate testing and potential regulatory approval of our product candidates, which could harm our business and results of operations.

We and our collaborators and contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or a product candidate used in late-stage clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational product candidates and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaborators or our contract manufacturers must supply all necessary documentation in support of an NDA, or Marketing Authorization Application, or MAA, on a timely basis and must adhere to GLP and cGMP QSR regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our collaborators and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the product candidates may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product candidate for sale, if ever, audit the manufacturing facilities of our collaborators and third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product candidate specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical study or commercial sales, or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we, our collaborators, or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product, withdrawal of an approval or suspension of production. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA or MAA amendment, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical studies, regulatory submissions, required approvals or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

Risks Related to Commercialization of Our Product Candidates

If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

Our projections of both the number of people who have our target diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

We face intense competition and rapid technological change and the possibility that our competitors may discover, develop or commercialize therapies that are similar, more advanced or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

The biotechnology and pharmaceutical industries are highly competitive. There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to our product candidates.

The first THC-based pharmaceutical, a pill sold under the commercial name of Marinol (scientific name: dronabinol), was developed by a company called Unimed Pharmaceuticals, with funding provided by the National Cancer Institute. In 1985, Marinol received FDA approval as a treatment for chemotherapy-related nausea and vomiting. Today, Marinol is marketed by AbbVie, Inc. Since the introduction of Marinol into the market, other pharmaceuticals containing THC have also been developed. These include generic oral capsules of dronabinol, such as those marketed by SVC Pharma LP and Akorn Inc., Insys Therapeutic Inc.'s Syndros, an orally administered liquid formulation of dronabinol, Meda AB's Cesamet (nabilone), a synthetic derivative of THC, and Sativex (nabiximols), a whole cannabis extract administered as an oral spray. Furthermore, we are aware of multiple companies that are working in the cannabis therapeutic area and are pursuing regulatory approval for their product candidates. For example, GW Pharmaceuticals PLC, which markets Sativex, a botanical cannabinoid oral mucosal for the treatment of spasticity due to multiple sclerosis is seeking FDA approval in the United States, and is developing Epidiolex, a liquid formulation of highly purified cannabidiol extract, as a treatment for Dravet's Syndrome, Lennox Gastaut Syndrome, and various childhood epilepsy syndromes. Insys Therapeutics, Inc. is also seeking FDA approval for an orally-administered liquid formulation of its synthetic cannabidiol compound as a treatment for Dravet's Syndrome, Lennox Gastaut Syndrome, and other childhood epilepsy syndromes. Zynerba Pharmaceuticals, Inc. is developing a transdermal formulation of cannabidiol, and Nemus Bioscience, Inc. is focused on the discovery, development and commercialization of cannabis therapeutics.

More established companies may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources. As a result of these factors, our competitors may have an advantage in marketing their approved products and may obtain regulatory approval of their product candidates before we are able to, which may limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and less expensive than ours, and may also be more successful than us in manufacturing and marketing their products. These advantages could materially impact our ability to develop and commercialize our product candidates successfully.

Our product candidates may also compete with medical and recreational marijuana, in markets where the recreational and/or medical use of marijuana is legal. There is support in the United States for further legalization of marijuana. In markets where recreational and/or medical marijuana is not legal, our product candidates may compete with marijuana purchased in the illegal drug market. We cannot assess the extent to which patients may utilize marijuana obtained illegally for the treatment of the indications for which we are developing our product candidates.

Even if we successfully develop our product candidates, and obtain marketing approval for them, other treatments or therapeutics may be preferred and we may not be successful in commercializing our product candidates or in bringing them to market.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than we do. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

We currently have no marketing and sales organization. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

Although our employees may have sold other similar products in the past while employed at other companies, we as a company have no experience selling and marketing our product candidates and we currently have no marketing or sales organization. To successfully commercialize any products that may result from our development programs, we will need to develop these capabilities, either on our own or with others. If our product candidates receive regulatory approval, we intend to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in major markets, which will be expensive, difficult and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products.

Further, given our lack of prior experience in marketing and selling pharmaceutical products, our initial estimate of the size of the required sales force may be materially more or less than the size of the sales force actually required to effectively commercialize our product candidates. As such, we may be required to hire substantially more sales representatives to adequately support the commercialization of our product candidates or we may incur excess costs as a result of hiring more sales representatives than necessary. With respect to certain geographical markets, we may enter into collaborations with other entities to utilize their local marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If our future collaborators do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We may be competing with companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our product candidates will depend in part on the medical community, patients and third-party payors accepting our product candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the safety and efficacy of the product as demonstrated in clinical studies and potential advantages over competing treatments;

- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which approval is granted;
- relative convenience and ease of administration;
- the cost of treatment, particularly in relation to competing treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage and reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical and clinical studies, market acceptance of the product will not be fully known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the product candidates may require significant resources and may never be successful. If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, patients, third-party payors and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The pricing, coverage and reimbursement of our product candidates, if approved, must be adequate to support our commercial infrastructure. Our per-patient prices must be sufficient to recover our development and manufacturing costs and potentially achieve profitability. Accordingly, the availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to be able to afford expensive treatments such as ours, assuming approval. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government authorities, private health insurers and other third-party payors. If coverage and reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by the Centers for Medicare & Medicaid Services (formerly the Health Care Financing Administration), or CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for products such as ours.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicinal products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, was passed. The Affordable Care Act is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and the health insurance industry, impose new taxes and fees on the healthcare industry and impose additional health policy reforms. This law revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, the law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. While the U.S. Supreme Court upheld the constitutionality of most elements of the Affordable Care Act in 2012, other legal challenges are still pending final adjudication in several jurisdictions. In addition, Congress has also proposed a number of legislative initiatives, including possible repeal of the Affordable Care Act. At this time, it remains unclear whether there will be any changes made to the Affordable Care Act, whether to certain provisions or its entirety. We can provide no assurance that the Affordable Care Act, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. In 2013, the 2% Medicare payment reductions went into effect. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain effective patent rights for our product candidates, we may not be able to compete effectively in our markets. If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.

Historically, we have relied on trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Since 2015, we have also sought patent protection for certain of our product candidates. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and new product candidates.

We have sought to protect our proprietary position by filing patent applications in the United States and in other countries, with respect to our novel technologies and product candidates, which are important to our business. Patent prosecution is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

Not including patents and applications which we are in the process of assigning, we have a portfolio of two provisional patent applications with the U.S. Patent and Trademark Office, or USPTO, and two patent applications filed under the Patent Cooperation Treaty of the World Intellectual Property Organization, or PCT. We cannot offer any assurances about which, if any, patent applications will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to our patents after issuance could deprive us of rights necessary for the successful commercialization of any new product candidates that we may develop.

We have also exclusively licensed: (i) one U.S. patent from Dekel Pharmaceuticals Ltd., or Dekel, (ii) one U.S. patent from Yissum Research Development Company of the Hebrew University of Jerusalem Ltd., or Yissum, and (iii) one PCT application from Ramot. In addition, we intend to negotiate a definitive agreement for the in-licensing of a patent application from Belvit Pharma LLC, or Belvit. We cannot assure you that we will ever enter into definitive license agreements with Belvit or any other third party licensor. See Item 4.B. “Business Overview —Intellectual Property—In-Licensed Patents and Patent Applications.” To the extent the licensed or future licensed patents are found to be invalid or unenforceable, we may be limited in our ability to compete and market our product candidates. Moreover, the terms of our licenses affect our ability to control the value of any of our product candidates. If we or any of the parties that control the enforcement of licensed patents elect not to enforce any or all of the licensed patents it could significantly undercut the value of any of our product candidates, which would materially adversely affect our future revenue, financial condition and results of operations. Moreover, fluctuating currency rates may create inconsistencies in the royalty payments we are obligated to make under our licenses.

Also, there is no guarantee that the patent registration applications that were submitted by us with regard to our technologies will result in patent registration. In the event of failure to complete patent registration, our developments will not be proprietary, which might allow other entities to manufacture our product candidates and compete with them.

Further, there is no assurance that all potentially relevant prior art relating to our patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patent applications and any future patents may not adequately protect our intellectual property, provide exclusivity for our new product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If we cannot obtain and maintain effective patent rights for our product candidates, we may not be able to compete effectively, and our business and results of operations would be harmed.

We may not be able to identify infringements of our patents and accordingly the enforcement of our intellectual property rights may be difficult.

The drug substance in some of our product candidates is repurposed, which means that it is available in other pharmaceutical products for the purpose of treating indications that are different from the indications for our product candidates. It is possible that if we receive regulatory approval to market and sell our drug candidates, some patients that receive a prescription could be sold the same drug substance but not our product candidate. It would be difficult, if not impossible for us to identify such instances that may constitute an infringement of our patents. In addition, because the drug substance of some of our product candidates is repurposed, such substance may not be eligible for patent protection or data exclusivity.

If we are unable to maintain effective proprietary rights for our product candidates, we may not be able to compete effectively in our markets.

In addition to the protection afforded by any patents currently owned and that may be granted, historically, we have relied on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes that are not easily known, knowable or easily ascertainable, and for which patent infringement is difficult to monitor and enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data, trade secrets and intellectual property by maintaining physical security of our premises and physical and electronic security of our information technology systems. Agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets and intellectual property may otherwise become known or be independently discovered by competitors.

We cannot provide any assurances that our trade secrets and other confidential proprietary information will not be disclosed in violation of our confidentiality agreements or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Also, misappropriation or unauthorized and unavoidable disclosure of our trade secrets and intellectual property could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets and intellectual property are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secret.

Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates, and we might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

It is inherently difficult to conclusively assess our freedom to operate without infringing on third party rights. Our competitive position may be adversely affected if existing patents or patents resulting from patent applications issued to third parties or other third party intellectual property rights are held to cover our product candidates or elements thereof, or our manufacturing or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize product candidates or our product candidates unless we successfully pursue litigation to nullify or invalidate the third party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may also be pending patent applications that if they result in issued patents, could be alleged to be infringed by our new product candidates. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, be forced to abandon our new product candidates or seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

It is also possible that we have failed to identify relevant third party patents or applications. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our new product candidates or platform technology could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our new product candidates or the use of our new product candidates. Third party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in pursuing the development of and/or marketing our new product candidates. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing our new product candidates that are held to be infringing. We might, if possible, also be forced to redesign our new product candidates so that we no longer infringe the third party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing new product candidates. As our industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, designs or methods of manufacture related to the use or manufacture of our product candidates. There may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

If any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for designs, or methods of use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing product candidates or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of any patents that may issue from our patent applications, or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that we were the first to file the invention claimed in our owned and licensed patent or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming all other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention without undue delay in filing, is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents, all of which could have a material adverse effect on our business and financial condition.

We may be involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our new product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Under the Leahy-Smith Act, the validity of U.S. patents may also be challenged in post-grant proceedings before the USPTO. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Derivation proceedings initiated by third parties or brought by us may be necessary to determine the priority of inventions and/or their scope with respect to our patent or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our new product candidates to market.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our Ordinary Shares.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in, or right to compensation, with respect to our current patent and patent applications, future 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 or claiming the right to compensation. 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.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on product candidates, as well as monitoring their infringement in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates. Future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, which could make it difficult for us to stop the marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to monitor and enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Actual or perceived conflicts of interest may exist with respect to intellectual property rights that we license from an entity controlled by our Chairman.

In May 2015, we entered into a license agreement, which became effective in August 2015, with Dekel, an Israeli private company controlled by Dr. Ascher Shmulewitz, the Chairman of our Board of Directors, under which we were granted an irrevocable, worldwide, exclusive, royalty-bearing license to certain of Dekel's technology. See Item 7.B. "Related Party Transactions — Dekel License Agreement."

We do not have any agreement with Dr. Shmulewitz to present us with business opportunities he may wish to pursue, subject only to his duties under Israeli law. When negotiating and entering into the agreement with Dekel, Dr. Shmulewitz faced an actual conflict of interest between achieving the most favorable terms for Dekel, as holder of controlling interest in Dekel, and owing fiduciary duties to us, as a member of our Board of Directors. Due to this conflict, we may not have obtained as favorable terms for this license as with an unrelated party. Under applicable Israeli law, fiduciary duties include a duty of care and a duty of loyalty. The approval of transactions with interested parties under the Israeli Companies Law, or the Companies Law included audit committee and shareholders' approval, which were obtained prior to the entering into the transaction. See Item 6 C. "Board Practices – Approval of Related Party Transactions under Israeli Law."

If there is a dispute between us and Dekel, Dr. Shmulewitz will have a conflict of interest because he may, at the time of a prospective dispute, simultaneously have a financial interest in and owe a fiduciary duty to Dekel and simultaneously have a financial interest in and owe a fiduciary duty to us. If a contractual dispute arises between us and Dekel under the license agreement, Dr. Shmulewitz may be in a position where he would benefit if Dekel prevails, to the detriment of our business or our investors, due to his controlling interest in Dekel. We cannot assure you that any conflicts will be resolved in our favor, and as a result, our business could be impeded or materially harmed. Furthermore, any future transactions that we enter into with Dekel may be considered as related party transactions under Israeli law, and in many instances may require the approval of our shareholders. Seeking shareholder approval can be a lengthy and costly process, and we cannot be certain that our shareholders will approve any such transactions.

Risks Related to Our Business Operations

We manage our business through a small number of employees and key consultants. We depend on them even more than similarly-situated companies.

We have a total of five full-time employees and three dedicated consultants that work for us on a part-time basis. Our chief financial officer and chief strategy officer each work for us on a part-time basis (approximately 55% and 20% of their business hours, respectively). In addition, any of our employees and consultants may leave our company at any time, subject to certain notice periods. The loss of the services of any of our executive officers or any key employees or consultants would adversely affect our ability to execute our business plan and harm our operating results.

We do not currently carry "key person" insurance on the lives of members of management.

We will need to expand our organization and we may experience difficulties in recruiting needed additional employees and consultants, which could disrupt our operations.

As our development and commercialization plans and strategies develop and because we are so leanly staffed, we will need additional managerial, operational, sales, marketing, financial, legal and other resources. The competition for qualified personnel in the pharmaceutical field is intense. Due to this intense competition, we may be unable to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We may not be successful in our efforts to identify, license or discover additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of our existing product candidates, the success of our business also depends in part upon our ability to identify, license or discover additional product candidates. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license or discover additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Affordable Care Act requires manufacturers of drugs, devices and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States or Israel.

Other than our headquarters and other operations which are located in Israel (as further described below), we currently have limited international operations, but our business strategy incorporates potentially significant international expansion, particularly in anticipation of approval of our product candidates. We plan to maintain sales representatives and conduct physician and patient association outreach activities, as well as clinical trials, outside of the United States and Israel. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;

- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts, business operations and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

The use of any of our product candidates could result in product liability or similar claims that could be expensive, damage our reputation and harm our business.

Our business exposes us to an inherent risk of potential product liability or similar claims. The pharmaceutical industry has historically been litigious, and we face financial exposure to product liability or similar claims if the use of any of our products were to cause or contribute to injury or death. There is also the possibility that defects in the design or manufacture of any of our products might necessitate a product recall. Although we plan to maintain product liability insurance, the coverage limits of these policies may not be adequate to cover future claims. In the future, we may be unable to maintain product liability insurance on acceptable terms or at reasonable costs and such insurance may not provide us with adequate coverage against potential liabilities. A product liability claim, regardless of merit or ultimate outcome, or any product recall could result in substantial costs to us, damage to our reputation, customer dissatisfaction and frustration and a substantial diversion of management attention. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

Security breaches and other disruptions could compromise our information, expose us to liability and harm our reputation and business.

In the ordinary course of our business we collect and store sensitive data, including intellectual property, personal information and our proprietary business information. The secure maintenance and transmission of this information is critical to our operations and business strategy. We rely on commercially available systems, software, tools and domestically available monitoring to provide security for processing, transmitting and storing this sensitive data.

Hackers may attempt to penetrate our computer systems, and, if successful, misappropriate personal or confidential business information. In addition, an associate, contractor or other third-party with whom we do business may attempt to circumvent our security measures in order to obtain such information, and may purposefully or inadvertently cause a breach involving such information. While we continue to implement additional protective measures to reduce the risk of and detect cyber incidents, cyber-attacks are becoming more sophisticated and frequent, and the techniques used in such attacks change rapidly.

Also, our information technology networks and infrastructure may still be vulnerable to damage, disruptions or shutdowns due to attack by hackers or breaches, employee error or malfeasance, power outages, computer viruses, telecommunication or utility failures, systems failures, natural disasters or other catastrophic events. Any such compromise could disrupt our operations, damage our reputation and subject us to additional costs and liabilities, any of which could adversely affect our business.

Risks Related to the Ownership of Our ADSs

The market price of our securities may be highly volatile, and you may not be able to resell your ADSs at or above the price you paid.

Our ADSs began trading on NASDAQ in March 2017 and you may not be able to sell your ADSs quickly or at the market price if trading in our ADSs is not active.

The market price of the ADSs is likely to be volatile. The ADS price could be subject to wide fluctuations in response to a variety of factors, including the following:

- adverse results or delays in preclinical studies or clinical trials;
- reports of adverse events in our product candidates or clinical trial failures of our product candidates;
- inability to obtain additional funding;
- any delay in filing a regulatory submission for any of our product or product candidates and any adverse development or perceived adverse development with respect to the review of that regulatory submission by the FDA or European or Asian authorities;
- failure to successfully develop and commercialize our products or product candidates;
- failure to enter into strategic collaborations;
- failure by us or strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to future products;
- inability to scale up our manufacturing capabilities through third-party manufacturers, inability to obtain adequate product supply for our products or the inability to do so at acceptable prices;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial expectations of the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our platform technologies, technologies, products or product candidates;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or shareholder litigation;
- changes in the market valuations of similar companies;
- sales of our securities by us or our shareholders in the future; and
- trading volumes of our securities.

In addition, companies trading in the stock market have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of the ADSs, regardless of our actual operating performance.

Our securities are traded on more than one market or exchange and this may result in price variations.

Our Ordinary Shares have been trading on the TASE since 2005, and the ADSs were quoted on the OTC Markets since 2014 and have been trading on the NASDAQ since March 2017. Trading in our Ordinary Shares and ADSs on these markets takes place in different currencies (U.S. dollars on the NASDAQ Capital Market and NIS on the TASE), and at different times (resulting from different time zones, trading days, and 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 Ordinary Shares on the TASE could cause a decrease in the trading price of our ADSs on the NASDAQ Capital Market.

Sales of a substantial number of our ADSs or Ordinary Shares in the public market by our existing shareholders could cause our share price to fall.

Sales of a substantial number of the ADSs or Ordinary Shares in the public market, or the perception that these sales might occur, could depress the market price of the ADSs or Ordinary Shares and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of the ADSs or Ordinary Shares.

The JOBS Act will allow us to postpone the date by which we must comply with some of the laws and regulations intended to protect investors and to reduce the amount of information we provide in our reports filed with the SEC, which could undermine investor confidence in our company and adversely affect the market price of the ADSs or Ordinary Shares.

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of certain exemptions from various requirements that are applicable to public companies that are not "emerging growth companies" including:

- the provisions of the Sarbanes-Oxley Act requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements; and
- our ability to furnish two rather than three years of income statements and statements of cash flows in various required filings.

We intend to take advantage of these exemptions until we are no longer an "emerging growth company." We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date of our first sale of equity securities pursuant to an effective registration statement under the Securities Act, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our Ordinary Shares that is held by non-affiliates exceeds $700 million as of the prior June 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We cannot predict if investors will find the ADSs or Ordinary Shares less attractive because we may rely on these exemptions. If some investors find the ADSs or Ordinary Shares less attractive as a result, there may be a less active trading market for the ADSs or Ordinary Shares, and our market prices may be more volatile and may decline.

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

Our status as a foreign private issuer also exempts us from compliance with certain SEC laws and regulations and certain regulations of the NASDAQ Stock Market, including the proxy rules, the short-swing profits recapture rules, and certain governance requirements such as independent director oversight of the nomination of directors and executive compensation. In addition, we will not be required under the Exchange Act to file current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act and we will generally be exempt from filing quarterly reports with the SEC. Also, although a recent amendment to the Companies Law will require us to disclose the annual compensation of our five most highly compensated senior officers on an individual basis, this disclosure will not be as extensive as that required of a U.S. domestic issuer. Furthermore, as a foreign private issuer, we are also not subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act.

These exemptions and leniencies will reduce the frequency and scope of information and protections to which you are entitled as an investor.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, results of operation or financial condition. In addition, current and potential shareholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of the ADSs.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. We will be required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which requires annual management assessments of the effectiveness of our internal control over financial reporting. In addition, if we fail to maintain the adequacy of our internal control, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. Disclosing deficiencies or weaknesses in our internal control, failing to remediate these deficiencies or weaknesses in a timely fashion or failing to achieve and maintain an effective internal control environment may cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of the ADSs. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed.

We may be a "passive foreign investment company", or PFIC, for U.S. federal income tax purposes in the current taxable year or may become one in any subsequent taxable year. There generally would be negative tax consequences for U.S. taxpayers that are holders of the ADSs or Ordinary Shares if we are or were to become a PFIC.

In general, we will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (1) at least 75% of our gross income is "passive income" or (2) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account. We believe that we may be deemed a PFIC for 2016. If we are a PFIC in any taxable year during which a U.S. taxpayer holds the ADSs or Ordinary Shares, such U.S. taxpayer would be subject to certain adverse U.S. federal income tax rules. In particular, if the U.S. taxpayer did 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 the U.S. taxpayer, and any gain realized on the sale or other disposition of the ADSs or Ordinary Shares by the U.S. taxpayer: (1) would be allocated ratably over the U.S. taxpayer's holding period for the ADSs or Ordinary Shares; (2) 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 (3) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, if the U.S. Internal Revenue Service, or the IRS, determines that we are a PFIC for a year with respect to which we have determined that we were not a PFIC, it may be too late for a U.S. taxpayer to make a timely QEF or mark-to-market election. U.S. taxpayers that have held the ADSs or Ordinary Shares during a period when we were 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. taxpayer who made a timely QEF or mark-to-market election. A U.S. taxpayer can make a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. We intend to make available to U.S. taxpayers upon request the information needed in order to complete IRS Form 8621 and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC. U.S. taxpayers that hold the ADSs or Ordinary Shares are strongly urged to consult their tax advisors about the PFIC rules, including tax return filing requirements and the eligibility, manner, and consequences to them of making a QEF or mark-to-market election with respect to the ADSs or Ordinary Shares in the event that we are a PFIC. See "Item 10.E. Taxation — U.S. Federal Income Tax Considerations — Passive Foreign Investment Companies" for additional information.

We have not paid, and do not intend to pay, dividends on our Ordinary Shares and, therefore, unless our traded securities appreciate in value, our investors may not benefit from holding our securities.

We have not paid any cash dividends on our Ordinary Shares since inception. We do not anticipate paying any cash dividends our Ordinary Shares in the foreseeable future. Moreover, the Companies Law imposes certain restrictions on our ability to declare and pay dividends. As a result, investors in the ADSs or Ordinary Shares will not be able to benefit from owning these securities unless their market price becomes greater than the price paid by such investors and they are able to sell such securities. We cannot assure you that you will ever be able to resell our securities at a price in excess of the price paid.

You may not receive the same distributions or dividends as those we make to the holders of our Ordinary Shares, and, in some limited circumstances, you may not receive dividends or other distributions on our Ordinary Shares and you may not receive any value for them, if it is illegal or impractical to make them available to you.

The depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on Ordinary Shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. You will receive these distributions in proportion to the number of Ordinary Shares your ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, conversion into U.S. dollars from foreign currency that was part of a dividend made in respect of deposited Ordinary Shares may require the approval or license of, or a filing with, any government or agency thereof, which may be unobtainable. In these cases, the depositary may determine not to distribute such property and hold it as "deposited securities" or may seek to effect a substitute dividend or distribution, including net cash proceeds from the sale of the dividends that the depositary deems an equitable and practicable substitute. We have no obligation to register under U.S. securities laws any ADSs, Ordinary Shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, Ordinary Shares, rights or anything else to holders of ADSs. In addition, the depositary may withhold from such dividends or distributions its fees and an amount on account of taxes or other governmental charges to the extent the depositary believes it is required to make such withholding. This means that you may not receive the same distributions or dividends as those we make to the holders of our Ordinary Shares, and, in some limited circumstances, you may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the ADSs.

Holders of ADSs must act through the depositary to exercise their rights as our shareholders.

Holders of the ADSs do not have the same rights of our shareholders and may only exercise the voting rights with respect to the underlying Ordinary Shares in accordance with the provisions of the deposit agreement for the ADSs. Under Israeli law, the minimum notice period required to convene a shareholders meeting is no less than 35 or 21 calendar days. When a shareholder meeting is convened, holders of the ADSs may not receive sufficient notice of a shareholders' meeting to permit them to withdraw their Ordinary Shares to allow them to cast their vote with respect to any specific matter. In addition, the depositary and its agents may not be able to send voting instructions to holders of the ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to holders of the ADSs in a timely manner, but we cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their ADSs. Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of the ADSs may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they requested. In addition, in the capacity as a holder of ADSs, they will not be able to call a shareholders' meeting.

You may be subject to limitations on transfer of your ADSs.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason in accordance with the terms of the deposit agreement.

We may be subject to securities litigation, which is expensive and could divert management attention.

In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could seriously hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our shares, the share price and trading volume of our securities could decline.

The trading market for the ADSs or Ordinary Shares will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts and we cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding our securities, or provide more favorable relative recommendations about our competitors, the price of our securities would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price or trading volume of our securities to decline.

Risks Related to Israeli Law and Our Operations in Israel

Our operations are subject to currency and interest rate fluctuations.

We incur expenses in U.S. dollars and NIS, but our financial statements are denominated in NIS and presented in NIS and have a convenience translation to U.S. dollars. NIS is our functional currency. The NIS is the currency that represents the principal economic environment in which we operate. As a result, we are affected by foreign currency exchange fluctuations through both translation risk and transaction risk. As a result, we are exposed to the risk that the NIS may appreciate relative to the dollar, or, if the NIS instead devalues relative to the dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected.

Provisions of Israeli law and our articles of association 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.

As a company incorporated under the law of the State of Israel, we are subject to Israeli corporate law. 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 such types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date on which a merger proposal is filed by each merging company with the Israel Registrar of Companies and at least 30 days have passed from the date on which the shareholders of both merging companies have approved the merger. In addition, a majority of each class of securities of the target company must approve a merger. Moreover, a tender offer for all of a company's issued and outstanding shares can only be completed if the acquirer receives positive responses from the holders of at least 95% of the issued share capital and a majority of the offerees that do not have a personal interest in the tender offer approves the tender offer, unless, following consummation of the tender offer, the acquirer would hold at least 98% of the company's outstanding shares. Furthermore, the shareholders may, at any time within six months following the completion of the tender offer, claim that the consideration for the acquisition of the shares does not reflect their fair market value, and petition an Israeli court to alter the consideration for the acquisition accordingly, other than those who indicated their acceptance of the tender offer in case the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek such appraisal rights, and the acquirer or the company published all required information with respect to the tender offer prior to the tender offer's response date. See "Item 10.B. Memorandum and Articles of Association — Provisions Restricting Change in Control of Our Company - Acquisitions under Israeli Law" for additional information.

Israeli tax considerations also 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 a number of conditions, including, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies may be subject to certain restrictions and additional terms. 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 disposition of the shares has occurred. See "Item 10.E. Taxation —Israeli Tax Considerations and Government Programs" for additional information.

It may be difficult to enforce a judgment of a United States court against us and our officers and directors and the Israeli experts named in this annual report on Form 20-F in Israel or the United States, to assert United States securities laws claims in Israel or to serve process on our officers and directors and these experts.

We were incorporated in Israel and our corporate headquarters are located in Israel. All of our executive officers and directors and the Israeli experts named in this annual report on Form 20-F are located in Israel. All of our assets and most of the assets of these persons are located in Israel. Therefore, a judgment obtained against us, or any of these persons, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not necessarily be enforced by an Israeli court. It also may be difficult to affect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel. Additionally, it may be difficult for an investor, or any other person or entity, to initiate an action with respect to United States securities laws in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of United States securities laws reasoning that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not United States law is applicable to the claim. If United States law is found to be applicable, the content of applicable United States law must be proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may not be able to collect any damages awarded by either a United States or foreign court.

Our headquarters and other significant operations are located in Israel, and, therefore, our results may be adversely affected by political, economic and military instability in Israel.

Our executive offices and our corporate headquarters are located in Israel. In addition, all of our officers and 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 neighboring Arab countries, the Hamas militant group and the Hezbollah. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. Since October 2000, there have been increasing occurrences of terrorist violence. In 2006, a conflict between Israel and the Hezbollah in Lebanon resulted in thousands of rockets being fired from Lebanon into Israel. In 2008, Israel engaged in an armed conflict with Hamas in the Gaza Strip, which involved missile strikes against Israel and negatively affected business conditions in Israel. In 2012, Israel experienced a similar armed conflict, resulting in hundreds of rockets being fired from the Gaza Strip. Most recently, in 2014, Israel yet again experienced rocket strikes against civilian targets in various parts of Israel, as part of an armed conflict commenced between Israel and Hamas. Ongoing and revived hostilities or other Israeli political or economic factors, such as, an interruption of operations at the Tel Aviv airport, could prevent or delay shipments of our components or products. If continued or resumed, these hostilities may negatively affect business conditions in Israel in general and our business in particular. In the event that hostilities disrupt the ongoing operation of our facilities or the airports and seaports on which we depend to import and export our supplies and product candidates, our operations may be materially adversely affected.

In addition, since 2010 political uprisings and conflicts in various countries in the Middle East, including Egypt and Syria, are affecting the political stability of those countries. It is not clear how this instability will develop and how it will affect the political and security situation in the Middle East. This instability has raised concerns regarding security in the region and the potential for armed conflict. In Syria, a country bordering Israel, a civil war is taking place. In addition, it is widely believed that Iran, which has previously threatened to attack Israel, has been stepping up its efforts to achieve nuclear capability. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza and Hezbollah in Lebanon. Additionally, the Islamic State of Iraq and Levant, or ISIL, a violent jihadist group, is involved in hostilities in Iraq and Syria and has been growing in influence. Although ISIL's activities have not directly affected the political and economic conditions in Israel, ISIL's stated purpose is to take control of the Middle East, including Israel. The tension between Israel and Iran and/or these groups may escalate in the future and turn violent, which could affect the Israeli economy in general and us in particular. Any potential future conflict could also include missile strikes against parts of Israel, including our offices and facilities. Such instability may lead to deterioration in the political and trade relationships that exist between the State of Israel and certain other countries. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions, could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business may sometimes decline to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. Several countries, principally in the Middle East, still restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities in Israel or political instability in the region continues or increases. Similarly, Israeli companies are limited in conducting business with entities from several countries. For instance, in 2008, the Israeli legislature passed a law forbidding any investments in entities that transact business with Iran. 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.

Our insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East or for any resulting disruption in our operations. Although the Israeli government has in the past covered the reinstatement value of direct damages that were caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained or, if maintained, will be sufficient to compensate us fully for damages incurred and the government may cease providing such coverage or the coverage might not suffice to cover potential damages. 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 generally and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. 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 conditions or the expansion of our business.

Your rights and responsibilities as a holder of our securities will be governed by Israeli law, which differs in some material respects from the rights and responsibilities of shareholders of U.S. companies.

The rights and responsibilities of the holders of our Ordinary Shares (and therefore indirectly the ADSs) are governed by our articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in typical U.S.-based corporations. In particular, a shareholder of an Israeli company has certain duties to act in good faith and fairness and in a customary manner in exercising its rights and performing its obligations towards 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 certain matters, such as an amendment to the company's articles of association, an increase of the company's authorized share capital, a merger of the company, and approval of related party transactions that require shareholder approval. A shareholder also has a general duty to refrain from discriminating against other shareholders. In addition, a controlling shareholder or 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 an officer of the company has a duty to act in fairness towards the company with regard to such vote or appointment. However, Israeli law does not define the substance of this duty of fairness. See "Item 6.C. Board Practices —Duties of Shareholders" for additional information. There is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations on holders of our Ordinary Shares that are not typically imposed on shareholders of U.S. corporations.

We received Israeli government grants for certain of our past research and development activities and programs, some of which we sold or are in the process of selling. The terms of such grants may require us, in the future, to pay royalties and to satisfy specific conditions if and to the extent we receive future royalties or in order to complete the sale of such grant based technologies and programs. We may be required to pay penalties in addition to payment of the royalties.

Our research and development efforts with respect to some of our past activities, including our previous immunotherapy programs such as the BBS Technology, which was focused on developing an immunotherapeutic monoclonal antibody for the treatment of Alzheimer's, which we sold in March 2015, and our Anti-CD3 technology directed toward the treatment of inflammatory and autoimmune diseases, which is in the process of being sold, were financed in part through royalty-bearing grants from the Israeli Innovation Authority, or the IIA, formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry. As of December 31, 2016, we have received the aggregate amount of approximately $4.1 million from the IIA for the development of our abovementioned technologies. With respect to such grants we are committed to pay certain royalties up to $1.1 million relating only to technologies in our possession and excluding any royalties for technologies that we sold to third parties. We are required to comply with the requirements of the Israeli Encouragement of Research, Development and Technological Innovation in the Industry Law, 5744-1984, as amended, and related regulations, or the Research Law, with respect to these past grants. The discretionary approval of an IIA committee would be required for any assignment and/or transfer to third parties inside or outside of Israel of know-how or transfer outside of Israel of manufacturing or manufacturing rights related to those aspects of such activities and programs (including selling it). We may not receive these approvals. Although we do not believe that these requirements will materially restrict us in any way, the IIA may impose certain conditions on any arrangement under which it permits us to transfer or assign technology or development in or out of Israel. If we fail to comply with the Research Law, we may be required to refund certain grants previously received and/or to pay interest and penalties and we may become subject to criminal charges. None of our current projects in the field of cannabinoid therapeutics are supported by the IIA, yet if eligible, we may apply for such support in the future.

We are in the process of selling one of our past research and development activities which may not be completed due to factors not in our control, and we may be required to assume the sale activity or abandon it, subject to certain payments and liabilities.

In June 2016, we entered into a share transfer agreement with our former subsidiary, Orimmune Bio Ltd., or Orimmune, and Karma Link Ltd., or Karma Link, a private company incorporated under the laws of the State of Israel. According to the agreement, we sold our holdings in Orimmune to Karma Link and will assist the assignment of the antibody Anti-CD3 technology (which was in-licensed by us from Hadasit Medical Research Services & Development Ltd., or Hadasit, and certain internally developed assets and technology relating thereto). We are assisting Karma Link with the activities related to the assignment of the license with all relevant parties and authorities. Although failure to complete the assignment will not constitute a breach of the agreement by us, such failure may obligate us to decide whether to continue with the program (including continuing the search for other potential collaborators for the assignment of the license) or to abandon the license pursuant to the provisions of the original license agreement with Hadasit. In either of such events, we may bear certain payments and liabilities to third parties including the IIA. To date, IIA has declined our request for a joint ownership registration with Hadasit of the patent underlying the assets, according to the license agreement with Hadasit due to IIA's claim that such registration is not in compliance with the IIA rules regarding use of its grants. We are currently negotiating the issues with IIA in order to facilitate the transfer.

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

Our employees and consultants in Israel, including members of our senior management, may be obligated to perform one month, and in some cases longer periods, of military reserve duty until they reach the age of 40 (or older, for citizens who hold certain positions in the Israeli armed forces reserves) and, in the event of a military conflict or emergency circumstances, may be called to immediate and unlimited active duty. In the event of severe unrest or other conflict, individuals could be required to serve in the military for extended periods of time. 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 similar large-scale military reserve duty call-ups in the future. Our operations could be disrupted by the absence of a significant number of our officers, directors, employees and consultants related to military service. Such disruption could materially adversely affect our business and operations. Additionally, the absence of a significant number of the employees of our Israeli suppliers and contractors related to military service or the absence for extended periods of one or more of their key employees for military service may disrupt their operations.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our legal and commercial name is Therapix Biosciences Ltd. We were incorporated in the State of Israel on August 23, 2004, and are subject to the Companies Law. In December 26, 2005, we became a public company in Israel and our shares were listed for trade on the TASE. Our Ordinary Shares are currently traded on the TASE under the symbol THXBY. Our ADSs representing our Ordinary Shares currently trade in the United States on the NASDAQ Capital Market under the symbol "TRPX".

Our registered office and principal place of business is located at 5 Azrieli Center (Square Tower) Tel-Aviv 6702501, Israel. Our telephone number in Israel is: +972-3-6167055.

Our website address is http://therapixbio.com. The information contained on our website or available through our website is not incorporated by reference into and should not be considered a part of this annual report on Form 20-F, and the reference to our website in this annual report on Form 20-F is an inactive textual reference only. Zysman, Aharoni, Gayer and Sullivan & Worcester LLP is our agent in the United States, and its address is 1633 Broadway, New York, NY 10019.

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the JOBS Act. As such, we are eligible to, and intend to, take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not "emerging growth companies" such as not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. We could remain an "emerging growth company" for up to five years, or until the earliest of (a) the last day of the first fiscal year in which our annual gross revenue exceeds $1 billion, (b) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of the ADSs that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (c) the date on which we have issued more than $1.07 billion in nonconvertible debt during the preceding three-year period.

We are a foreign private issuer as defined by the rules under the Securities Act and the Exchange Act. Our status as a foreign private issuer also exempts us from compliance with certain laws and regulations of the SEC and certain regulations of the NASDAQ Stock Market, including the proxy rules, the short-swing profits recapture rules, and certain governance requirements such as independent director oversight of the nomination of directors and executive compensation. In addition, we will not be required to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies registered under the Exchange Act.

Our capital expenditures for 2016, 2015 and 2014 amounted to NIS 16,000 (approximately $4,000), NIS 4,000 and NIS 2,000, respectively. These expenditures were primarily for purchases of fixed assets. Our purchases of fixed assets primarily include, computers, and equipment used for the development of our products, and we financed these expenditures primarily from cash on hand.

B. Business Overview

Overview

We are a specialty clinical-stage pharmaceutical company led by an experienced team of senior executives and scientists, focused on creating and enhancing a portfolio of technologies and assets based on cannabinoid pharmaceuticals. With this focus, we have initiated two internal drug development programs based on repurposing an FDA approved synthetic cannabinoid (dronabinol): *Joint Pharma* developing THX-TS01 targeted to the treatment of TS and *BrainBright Pharma* developing THX-ULD01 targeted to the high value and under-served market of MCIs.

We intend to seek FDA approval for the commercialization of our drug candidates through the Section 505(b)(2) regulatory pathway under the Federal Food, Drug, and Cosmetic Act of 1938, as amended, or the FDC Act. The FDA's 505(b)(2) regulatory pathway permits the filing of a new drug application, or NDA, where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference. See "—Clinical Strategy and Preclinical Results." This approach could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. In addition, with respect to our Joint Pharma program, we intend to pursue orphan drug designation in the United States and Europe. In June 2016, we submitted a request for orphan drug designation to the FDA for THX-TS01 for the treatment of TS. In a letter dated September 29, 2016, the FDA informed us that our request cannot be granted at this time, and is being held in abeyance until and subject to us providing additional information pertaining to the overall prevalence of TS in both children and adults, and further clinical data to support our scientific rationale for our request for orphan drug designation within 12 months. We intend to respond within the 12 month period, or during any extension thereof.

Joint Pharma

Our Joint Pharma program is dedicated to developing a cannabinoid based drug for the treatment of TS, which is an inherited neuropsychiatric disorder usually onset in childhood. TS is characterized by multiple physical (motor) tics and at least one vocal (phonic) tic. Although TS and other tic disorders were once thought to be very rare, it has become increasingly apparent that they are common conditions. While epidemiological study results may vary, according to the U.S. Centers for Disease Control and Prevention, or the CDC, as of 2012, one out of every 360 U.S. children (about 138,000) aged six to 17 years had been diagnosed with TS in the United States. To date, only three drugs have been approved by the FDA to treat TS, most of which are limited to treating only a narrow range of TS symptoms (mainly tics). Additionally, the usefulness of these drugs is also limited, since they are associated with severe side effects that have resulted in the need for a "black box" warning. In many cases "off-label" use of prescription medications not approved for the indication are associated with unwanted severe side effects that, in our opinion, are also detrimental. Therefore, we believe there continues to be a great need for more effective, safer medications targeted at treating tics as well as other features of TS.

We believe our proprietary THX-TS01 drug candidate takes a unique approach to the treatment of TS. THX-TS01 is a combination drug candidate based on two components: (1) dronabinol, the active ingredient in an FDA approved synthetic analog of tetrahydrocannabinol, or THC, which is the psychoactive molecule in the cannabis plant, and (2) palmitoylethanolamide, or PEA, which is an endogenous fatty acid amide that belongs to the class of nuclear factor agonists, which are proteins that regulate the expression of genes. We believe that the combination of THC and PEA may induce a reaction known as the "entourage effect."

The basic tenet of the entourage effect is that cannabinoids work together, or possess synergy, and affect the body in a mechanism similar to the body's own cannabinoid system, which is a group of molecules and receptors in the brain that mediates the psychoactive effects of cannabis. This entourage effect may account for the pharmacological actions of PEA. Based on an activity enhancement of other physiological compounds, PEA may indirectly stimulate the cannabinoid receptors by potentiating their affinity for a receptor or by inhibiting their metabolic degradation, and by doing so, may increase the uptake of cannabinoid compounds, such as THC. Thus, we believe that the presence of the PEA molecule likely increases the efficacy of orally administered THC, while reducing the required dosage and decreasing associated deleterious adverse events.

We have completed the preclinical phase of development of THX-TS01 and recently initiated a proof of concept, or POC, Phase IIa clinical trial in the United States. In addition, we expect to initiate a Phase IIb clinical trial in Europe in the third quarter of 2017.

BrainBright Pharma

Our BrainBright Pharma program takes a unique approach to developing a treatment for MCI. MCI refers to the transitional state between the cognitive changes of normal aging and very early dementia. Signs of MCI have also been observed with respect to sports-related brain injuries. It can involve problems with memory, language, thinking and judgment that are greater than normal changes related to age. According to the Mayo Clinic Study of Aging published in 2008, the prevalence of MCI increases with age, at a rate of 10% in those aged 70-79 years and 25% in those aged 80-89 years. There is no FDA approved treatment for MCI. As MCI is believed to represent an early state of Alzheimer's, several Alzheimer's treatments have been proposed for MCI. However, Alzheimer's treatments are not currently widely recommended by the medical community for the routine treatment of MCI, and have not been shown to delay or prevent the progression of MCI.

Our proprietary THX-ULD01 drug candidate is based on an ultra-low dose of FDA approved dronabinol. While the safety and efficacy of drug delivery methods are solely FDA determinations, we believe that both sublingual and nasal administration of dronabinol present several advantages over alternative administration routes, such as oral administration, and may enhance the bioavailability, or the rate and extent of the drug when it reaches the site of action, of an ultra-low dose dronabinol. Sublingual administration has certain advantages over oral administration. For example, it is often faster and it ensures that the substance will risk degradation only by salivary enzymes before entering the bloodstream, whereas orally administered drugs must survive passage through the hostile environment of the gastrointestinal tract, which risks degrading them, either by stomach acid or bile, or by the many enzymes therein. Furthermore, after absorption from the gastrointestinal tract, such drugs must pass to the liver, where they may be extensively altered; this is known as the first pass effect of drug metabolism. Similar advantages can be found in nasal drug administration as the nasal cavity is covered by a thin well vascularized mucosa and therefore, a drug molecule can be transferred quickly across the single epithelial cell layer directly to the systemic blood circulation without first-pass hepatic (i.e., through the liver) and intestinal metabolism.

We have preclinical data that suggests that using an ultra-low dose of dronabinol may improve cognitive abilities. In the second quarter of 2017, we intend to conduct a Phase I clinical trial to document the pharmacokinetic parameters of THX-ULD01 and to evaluate drug safety. During the first half of 2018 we expect to initiate a POC Phase IIa clinical trial to evaluate safety, tolerability and efficacy of THX-ULD01 in treating patients with cognitive impairment. In addition, we may conduct further preclinical studies in parallel to our clinical plans as part of the development of our innovative pipeline and for registration purposes.

With respect to both our Joint Pharma and BrainBright Pharma programs, we intend to pursue a section 505(b)(2) regulatory path, which may expedite the development of these programs by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. We believe that the key benefits of this strategy include a relatively low scientific-technological risk (compared to the risk of developing drugs based on new molecular entities) combined with relatively low costs and fast time to market.

Other indications

Cannabis and cannabinoids have great therapeutic potential and have been used for years for medicinal purposes. For example, cannabis and cannabinoids are being used to improve the quality of life of patients with numerous and diverse indications (oncological patients, chronic pain conditions, etc.). We believe that the novel approaches and unique mechanism of action of our proprietary technology platforms, including our drug delivery systems and unique combination and specific dosages, may be expanded to treat additional diseases and unmet medical needs.

In November 2016, we signed a non-binding memorandum of understanding for strategic cooperation with Rafa Laboratories Ltd., or Rafa, for the purpose of conducting a proof-of-concept clinical trial for a cannabinoid based product candidate to treat various medical indications characterized by lower abdominal pain. Similar to our Joint Pharma program for the treatment of TS, we plan to make use of our licensed entourage technology for the purpose of integrating PEA with dronabinol. According to the non-binding memorandum of understanding and subject to entry into a definitive agreement, Rafa will supply us with dronabinol for conducting the clinical trial, and will bear the costs of, and manage the logistical and regulatory aspects related to the clinical trial, and we will (i) bear all costs and expenses associated with the performance of the trial and the development and manufacturing of the PEA, and (ii) provide Rafa with an exclusive worldwide (excluding North America) right to manufacture the product candidate, and the right to market the product candidate in Israel, with respect to medical indications characterized by lower abdominal pain.

In January 2017, we announced that we intend to initiate an additional program in the area of antimicrobial therapies. Our objective is to use our entourage technology in association with THC to increase the efficacy of existing antibiotic drugs especially in antibiotic-resistant bacteria strains. The resistance to antimicrobials has become a global hazard. We believe that there is an urgent need for the development of novel antimicrobial agents. THC has been shown to have a wide range of important biological activities, including potential antibacterial activity. This antimicrobial program is currently in a preliminary stage. We intend to explore the potential of our technology in this program through low cost research and development activities prior to investing any meaningful capital into this program.

In addition, in March 2017, we announced that we signed an additional non-binding memorandum of understanding with Rafa regarding the formation of a joint venture to research and develop a cannabinoid-based drug for the treatment of toothaches and various periodontal diseases. According to this non-binding memorandum of understanding and subject to entry into a definitive agreement, we, Rafa and a third party delivery technology manufacturer to be decided, will invest seed capital in the venture in consideration for holdings therein, according to a ratio and percentage that were determined in the memorandum of understanding. The joint venture will raise capital, as necessary for its activity, and will bear all of the expenses and payments related to the research and development of the drug, the performance of the clinical trials, and the manufacture and marketing of the drug. The joint venture shall own all the intellectual property rights related to the product. Rafa will receive an exclusive right to manufacture the drug in the aforesaid indications in certain territories, and a right to offer supply of the drug in additional territories, as well as an exclusive right to market it in Israel. Pursuant to the memorandum of understanding, we will only invest an immaterial amount into the venture. In the end of March 2017, we and Rafa signed a joinder to the non-binding memorandum of understanding according to which Sanmmand Pharmaceuticals BV has joined to a non-binding memorandum of understanding as the third party of the joint venture as the delivery technology manufacturer.

In the future, we may consider expanding our pipeline to include these additional indications.

Our Technology and Unique Approach to Drug Development

The Entourage Effect

Cannabinoids are a diverse group of chemical compounds that operate on specific receptors in the body. Cannabinoids participate in a large number of physiological processes and are used for treating a wide range of medical conditions. Cannabinoids have been proven as pain relievers and anti-inflammatory, prevent nausea and enhance appetite and are therefore widely used among cancer patients who undergo chemotherapy. Other uses include mental health and psychological conditions such as posttraumatic stress disorder and anxiety. Cannabinoid compounds have also found to be effective in treating epilepsy, Parkinson's disease, cancer and multiple sclerosis.

In 1998, Prof. Raphael Mechoulam, Israel Prize laureate, known for his pioneer work in the isolation, structure elucidation and total synthesis of THC, described what he referred to as the "entourage effect," which explains how an allegedly inactive compound synergizes with an active cannabinoid. The entourage effect represents a novel endogenous cannabinoid molecular regulation route. The basic idea of the entourage effect is that cannabinoids work better together, and may affect the body in a manner similar to the body's own endocannabinoid system, which may lead to a synergistic pharmacological effect, due to: (i) the ability to affect multiple targets within the body; (ii) improvement of absorption of active ingredients; (iii) ability to overcome bacterial defense mechanism; and/or (iv) minimizing adverse side effects. Entourage effect research has greatly focused on PEA, which is part of the endocannabinoid family and derived from fatty acids. PEA has additional pharmacological benefits such as relieving pain and inflammation.

According to a paper published by the Italian Department of Addiction & Mental Health, PEA has been shown to possess anti-craving effects in cannabis dependent patients, is efficacious in the treatment of withdrawal symptoms, and is effective in the prevention of cannabis induced neurotoxicity and neuro-psychiatric disorders. Moreover, we believe that because of PEA's ability to stabilize mucosal mast cells and to prevent their degranulation, by combining THC therapy with PEA, one can overcome the over-sensitization/irritation to the respiratory tract that THC may cause. PEA is not considered to be an API by the FDA. PEA is naturally occurring in various food sources such as egg yolk, soybeans and milk. In parts of Europe, PEA derived products (e.g., Normast® and Pelvilen®) have been marketed as a food for special medical purposes. In April 2015, Health Canada added PEA to its list of Natural Health Products, a class of health products which includes vitamins, mineral supplements, herbal preparations, traditional and homeopathic medicines, probiotics and enzymes.

Several lines of evidence suggest that cannabis and THC may be effective in the treatment of tic disorders. Unfortunately, due to adverse psychoactive side effects involved with cannabis and high dosages of THC, cannabis has not become a viable treatment option for TS and other tic related disorders. We believe that in order to harness the therapeutic potential of THC for the treatment of TS, there is a need to reduce the accompanied adverse effects.

We intend to stimulate the entourage effect to maximize the therapeutic benefits of dronabinol to reduce tics, with decreased adverse and psychoactive effects. The capacity of PEA to exert "entourage effects" comes from its ability to affect multiple targets within the body, improve the absorption rate of active ingredients and minimize adverse side effects.

The Ultralow Dose Technology

Preclinical studies conducted in recent years by Prof. Yosef Sarne at the Tel-Aviv University Faculty of Medicine found that an ultralow dose of THC protects the brain from different degrees of long-term cognitive impairment which is liable to occur as a result of lack of oxygen supply, seizures or use of drugs. Prof. Sarne's research of preclinical models demonstrated that an ultralow dose of THC injected to small animals one to seven days before the injury to the brain can prevent the development of damage. Treatment with an ultralow dose triggers defense mechanisms in the brain such as enhanced production of nerve growth factor, or brain-derived neurotrophic factor (related to the canonical nerve growth factor), that protect the brain's nerve cells and retain long-term cognitive capabilities. The research conducted by Prof. Sarne and his colleagues revealed that ultralow doses of THC can affect brain cell signals, prevent cell death and encourage the release of growth factors. Accordingly, we believe that an ultralow dose of dronabinol may be an effective treatment for MCI.

MCI often refers to the transitional state between the cognitive changes of normal aging and very early dementia, and can involve problems with memory, language, thinking and judgment that are greater than normal changes related to age. MCI has been proposed as a condition of intermediate symptomatology between the cognitive changes of aging and fully developed symptoms of dementia, such as those seen in Alzheimer's. Although MCI can present with a variety of symptoms, when memory loss is the predominant symptom it is frequently seen as a prodromal stage of Alzheimer's. Signs of MCI have also been observed with respect to sports-related brain injuries.

To the best of our knowledge, there is no approved medicinal treatment for MCI. While it was once thought that Alzheimer's drugs may present a viable treatment option for MCI patients, clinical trials have failed to demonstrate that any of these drugs delay or prevent the progression of MCI, and Alzheimer's treatments are not currently widely recommended by the medical community for the routine treatment of MCI. We seek to develop the first effective solution for MCI based on a significantly lower dose of FDA approved dronabinol as compared to other FDA approved drugs.

Our Initial Disease Targets and Market Opportunity

Tourette Syndrome

TS is a neuropsychiatric disorder, characterized by physical (motor) tics and vocal (phonic) tics. Motor or phonic tics are sudden, brief, intermittent, involuntary or semi-voluntary movements or sounds, respectively. They typically consist of brief, coordinated, repetitive movements, gestures, or utterances that mimic fragments of normal behavior.

Motor tics may range from simple tics, including eye blinking, nose twitching, facial grimacing, shoulder shrugging, neck stretching and head jerking, to more complex tics, including throwing, hitting, or making rude gestures. Phonic tics include sniffling, grunting, throat clearing, blowing or coughing but can develop into words or parts of words including coprolalia (uttering swear words). According to a paper published in 2009 by researchers affiliated with the Yale University School of Medicine, tic symptoms of TS typically manifest between 4 and 6 years of age, and peak in severity between the ages of 10 and 12 years. However, they often improve over the course of adolescence. Motor tics generally precede the development of phonic tics in TS, and the onset of simple tics usually predates that of complex tics.

TS appears in a wide range of tics severity, from mild symptoms that do not cause serious impairment and often go unnoticed, to loud noises and forceful movements that can result in self-injury. The most dramatic and disabling tics are those that result in self-harm such as punching oneself in the face, or vocal tics including echolalia (repeating other people's words), or coprolalia. Many with TS experience additional neurobehavioral problems and comorbidities including inattention, hyperactivity and impulsivity, anger control problems, sleep difficulties (including motor and vocal tics during all stages of sleep, sleep apnea, abnormal arousal pattern, and other sleep disturbances) and obsessive-compulsive symptoms, such as intrusive thoughts/worries and repetitive behaviors. Due to the potentially disabling nature of the physical symptoms, some patients face problems with daily activities, beyond those caused by the social stigma associated with the disorder. Pharmacotherapy is used when symptoms are more severe and interfere with the ability to function. Furthermore, according to the CDC, in most cases, the prevalence of tics decrease during adolescence and early adulthood, and sometimes disappear entirely; therefore adults with TS are very limited in numbers and usually manifest mainly moderate to severe TS symptoms.

Market Size

The exact number of people with TS is unknown. The prevalence of TS and TS symptoms is greater in children than adults. CDC scientists recently used data from the 2011-2012 National Survey on Children's Health, or NSCH, to estimate that one out of every 360 children between the ages of six through 17 have been diagnosed with TS in the United States. This accounts for an estimated 138,000 children.

Most cases of TS are mild and do not require pharmacological treatment. In these cases, psycho-behavioral therapy, education, and reassurance may be sufficient. According to the 2011-2012 NSCH data, among children with current TS, 63% were reported to have mild TS and 37% were reported as having moderate or severe forms of the condition. Thus, approximately 35,000 children in the U.S. had moderate or severe TS in 2011-2012.

We intend to pursue Orphan Drug designation with the FDA and European Commission for THX-TS01 for the treatment of TS.

Current Treatment

Pharmacological intervention is considered the first line of therapy for TS, but is reserved for more severe symptoms that interfere with the individual's ability to function. Investigation of pharmacological therapies in TS started with the work of Arthur Shapiro and his colleagues in the 1960s and 1970s, which showed that the dopamine activity blocker, haloperidol, reduces tic severity. Today, a full class of drugs that interact with dopamine and non-dopamine systems in the brain are used in the treatment of TS symptoms. Many of the drugs used to treat TS are limited to the treatment of a narrow range of TS symptoms (mainly tics), and are associated with severe side effects, both of which limit their usefulness. Furthermore, several of these drugs have a black box warning on their label due to their potentially lethal effect. A black box warning is the strictest warning put in the labeling of prescription drugs or drug products by the FDA when there is reasonable evidence of an association of a serious hazard with the drug.

The medications commonly used to treat symptoms of TS can be divided into the following groups:

- Antipsychotic medications: belong to a class of drugs primarily used to manage psychosis. Of these, haloperidol and pimozide are approved for use in TS patients and aripiprazole is approved for use in TS pediatric patients. Fluphenazine is another antipsychotic medication that is often used to treat TS, off-label. The effectiveness of these drugs are limited to reducing tics. These drugs are associated with severe side effects. Common side effects of antipsychotics include: weight gain, sedation, akathisia (a state of agitation, distress, and restlessness), nausea and tardive dyskinesia (involuntary movements of the face and jaw). Other side effects associated with the use of antipsychotics may lead to lethal consequences. Some of these side effects may not disappear when the medication is discontinued.
- Alpha2 Adrenergic Agonists: belong to a class of drugs primarily used to manage hypertension and migraine headaches prevention. Clonidine and guanfacine are used off-label for the reduction of tics in TS patients. Their usefulness was found to be limited, with modest favorable effects in children with Attention Deficit Hyperactivity Disorder, or ADHD. These drugs are often used in TS, given their improved tolerability when compared to antipsychotics. Yet, the exposure to these drugs is also associated with a wide list of side effects, and some of them, such as clonidine, might even be lethal.
- Benzodiazepines, an anticonvulsant or antiepileptic drug: belong to a class of drugs primarily used to manage seizures, panic disorder and movement disorders. Of these, cloazepam is used off-label for the reduction of tics in TS patients. The exposure to these drugs is also associated with a series of negative side effects.

As the currently used medications are managing only a small number of disease symptoms with limited efficacy and questionable safety, there is a clear unmet medical need for the management of TS.

Mild Cognitive Impairment (MCI)

MCI is a brain function syndrome involving the onset and evolution of cognitive impairments. It can involve problems with memory, language, thinking and judgment that are greater than normal age-related changes. MCI has been proposed as a condition of intermediate symptomatology between the cognitive changes of aging and fully developed symptoms of dementia, such as those seen in Alzheimer's. Recently MCI has been given more specific criteria as it was recognized that MCI is a heterogeneous condition. The most relevant population for our product is the amnestic subtype of MCI, in which memory impairment is a key feature. In general, this population is characterized by a subset of individuals with MCI who are likely to progress to clinically probable Alzheimer's.

Market Size

According to data published by the Information Resources Management Association, the prevalence of MCI in the United States ranges between 3%-4% of the general population in their eighth decade. Amongst community-dwelling African Americans, the estimated prevalence is 19.2% for those aged 65-74 years, 27.6% for those aged 75-84 years, and 38% for those aged 85 years and older. The prevalence of mild cognitive impairment increases with age, at a rate of 10% in those aged 70-79 years and 25% in those aged 80-89 years. Many studies indicate that the risk of developing Alzheimer's is significantly higher in women than in men, and it is therefore presumed that the likelihood of developing MCI is greater in women than in men.

MCI refers to the gradual, progressive, and transitional state between the cognitive changes of normal aging and very early dementia. Dementia is a syndrome caused by a number of progressive illnesses that affect memory, thinking behavior and the ability to perform everyday activities. It mainly affects older people, though 2% to 10% of all cases are estimated to start before the age of 65. After that, the prevalence doubles with every five year increment in age. According to the World Alzheimer Report 2015, as of 2015, there were an estimated 46.8 million people with dementia worldwide. According to the World Alzheimer Report 2015, this number is estimated to increase by 2030 to an estimated 74.7 million. Delaying or preventing the transition between MCI and dementia could potentially affect the prevalence of dementia in the general population.

Also according to the World Alzheimer Report 2015, the global societal economic cost of dementia for 2015 is estimated at $818 billion, a 35% increase from the cost estimate for 2010, which was $604 billion. Projecting this trend forwards, the estimation is that the global cost of dementia will reach $1 trillion in 2018. Around half of this increase can be attributed to growth in the numbers of people with dementia, and half to increases in per capita costs, particularly in low and middle income countries.

Current Treatment

There is no FDA approved treatment or therapy for MCI. As MCI may represent an early state of Alzheimer's, several treatments proposed for Alzheimer's, such as cholinesterase inhibitors, have been proposed for MCI. However, clinical trials have failed to demonstrate that any of these drugs delay or prevent the progression of MCI, and Alzheimer's treatments are not currently widely recommended by the medical community for the routine treatment of MCI. Furthermore, there are some indications that cognitive decline of MCI patients may be accelerated by using Alzheimer's drugs.

Medicinal Cannabis Market

The medicinal cannabis market is an important and evolving segment in global medical therapy. The growing awareness of the medicinal benefits of the active cannabinoids in the plant and its use for improving the quality of life of patients with numerous and diverse indications (oncological patients, chronic pain conditions etc.), as well as the global trends of regulatory changes relating to the use of the plant and of cannabinoids, have all led to a rapid growth in this market. The recent changes in the perception of medicinal cannabis and the scientific and medical acknowledgement of its benefits have created a growing need for more efficient drugs with an improved tolerance profile. The market for medicinal cannabis (and its medical substitutes) is estimated at approximately $2 billion per year in the United States alone and is expected to continue showing significant growth in the coming years.

During the past five years, the medical cannabis industry has experienced high growth rates due to increasingly favorable conditions across the United States, including support from the general public and state legislators for legislation legalizing the use of medical cannabis. In the United States, the combined retail and wholesale cannabis industry (both medical and recreational) grew by 80%, from $1.5 billion in 2013 to $2.7 billion in 2014, firmly establishing cannabis as one of the fastest growing industries in America. According to the 2014 edition of the Marijuana Business Factbook, U.S. retail cannabis sales are expected to triple in the next five years to approximately $8.2 billion by 2018.

The Canadian market for medicinal use was estimated at $144 million in 2014, and is expected to reach $380 million by 2018. The growth rate is expected to reach 25% per annum, which will bring the market to $1.4 billion within the next ten years. According to a recent Health Canada projection, the Canadian market has grown from 500 authorized users in 2002 to more than 40,000 authorized users in 2014, and official forecasts predict that approved patients will grow to over 1.2% of the total population in ten years, reaching more than 400,000 patients by 2024.

Clinical Strategy and Preclinical Results

Our strategy is to build a leading specialty pharmaceutical company focused around the repurposing, repositioning and improvement of FDA approved cannabinoid molecules for various indications, including TS and MCI. The key benefits of this strategy include a relatively low scientific-technological risk (compared to the risk of developing drugs based on new molecular entities) combined with relatively low costs and fast time to market achieved through fast-track regulatory paths.

With respect to both our Joint Pharma and BrainBright programs, we intend to seek regulatory approval through the FDA's 505 (b)(2) regulatory path. The FDA's 505(b)(2) regulatory pathway permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference. We intend to rely both on published literature and upon the FDA's finding of safety and effectiveness for a previously approved drug product – dronabinol (trade name Marinol®). As we intend to use either the same or a lower dose of dronabinol compared to other FDA approved drugs, we believe that we will be able to rely upon the general safety findings of these other approved dronabinol products. This approach could expedite the development program for our product candidates by potentially decreasing the amount of clinical data regarding safety that we would need to generate in order to obtain FDA approval. The safety literature for dronabinol indicates that serious, uncommon side-effects include seizure, paranoia, disorganized/unusual behavior and tachycardia, or an abnormally rapid heart rate. We expect to use AbbVie, Inc.'s Marinol® (dronabinol) as the reference drug for 505(b)(2) regulatory path purposes. Marinol® is a registered trademark of Unimed Pharmaceuticals, Inc., and was initially approved by the FDA in May 1985 for use in nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments and in December 1992 for anorexia associated with weight loss in patients with acquired immune deficiency syndrome, or AIDS.

Furthermore, we have submitted a request for Orphan Drug designation from the FDA for our Joint Pharma program. This request is still being held in abeyance. We intend to pursue orphan designation with the European Commission.

Joint Pharma Strategy

We are currently conducting a 12-week POC Phase IIa investigator initiated clinical trial in the United States. Our collaborators from Yale University submitted an IND for this trial, and we received a "study may proceed" notification from the FDA. In November 2016, the Yale University IRB approved the trial protocol, and in December 2016, the first patient was enrolled. The proposed trial will evaluate the safety, tolerability and efficacy of THX-TS01 in treating approximately 18 TS subjects aged 18 to 60 that meet Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition criteria for the diagnosis of TS. Severity of tics and disease, common comorbid symptoms such as Obsessive Compulsive Disorder, or OCD, ADHD, depression and anxiety severity will also be assessed. Study patients will receive oral THX-TS01 once daily for the duration of the study. The overall estimated study duration is 10-12 months.

The primary efficacy endpoint is the change from baseline to end of 12 weeks treatment in the Yale Global Tic Severity Scale Total Tic Score, which is a clinical rating instrument designed to provide an evaluation of tic severity. Secondary efficacy endpoints include demonstrating the safety and tolerability of THX-TS01 and to evaluate the benefit of THX-TS01 on premonitory urges, quality of life, disease severity, and comorbidities including ADHD, OCD, depression and anxiety.

We expect to initiate a similar 13-week Phase IIb trial in Europe in the third quarter of 2017. The investigator initiated study will include approximately 20 patients. The proposed Phase IIb trial will be a randomized, double-blind, parallel-group, placebo-controlled study. Study patients will be randomized to either oral THX-TS01 or placebo at a 1:1 ratio. The overall estimated study duration is 10-12 months. We may also conduct further preclinical studies in parallel to our clinical plans as part of registration process. Based on these studies, we intend to conduct a Phase III, multinational, multicenter, randomized, double-blind, parallel-group, placebo controlled study to evaluate the safety, tolerability and efficacy of up to twice daily oral THX-TS01 in treating TS.

Joint Pharma Preclinical Data

We have completed the preclinical phase of testing for TS. We have completed a POC study to evaluate the entourage effect of PEA and dronabinol in a murine (mice) model. In the study PEA was co-administered with THC. Animals were measured for the following facets of behavior: (i) total distance traveled, (ii) velocity, and (iii) time spent in the center of the arena. Total distance traveled may indicate the overall change in animal behavior, where increased values indicate agitation, while decreased values may indicate calmness. Results showed that THC alone did not affect the total distance traveled but PEA in combination with THC reduced the total distance traveled. We believe that these results indicate the effect of PEA on stress reduction. With respect to velocity, an increase in average animal velocity may indicate uncontrolled movement. Results showed that high doses of THC (50 mg/kg) led to an increase in average animal velocity in treated mice whereas addition of PEA to high dose THC treatment resulted in a slight reduction and normalization of this effect. Low dose THC (12.5 mg/kg) did not affect animal velocity and was comparable to control, while the addition of PEA was found to further reduce this value. Reduction in time spent in the arena may indicate increased anxiety of the animal. A high dose of THC significantly reduced the value of time spent in the center of the arena, as compared to the control group, suggesting that a high dosage of THC increased anxiety in the test subject. Co-administration of PEA with high dose THC markedly increased this value, bringing it back, close to the value observed in control mice. We believe that this may indicate that PEA prevents high dose THC-induced anxiety.

BrainBright Pharma Strategy

In the second quarter of 2017, we intend to conduct an open-label Phase I clinical trial in Canada or the United States, to document the pharmacokinetic parameters of THX-ULD01 and to evaluate drug safety.

During the first half of 2018, we expect to initiate a prospective, open label, randomized Phase IIa clinical trial in Israel or Europe, to evaluate safety, tolerability and efficacy of THX-ULD01 in treating patients with cognitive impairment, including cognitive impairment brought on by sports-related brain injury. The primary efficacy endpoint of this prospective trial will be to change from baseline to end of 6-weeks in the Computerized Neurocognitive Battery, or CNB. CNB is designed to measure the performance accuracy and speed of specific neurobehavioral domains using previously validated tests. These tests have been applied in neuroimaging studies for measuring individual differences in performance, and measure accuracy and speed of performance in major domains of cognition, including executive-control functions (abstraction, attention, working memory), episodic memory (verbal, facial, spatial), complex cognitive processing (language reasoning, nonverbal reasoning, spatial processing), social cognition (emotion identification, emotion intensity differentiation, age differentiation) and sensorimotor and motor speed. CNB measurements will be used to detect cognitive impairment and improvements.

Secondary efficacy end points are to demonstrate safety and tolerability of THX-ULD01 and to evaluate the benefit of THX-ULD01 on the patients' mood, anxiety and overall quality of life using the Hamilton scale.

BrainBright Pharma Preclinical Data

We have licensed the results of multiple experiments performed by Prof. Sarne's group from the Tel-Aviv University, which suggest that using an ultra-low dose administration of dronabinol may improve cognitive abilities.

These experiments and preclinical studies have shown that an ultra-low dose of THC may protect mice's brains from a variety of brain insults. A single injection of an ultra-low dose of THC prevented the cognitive damage that was induced by either hypoxia (oxygen deficiency), deep anesthesia, methylenedioxy-methamphetamine-toxicity, epileptic seizures or neuroinflammation. THC was applied either 1-3 days before or 1-7 days after the insult. The protective effect of the single injection of ultra-low THC lasted for at least 7 weeks.

An additional study tested whether a similar ultra-low dose of THC could reverse age-dependent cognitive decline in mice. Old (18-24 months) mice performed significantly worse than young (3-4 months) mice in a battery of cognitive assays. However, study results indicate that old mice that had been injected once with an ultra-low dose of THC performed significantly better than placebo (control)-treated old mice, and performed similar to young mice in all applied assays. The improvement in cognitive functioning lasted for at least 7 weeks following a single injection of ultra-low THC.

We believe that these findings suggest that extremely low doses of THC may support future development of a treatment for mild cognitive impairment.

We may conduct further preclinical studies in parallel to our clinical plans as part of the development of our innovative pipeline and for registration purposes.

Intellectual Property

Our intellectual property portfolio comprises two granted U.S. patent and six pending patent applications, of which four applications have either the Patent Cooperation Treaty of the World Intellectual Property Organization, or PCT, pending status or have entered national stage and are under examination by national authorities. Of this portfolio, we have exclusively licensed: (i) one granted U.S. patent from Dekel, (ii) one U.S. granted patent from Yissum, and (iii) one PCT patent application from Ramot. We also intend to negotiate a definitive agreement for the in-licensing of a patent application from Belvit, as further described below.

Internally Developed Patent Applications

In April 2015, we filed a provisional application with the U.S. Patent and Trademark Office, or USPTO, for combinations of cannabinoids, n-acylethanolamines, and inhibitors of n-acylethanolamine degradation, which, on April 2016 was converted into the international PCT stage. The technology is based on the entourage effect paradigm, and is directed to utilizing the potentiating effect of n-acylethanolamines on cannabinoids for any cannabinoid amenable indication, including but not limited to analgesia and TS. Any resulting patent from this application would be expected to expire in April 2036.

In May 2015, we filed a provisional application with the USPTO for combinations of opioids, n-acylethanolamines, and inhibitors of n-acylethanolamines degradation, which, on May 2016 entered the PCT stage. The technology is also based on the entourage effect paradigm, purposed with utilizing the potentiating effect of N-acylethanolamines on opioids for opioid amenable indications. Any resulting patent from this application would be expected to expire in May 2036.

In August 2016, we filed a provisional application with the USPTO for the technology which is also based on the entourage effect, and is directed to potentiating the efficacy of retinoids and retinoid derived molecule based therapies for any retinoid amenable indication. This application is due to be converted to a non-provisional application in 2017 and any resulting patent from this application would be expected to expire in August 2037.

In July 2016, we filed a provisional application with the USPTO for the technology which is based on potentiating the efficacy of currently used antibiotics. This application is due to be converted to a non-provisional application in July 2017 and any resulting patent from this application would be expected to expire in July 2037.

In-Licensed Patents and Patent Applications

In May 2015, we entered into an exclusive, irrevocable, worldwide license agreement with Dekel for certain technology and one granted U.S. patent related to compositions and methods for treating inflammatory disorders. The agreement became effective in August 2015. Pursuant to the license agreement, we granted Dekel an option to purchase 3,876,000 of our Ordinary Shares at an exercise price of NIS 0.5 per share, exercisable for 90 days. The option was fully exercised as of November 2015. We also granted Dekel an additional option to purchase 11,926,154 of our Ordinary Shares at an exercise price of NIS 0.65 per share, exercisable for 12 months. To date, 65% of the second option (representing options to purchase 7,760,256 Ordinary Shares) has been exercised, for aggregate consideration of NIS 5 million, and the remainder of the option has expired. Pursuant to the license agreement, in May 2016 we issued Dekel 200,000 of our Ordinary Shares at a price per share of NIS 0.5 on account of future royalty payments. Also, pursuant to the license agreement, we are obligated to pay Dekel fees based on specific milestones and royalties upon commercialization. The milestone payments include: (i) $25,000 upon the successful completion of preclinical trials (which milestone was met in November 2016, resulting in this payment becoming due, and which was paid in March 2017); (ii) $75,000 upon the successful completion of a Phase I/IIa trial; and (iii) $75,000 upon the earlier of generating net revenues of at least $200,000 from the commercialization of the technology or the approval of the FDA / the EMA of a drug based on the licensed assets. In each case, and subject to our discretion, the respective milestone payments are payable in cash or equity based on a price per Ordinary Share of NIS 0.5. The royalty payments are 8% for commercialization and 35% pursuant to a sub-license of the licensed assets. The patent expiration dates of any patents maturing from this application would likely be 2029.

In February 2016, we entered into an exclusive, worldwide research and license agreement with Ramot for a patent application relating to methods for treatment of cognitive decline with low doses of THC. Pursuant to the agreement, we are obligated to pay patent filing and prosecution expenses, including past expenses, and to fund further research in an amount of approximately NIS 237,630. Furthermore, we are obligated to pay fees (aggregating approximately $3.5 million) upon the occurrence of certain milestones, including achieving the completion of a Phase II clinical trial, pivotal clinical trial, filing an NDA with the FDA, the receipt of regulatory approvals and the achievement of worldwide sales which exceed certain thresholds. Pursuant to the agreement, we are obligated to pay royalties at a low single digit percentage rate upon commercialization of a product based on licensed asset, and a percentage rate in the low twenties pursuant to a sublicense of the licensed assets. Pursuant to the agreement we undertook to conduct technology research and we may terminate such obligation with no further obligation to fund it should the principal investigator cease to supervise the research and Ramot will be unable to locate an alternative scientist acceptable to us. The exclusivity under the license agreement expires and the agreement terminates upon expiration of all of our payment obligations under the agreement, after which Ramot shall be entitled to freely use, sell, and otherwise transfer the technology under the license and grant further licenses without accounting to us. The patent expiration date of any patent maturing from this application would likely be 2035. We expect the exclusivity period to end upon the earlier of the termination of the license agreement or the patent expiration date.

In June 2016, we entered into a binding term sheet-agreement with Belvit for the grant of certain intellectual property rights, including a provisional patent application covering the method and formulation for the sublingual administration of THC with enhanced bioavailability, upon the entry into of a definitive license agreement. Entry into a definitive license agreement is subject to our successful completion of a PK/bioavailability study, which we intend to conduct in the second quarter of 2017. We initially intend to exploit this technology with respect to MCI. Pursuant to the term sheet, we will receive an exclusive, irrevocable, worldwide, license to develop, manufacture, and commercialize a drug based on a low-dose of THC and a right of first negotiation with respect to normal-dose technology within the twenty four months of the effective date of the term sheet. We agreed to pay all costs and expenses related to the development of the technology, and to conduct, at our own expense, the PK/bioavailability study. We currently estimate that the cost of the study will be approximately $350,000. We shall further pay the licensor a low single-digit royalty rate upon commercialization of a product based on the licensed assets. Furthermore, the licensor shall have the right to use the study results. Belvit shall pay us a low single-digit royalty rate from any income from other uses of the technology. While we will be responsible for the development of the technology, Belvit will be responsible for the formulation development. The term sheet further includes the development stages and estimated development costs. Filing and patent prosecution will be borne by both parties. As of October 2016, Belvit has successfully completed the formulation of a sublingual THC tablet, which is to be used in the PK/bioavailability study we intend to conduct in the second quarter of 2017. The patent expiration date of any patent maturing from this application would likely be 2037.

In March 2017, we entered into a license agreement with Yissum for the grant of a license to an issued U.S. patent, including foreign counterparts, that covers nasal delivery of cannabinoids, excluding any use or exploitation of cannabinoids in conjunction with Tramadol (but including exploitation of cannabinoids in conjunction with other substances), all subject to a development plan to be approved by Yissum for the purpose of research, developing, and commercializing. Pursuant to the license agreement, Yissum will grant us an exclusive, worldwide, sublicensable, royalty-bearing license to the patents and we will pay Yissum fees based on specific milestones (aggregating approximately $1 million) and medial single-digit royalties upon the commercialization of a product based on the licensed assets. Royalty rates will decrease to a low single-digit percentage upon commercialization of a competitive product or if we are required to pay a third party in order to sell the technology based product. We will further undertake to pay all patent filing and prosecution expenses, including past expenses. We will also compensate and indemnify Yissum from and against any damage, loss, cost and expenses incurred by us or by our subordinates by reason of any acts or omissions, or which derive from the exploitation or use of the technology or related product. Pursuant to the license agreement, the exclusivity under the license agreement expires if not terminated earlier, on a country-by-country, product-by-product basis, upon the later of: (i) the date of expiration in such country of the last to expire licensed patent included in the licensed technology; (ii) the date of expiration of any exclusivity on the product granted by a regulatory or government body in such country; or (iii) the end of a period of fifteen (15) years from the date of the first commercial sale in such country. The patent expiration dates for the patents covered by the license agreement are from 2026-2028.

Other Intellectual Property Protection

In addition to patent protection, we intend to use other means to protect our proprietary rights, including pursuing marketing or data exclusivity periods, orphan drug status, and similar rights that are available under regulatory provisions in certain countries, including but not limited to the United States, Europe, Japan, and China.

We also rely on trade secrets, know-how, and continuing innovation to develop and maintain our competitive position. We cannot be certain that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology.

We also seek regulatory approval for our products for indications with high unmet medical need, great market potential, and where we have a proprietary position through patents covering various aspects of our products, including but not limited to: composition, dosage, formulation, use, and manufacturing process. Our success depends, in part, on an intellectual property portfolio that supports future revenue streams and erects barriers to our competitors. We are maintaining and building our patent portfolio through filing new patent applications, prosecuting existing applications, and licensing and acquiring new patents and patent applications.

Despite these measures, any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed or misappropriated. Intellectual property and proprietary rights may not be sufficient to permit us to take advantage of current market trends or otherwise to provide competitive one. For more information, see Item 3D. “Risk Factors - Risks Related to our Intellectual Property.”

Sales of intellectual property assets

In June 2016, we entered into a share transfer agreement with our former subsidiary, Orimmune, and Karma Link, according to which we sold our holdings in Orimmune to Karma Link and will assist the assignment of certain rights to a certain antibody Anti-CD3 technology (which was in-licensed by us from Hadasit, and certain internally developed assets and technology relating thereto). In consideration of the sale and transfer, Karma Link paid us NIS 1.00 and will assume all liabilities of Orimmune. While we are entitled to receive a percentage rate in the mid-teens of all proceeds received by Karma Link from Orimmune or from third parties in connection with the Orimmune shares or assets, including fees, dividends and other forms of payment, we do not believe that these payments, if made at all, will provide us with any material revenue. The sale of our holdings in Orimmune was completed in August 2016. The transfer of the assets is pending the necessary permits and approvals of the IIA, which to date have been declined due to IIA’s claim that the registration of certain of the intellectual property rights is not in compliance with IIA rules. We are currently negotiating the issues with IIA in order to facilitate the transfer.

Commercialization

We intend to build a global commercial infrastructure to effectively support the commercialization of our product candidates, if and when we believe regulatory approval of a product candidate in a particular geographic market appears imminent.

To develop the appropriate commercial infrastructure, we will likely have to invest significant amounts of financial and management resources, some of which we expect to commit prior to completing the regulatory process for our product candidates. Where appropriate, we may elect in the future to utilize strategic partners, distributors, or contract sales forces to assist in the commercialization of our products. In certain instances we may consider building our own commercial infrastructure.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our scientific knowledge, technology and development experience provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

The first THC-based pharmaceutical, a pill sold under the commercial name of Marinol (scientific name: dronabinol), was developed by a company called Unimed Pharmaceuticals, with funding provided by the National Cancer Institute. In 1985, Marinol received FDA approval as a treatment for chemotherapy-related nausea and vomiting. Today, Marinol is marketed by AbbVie, Inc. Since the introduction of Marinol into the market, other pharmaceuticals containing THC have also been developed. These include generic oral capsules of dronabinol, such as those marketed by SVC Pharma LP and Akorn Inc., Insys Therapeutic Inc.'s Syndros, an orally administered liquid formulation of dronabinol, Meda AB's Cesamet (nabilone), a synthetic derivative of THC, and Sativex (nabiximols), a whole cannabis extract administered as an oral spray. Furthermore, we are aware of multiple companies that are working in the cannabis therapeutic area and are pursuing regulatory approval for their product candidates. For example, GW Pharmaceuticals PLC, which markets Sativex, a botanical cannabinoid oral mucosal for the treatment of spasticity due to multiple sclerosis is seeking FDA approval in the United States, and is developing Epidiolex, a liquid formulation of highly purified cannabidiol extract, as a treatment for Dravet's Syndrome, Lennox Gastaut Syndrome, and various childhood epilepsy syndromes. Insys Therapeutics, Inc. is also seeking FDA approval for an orally-administered liquid formulation of its synthetic cannabidiol compound as a treatment for Dravet's Syndrome, Lennox Gastaut Syndrome, and other childhood epilepsy syndromes. Zynerba Pharmaceuticals, Inc. is developing a transdermal formulation of cannabidiol, and Nemus Bioscience, Inc. is focused on the discovery, development and commercialization of cannabis therapeutics.

Our competitors, either alone or through their strategic partners, might have substantially greater name recognition and financial, technical, manufacturing, marketing and human resources than we do and significantly greater experience and infrastructure in researching and developing pharmaceutical products, obtaining FDA and other regulatory approvals of those products and commercializing those products around the world. They may also have intellectual property portfolios that provide them with significant competitive advantages or create substantial barriers in our target markets.

Manufacturing

We currently expect to contract with third parties for the manufacturing and testing of our product candidates for preclinical trials and clinical trials and intend to do so in the future. We do not own or operate manufacturing facilities for the production of clinical quantities of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. The use of contracted manufacturing and reliance on collaboration partners is relatively cost-efficient and has eliminated the need to directly investment in manufacturing facilities and additional staff.

To date, our third-party manufacturers have met our manufacturing requirements. We expect third-party manufacturers to be capable of providing sufficient quantities of our product candidates to meet anticipated full scale commercial demands. To meet our projected needs for commercial manufacturing, third parties with whom we currently work might need to increase their scale of production, or we will need to secure alternate suppliers. We believe that there are alternate sources of supply that can satisfy our clinical and commercial requirements, although we cannot be certain that identifying and establishing relationships with such sources, if necessary, would not result in significant delay or material additional costs.

Government Regulation

FDA Approval Process

In the United States, pharmaceutical product candidates are subject to extensive regulation by the FDA. The FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical product candidates. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, product candidate recalls, product candidate seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product candidate development in the United States typically involves pre-clinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate, well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product candidate or disease.

Pre-clinical tests include laboratory evaluation of product candidate chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product candidate. The conduct of the pre-clinical tests must comply with federal regulations and requirements, including GLP. The results of pre- clinical testing are submitted to the FDA as part of an IND along with other information, including information about product candidate chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not imposed a clinical hold on the IND or otherwise commented or questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the IND to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations, (ii) in compliance with GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The trial protocol and informed consent information for patients in clinical trials must also be submitted to an IRB for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with potentially serious outcome, and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product candidate may begin in the United States. The NDA must include the results of all pre-clinical, clinical, and other testing and a compilation of data relating to the product candidate's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee; the fee in the fiscal year 2016 was $2,374,200.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug product candidates are reviewed within 10 to 12 months, while most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for drugs intended to treat a serious or life-threatening disease relative to the currently approved product candidates. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug product candidates, or drug product candidates that present difficult questions of safety or efficacy, to an advisory committee, which is typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product candidate unless compliance with or cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a REMS to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for health care professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product candidate approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product candidate approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain FDA-regulated product candidates, including prescription drugs, are required to register and disclose certain clinical trial information on a public website maintained by the U.S. National Institutes of Health. Information related to the product candidate, patient population, phase of investigation, study sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these trials after completion. Disclosure of the results of these trials can be delayed until the product candidate or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the design and progress of our development programs.

Fast Track Designation and Accelerated Approval

TS may be considered as a serious condition with a potentially disabling nature. The FDA has programs to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition so these therapies for serious conditions are approved and available to patients as soon as it can be concluded that the therapies' benefits justify their risk. Under the Fast Track Program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the filing of the IND for the drug candidate. FDA must determine if the drug candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor's request.

Under the Fast Track Program and FDA's accelerated approval regulations, FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by FDA.

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with FDA, FDA may initiate review of sections of a Fast Track drug's NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, the Fast Track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

The Hatch-Waxman Act

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product candidate. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Product candidates with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product candidate that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product candidate. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product candidate in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product candidate. The ANDA applicant may also elect to submit a section viii statement, certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of- use, rather than certify to a listed method-of-use patent.

If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product candidate have expired.

A certification that the new product candidate will not infringe the already approved product candidate's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product candidate has expired.

As the Orange Book, among others, lists patents that are purported to protect each drug, patent listings and use codes are provided by the drug application owner, and the FDA is obliged to list them. In order for a generic drug manufacturer to win approval of a drug under the Hatch-Waxman Act, the generic manufacturer must certify that they will not launch its generic product until after the expiration of the Orange Book-listed patent, or that the patent is invalid, unenforceable, or that the generic product will not infringe the listed patent. Although our product candidates are based on repurposed drugs, there are at present no patents or other exclusivities listed in the Orange Book pertaining to a product containing the active ingredient dronabinol.

Exclusivity

Upon NDA approval of a new chemical entity, or NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which time the FDA cannot receive any ANDA seeking approval of a generic version of that drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA for a generic drug that includes the change.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification and thus no ANDA may be filed before the expiration of the exclusivity period.

For a botanical drug, FDA may determine that the active moiety is one or more of the principle components or the complex mixture as a whole. This determination would affect the utility of any five-year exclusivity as well as the ability of any potential generic competitor to demonstrate that it is the same drug as the original botanical drug.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase—the time between IND submission and NDA submission—and all of the review phase—the time between NDA submission and approval up to a maximum of five years. The time can be shortened if FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the PTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Advertising and Promotion

Once an NDA is approved, a product candidate will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse Event Reporting and GMP Compliance

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product candidate, or the FDA may place conditions on an approval that could restrict the distribution or use of the product candidate. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product candidate approvals or request product candidate recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing or if previously unrecognized problems are subsequently discovered.

Pediatric Exclusivity and Pediatric Use

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or non-patent—for a drug if certain conditions are met. Conditions for exclusivity include a determination by the FDA that information relating to the use of a new drug in the pediatric population may produce health benefits in that population; a written request by the FDA for pediatric studies; and agreement by the applicant to perform the requested studies and the submission to the FDA, and the acceptance by the FDA, of the reports of the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications.

In addition, under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective, unless the sponsor has received a deferral or waiver from the FDA. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted. The required pediatric assessment must assess the safety and effectiveness of the product candidate for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product candidate is safe and effective. The sponsor or FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data need to be collected before the pediatric studies begin. Under PREA, the FDA must send a non-compliance letter requesting a response with 45 days to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product candidate, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product candidate with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

In June 2016, we submitted a request for orphan drug designation to the FDA for THX-TS01 for the treatment of TS. In a letter dated September 29, 2016, the FDA informed us that our request cannot be granted at this time, and is being held in abeyance until and subject to us providing additional information pertaining to the overall prevalence of TS in both children and adults, and further clinical data to support our scientific rationale for our request for orphan drug designation within 12 months. We intend to respond within the 12 month period, or during any extension thereof.

Special Protocol Assessment

A company may reach an agreement with the FDA under the Special Protocol Assessment, or SPA, process as to the required design and size of clinical trials intended to form the primary basis of an efficacy claim. According to its performance goals, the FDA is supposed to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. An SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the administrative record. Under the FDC Act and FDA guidance implementing the statutory requirement, an SPA is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the study begins, public health concerns emerge that were unrecognized at the time of the protocol assessment, the sponsor and FDA agree to the change in writing, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA.

Controlled Substances

Dronabinol, the active ingredient in our product candidates is a Schedule I controlled substance. The CSA and its implementing regulations establish a "closed system" of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements under the oversight of the U.S. DEA. The DEA is the federal agency responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

The DEA categorizes controlled substances into one of five schedules—Schedule I, II, III, IV or V—with varying qualifications for listing in each schedule. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision. They may be used only in federally approved research programs and may not be marketed or sold for dispensing to patients in the United States. Pharmaceutical product candidates having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence. The regulatory requirements are more restrictive for Schedule II substances than Schedule III substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist in most situations and cannot be refilled.

Following NDA approval of a drug containing a Schedule I controlled substance, that substance must be rescheduled as a Schedule II, III, IV or V substance before it can be marketed. On November 17, 2015, H.R. 639, Improving Regulatory Transparency for New Medical Therapies Act, passed through both houses of Congress. On November 25, 2015 this bill was signed into law. The new law removes uncertainty associated with timing of the DEA rescheduling process after NDA approval. Specifically, it requires DEA to issue an "interim final rule," pursuant to which a manufacturer may market its product candidate within 90 days of FDA approval. The new law also preserves the period of orphan marketing exclusivity for the full seven years such that this period only begins after DEA scheduling. This contrasts with the previous situation whereby the orphan "clock" began to tick upon FDA approval, even though the product candidate could not be marketed until DEA scheduling was complete.

Facilities that manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies) and controlled substance schedule(s). For example, separate registrations are required for importation and manufacturing activities, and each registration authorizes which schedules of controlled substances the registrant may handle. However, certain coincident activities are permitted without obtaining a separate DEA registration, such as distribution of controlled substances by the manufacturer that produces them.

The DEA inspects all manufacturing facilities to review security, recordkeeping, reporting and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. An application for a manufacturing registration as a bulk manufacturer (not a dosage form manufacturer or a repacker/relabeler) for a Schedule I or II substance must be published in the Federal Register, and is open for 30 days to permit interested persons to submit comments, objections or requests for a hearing. A copy of the notice of the Federal Register publication is forwarded by DEA to all those registered, or applicants for registration, as bulk manufacturers of that substance. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances. As with applications for registration as a bulk manufacturer, an application for an importer registration for a Schedule I or II substance must also be published in the Federal Register, which remains open for 30 days for comments. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV and V narcotic, and submit import or export declarations for Schedule III, IV and V non-narcotics. In some cases, Schedule III non-narcotic substances may be subject to the import/export permit requirement, if necessary to ensure that the United States complies with its obligations under international drug control treaties.

For drugs manufactured in the United States, the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the United States based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. This limited aggregate amount of cannabis that the DEA allows to be produced in the United States each year is allocated among individual companies, which, in turn, must annually apply to the DEA for individual manufacturing and procurement quotas. The quotas apply equally to the manufacturing of the API and production of dosage forms. The DEA may adjust aggregate production quotas a few times per year, and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments for individual companies.

The states also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State Authorities, including Boards of Pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

Europe/Rest of World Government Regulation

In addition to regulations in the United States, we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our product candidates, if approved.

Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product candidate in those countries. Certain countries outside of the United States have a process that requires the submission of a clinical trial application, or CTA, much like an IND prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country.

The requirements and process governing the conduct of clinical trials, product candidate licensing, pricing and reimbursement vary from country to country, even though there is already some degree of legal harmonization in the European Union member states resulting from the national implementation of underlying E.U. legislation. In all cases, the clinical trials are conducted in accordance with GCP and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under E.U. regulatory systems, we must submit a marketing authorization application. This application is similar to the NDA in the United States, with the exception of, among other things, country-specific document requirements. Drugs can be authorized in the European Union by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, or MRP, (iii) the decentralized procedure or (iv) national authorization procedures. The initial Sativex approvals were a consequence of an application under the De-Centralized Procedure, or DCP, to the E.U. member states of the United Kingdom and Spain.

The EMA implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the European Union. This procedure results in a single marketing authorization granted by the European Commission that is valid across the European Union, as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated "orphan drugs" (drugs used for rare human diseases) and (iv) advanced-therapy medicines, such as gene- therapy, somatic cell-therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used for human drugs which do not fall within the above mentioned categories if the human drug (a) contains a new active substance which, on the date of entry into force of this Regulation, was not authorized in the Community; or (b) the applicant shows that the medicinal product candidate constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization in the centralized procedure is in the interests of patients or animal health at the European Community level.

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a MAA by the EMA is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Product candidates for Human Use, or CHMP, with adoption of the actual marketing authorization by the European Commission thereafter. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product candidate is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: the seriousness of the disease to be treated; the absence of an appropriate alternative therapeutic approach, and anticipation of exceptional high therapeutic benefit. In this circumstance, EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter.

The MRP, for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the European Union. Basically, the MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is applicable to the majority of conventional medicinal product candidates, and is based on the principle of recognition of an already existing national marketing authorization by one or more member states. Since the first approvals for Sativex were national approvals in the United Kingdom and Spain (following a DCP), the only route open to us for additional marketing authorizations in the European Union was the MRP.

The characteristic of the MRP is that the procedure builds on an already–existing marketing authorization in a member state of the E.U. that is used as a reference in order to obtain marketing authorizations in other E.U. member states. In the MRP, a marketing authorization for a drug already exists in one or more member states of the E.U. and subsequently MAAs are made in other European Union member states by referring to the initial marketing authorization. The member state in which the marketing authorization was first granted will then act as the reference member state. The member states where the marketing authorization is subsequently applied for act as concerned member states.

The MRP is based on the principle of the mutual recognition by European Union member states of their respective national marketing authorizations. Based on a marketing authorization in the reference member state, the applicant may apply for marketing authorizations in other member states. In such case, the reference member state shall update its existing assessment report about the drug in 90 days. After the assessment is completed, copies of the report are sent to all member states, together with the approved summary of product candidate characteristics, labeling and package leaflet. The concerned member states then have 90 days to recognize the decision of the reference member state and the summary of product candidate characteristics, labeling and package leaflet. National marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

Should any Member State refuse to recognize the marketing authorization by the reference member state, on the grounds of potential serious risk to public health, the issue will be referred to a coordination group. Within a timeframe of 60 days, member states shall, within the coordination group, make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA Committee is then forwarded to the Commission, for the start of the decision making process. As in the centralized procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Product candidates or Veterinary Medicinal Product candidates, as appropriate. Since the initial approvals of Sativex in the United Kingdom and Spain, there have been three “waves” of additional approvals under three separate MRPs. Each of these procedures have been completed without any referral, and therefore without any delay.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product candidate licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the other applicable regulatory requirements.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product candidate recalls, seizure of product candidates, operating restrictions and criminal prosecution.

In addition, most countries are parties to the Single Convention on Narcotic Drugs 1961, which governs international trade and domestic control of narcotic substances, including cannabis extracts. Countries may interpret and implement their treaty obligations in a way that creates a legal obstacle to our obtaining marketing approval for Sativex and our other product candidates in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit Sativex or our other product candidates to be marketed, or achieving such amendments to the laws and regulations may take a prolonged period of time. In that case, we would be unable to market our product candidates in those countries in the near future or perhaps at all.

Reimbursement

Sales of pharmaceutical product candidates in the United States will depend, in part, on the extent to which the costs of the product candidates will be covered by third-party payers, such as government health programs, commercial insurance and managed health care organizations. These third-party payers are increasingly challenging the prices charged for medical product candidates and services. Additionally, the containment of health care costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic product candidates. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payers do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidates after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our product candidates on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries and included a major expansion of the prescription drug benefit under Medicare Part D. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for product candidates for which we receive marketing approval. However, any negotiated prices for our product candidates covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payers.

On February 17, 2009, President Obama signed into law The American Recovery and Reinvestment Act of 2009. This law provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payers, it is not clear how such a result could be avoided and what if any effect the research will have on the sales of our product candidates, if any such product candidate or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product candidate could adversely affect the sales of our product candidates. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payer to not cover our product candidates could reduce physician usage of the product candidate and have a material adverse effect on our sales, results of operations and financial condition.

The Affordable Care Act is expected to continue to have a significant impact on the health care industry. With regard to pharmaceutical product candidates, among other things, the Affordable Care Act may expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare D program. Since the enactment of the Affordable Care Act, numerous regulations have been issued providing further guidance on its requirements. The Affordable Care Act continues to be implemented through regulation and government activity but is subject to possible amendment, additional implementing regulations and interpretive guidelines. Several states have decided not to expand their Medicaid programs and are seeking alternative reimbursement models to provide care to the uninsured. The manner in which these issues are resolved could materially affect the extent to which and the amount at which pharmaceuticals are reimbursed by government programs such as Medicare, Medicaid and Tricare.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal product candidates for which their national health insurance systems provide reimbursement and to control the prices of medicinal product candidates for human use. A member state may approve a specific price for the medicinal product candidate or it may instead adopt a system of direct or indirect controls on the profitability of our Company placing the medicinal product candidate on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical product candidates will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, product candidates launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Other Health Care Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, or VHCA, each as amended. If product candidates are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the VHCA, drug companies are required to offer certain drugs at a reduced price to a number of federal agencies including the U.S. Department of Veteran Affairs and U.S. Department of Defense, the Public Health Service and certain private Public Health Service–designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Recent legislative changes purport to require that discounted prices be offered for certain U.S. Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

In order to distribute product candidates commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical product candidates in a state, including, in certain states, manufacturers and distributors who ship product candidates into the state, even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product candidate in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product candidate as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities or register their sales representatives. Other legislation has been enacted in certain states prohibiting pharmacies and other health care entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and prohibiting certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Expanded Access to Investigational Drugs

An investigational drug may be eligible for clinical use outside the context of a manufacturer's clinical trial of the drug. "Expanded access" refers to the use of an investigational drug where the primary purpose is to diagnose, monitor, or treat a patient's disease or condition rather than to collect information about the safety or effectiveness of a drug. Expanded access INDs are typically sponsored by individual physicians to treat patients who fall into one of three FDA-recognized categories of expanded access: expanded access for individual patients, including for emergency use; expanded access for intermediate-size patient populations; and expanded access for large patient populations under a treatment IND or treatment protocol. For all types of expanded access, FDA must determine prior to authorizing expanded access that: (1) the patient or patients to be treated have a serious or life threatening disease or condition and there is no comparable or satisfactory alternative therapy; (2) the potential patient benefit justifies the potential risks of use and that the potential risks are not unreasonable in the context of the disease or condition to be treated; and (3) granting the expanded access will not interfere with the initiation, conduct, or completion of clinical studies in support of the drug's approval. In addition, the sponsor of an expanded access IND must submit IND safety reports and, in the cases of protocols continuing for one year or longer, annual reports to the FDA. Expanded access programs are not intended to yield information relevant to evaluating a drug's effectiveness for regulatory purposes. If a patient enrolled in one of our clinical trials is not eligible or able to continue enrollment, we may be required to continue to provide our product candidate to such patient through expanded access.

Grants from the IIA

Our research and development efforts mainly with respect to our past activities (for example, with respect to immunotherapy programs such as the BBS Technology and program and the Anti-CD3 program) were financed in part through royalty-bearing grants from the IIA. As of December 31, 2016, we have received the aggregate amount of approximately $4.1 million from the IIA for the development of these programs, which have since been sold. With respect to such grants we are committed to pay certain royalties up to an aggregate amount of approximately $1.1 million relating only to technologies in our possession and excluding any royalties for technologies that we sold to third parties. Regardless of any royalty payment, we are further required to comply with the requirements of the Research Law, with respect to those past grants. When a company develops know-how, technology or products using IIA grants, the terms of these grants and the Research Law restrict the transfer of such know-how inside or outside of Israel, and the transfer outside of Israel of manufacturing or manufacturing rights of such products, technologies or know-how, without the prior approval of the IIA. We do not believe that these requirements will materially restrict us in any way. None of our current projects in the field of cannabinoid therapeutics are supported by the IIA, yet if eligible, we might apply for such support in the future.

C. Organizational Structure

In June 2016, we entered into a share transfer agreement with our former subsidiary, Orimmune, and Karma Link, according to which we sold our holdings in Orimmune to Karma Link. The transfer of the Orimmune shares was completed in August 2016, following which we no longer hold any shares in Orimmune, and the transfer to Orimmune of certain intellectual property assets related to this agreement is still pending the necessary permits and approvals. To date, IIA has declined our request for a joint ownership registration with Hadasit of the patent underlying the assets, according to the license agreement with Hadasit due to IIA's claim that such registration is not in compliance with the IIA rules regarding use of its grants. We are currently negotiating the issues with IIA in order to facilitate the transfer. See also Item 4.B. "Business Overview – Intellectual Property – Sales of intellectual property assets."

In addition, we own approximately 27% of Lara Pharm Ltd., or Lara Pharm, a private company engaged in the field of medical cannabis and developing a formulation based on synthetic cannabinoids, for the provision through an inhaler. The founder of Lara Pharm holds a call option exercisable until May 22, 2017 to purchase all of our remaining holdings in Lara Pharm for $500,000.

D. Property, Plant and Equipment

Our offices are located at 5 Azrieli Center (Square Tower), Tel Aviv, Israel, where we currently occupy approximately 1076 square feet. We lease our facilities and our lease ends on June 30, 2017. Our current monthly rent payment is NIS 18,700 (approximately $5,000).

We consider that our current office space is sufficient to meet our anticipated needs for the foreseeable future and is suitable for the conduct of our business.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this annual report on Form 20-F. This discussion and other parts of this annual report on Form 20-F contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under Item 3.D. "Risk Factors" and elsewhere in this annual report in Form 20-F. We report financial information under IFRS as issued by the International Accounting Standards Board and none of the financial statements were prepared in accordance with generally accepted accounting principles in the United States.

Overview

We are a specialty clinical-stage pharmaceutical company led by an experienced team of senior executives and scientists, focused on creating and enhancing a portfolio of technologies and assets based on cannabinoid pharmaceuticals. With this focus, we have initiated two internal drug development programs based on repurposing an FDA approved synthetic cannabinoid (dronabinol): Joint Pharma developing THX-TS01 targeted to the treatment of TS and BrainBright Pharma developing THX-ULD01 targeted to the high value and under-served market of MCIs.

We intend to seek FDA approval for the commercialization of our drug candidates through Section 505(b)(2) regulatory pathway under the FDC Act. The FDA's 505(b)(2) regulatory pathway permits the filing of an NDA, where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference. This approach could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. In addition, with respect to our Joint Pharma program we intend to pursue orphan drug designation in the United States and Europe.

A. Operating Results

Operating Expenses

Our current operating expenses consist of two components — research and development expenses, and general and administrative expenses.

Research and Development Expenses, net

Our research and development expenses consist primarily of salaries and related personnel expenses, share-based compensation expenses, consulting and subcontractor expenses and other related research and development expenses.

The following table discloses the breakdown of research and development expenses:

	December 31,			December 31,
	2014	2015	2016	2016
	(in thousands of NIS)			(in thousands of USD-convenience translation)
Wages and related expenses	506	183	748	194
Materials	25	31	70	18
Share-based payments	8	6	383	100
Consulting and subcontractors	582	441	1,195	311
Depreciation	49	6	7	2
Patents	284	243	293	76
Other expenses	375	21	146	38
IIA participation	(29)	-	-	-
	1,800	931	2,842	739

We expect that our research and development expenses will materially increase as we plan to start clinical trials.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, share-based compensation expense, professional service fees for accounting, legal, bookkeeping, facilities and other general and administrative expenses.

The following table discloses the breakdown of general and administrative expenses:

	December 31,			December 31,
	2014	2015	2016	2016
	(in thousands of NIS)			(in thousands of USD-convenience translation)
Wages and related expenses	1,635	1,540	1,531	398
Professional services including business development	2,508	1,907	1,841	479
Insurance and directors' fees	244	214	245	64
Share-based payments	136	526	773	201
Depreciation	100	6	6	2
Office maintenance and rent and other	615	1,104	474	123
Total	5,238	5,297	4,870	1,267

Comparison of the year ended December 31, 2016 to the year ended December 31, 2015 and to the year ended December 31, 2014

Results of Operations

	December 31,			December 31,
	2014	2015	2016	2016
	(in thousands of NIS)			(in thousands of USD-convenience translation)
Research and development expenses	1,800	931	2,842	739
General and administrative expenses	5,238	5,297	4,870	1,267
Other expense (income), net	(115)	3,734	(30)	(7)
Operating loss	6,923	9,962	7,682	1,999
Financial Expense (income), net	26	15	26	6
Loss	7,292	10,174	7,708	2,005
Loss attributable to holders of Ordinary Shares	7,207	9,877	7,656	1,991

Research and Development Expenses

Our research and development expenses for the year ended December 31, 2016 amounted to NIS 2,842,000 (approximately $739,000), representing an increase of NIS 1,911,000 (approximately $497,000), or 205%, compared to NIS 931,000 for the year ended December 31, 2015. The increase was primarily attributable to an increase of NIS 754,000 (approximately $196,000) in consulting and subcontractors fees and an increase of NIS 565,000 (approximately $147,000) in wages and related expenses, reflecting an increase in the number of employees and an increase of NIS 375,000 (approximately $98,000) in share-based payments. Research and development expenses for the year ended December 31, 2016 reflect increased R&D operations due to preparations of clinical trials of cannabinoid projects.

Our research and development expenses for the year ended December 31, 2015 amounted to NIS 931,000, representing a decrease of NIS 869,000, or 48%, compared to NIS 1,800,000 for the year ended December 31, 2014. The decrease was primarily attributable to a decrease of NIS 323,000 in salaries and related personnel expenses, reflecting a decrease in the number of employees and a decrease of NIS 354,000 in other research and development expenses. Research and development expenses for the year ended December 31, 2015 reflects reduced R&D operations which mainly consisted of maintaining our previous Anti-CD3 project, which is no longer our focus, and the initiation of cannabinoid projects.

General and administrative expenses

Our general and administrative expenses totaled NIS 4,870,000 (approximately $1,257,000) for the year ended December 31, 2016, representing a decrease of NIS 427,000 (approximately $111,000), or 8%, compared to NIS 5,297,000 for the year ended December 31, 2015. The decrease was primarily attributable to decrease in office maintenance and rent and other expenses.

Our general and administrative expenses totaled NIS 5,297,000 for the year ended December 31, 2015, representing an increase of NIS 59,000, or 1%, compared to $1,347,000 for the year ended December 31, 2014.

Operating loss

Our operating loss for the year ended December 31, 2016 was NIS 7,682,000 (approximately $1,999,000), representing a decrease of NIS 2,280,000 (approximately $592,000), or 22.9%, as compared to an operating loss of NIS 9,962,000 for the year ended December 31, 2015.

Our operating loss for the year ended December 31, 2015 was NIS 9,962,000, representing an increase of NIS 3,039,000, or 44%, as compared to an operating loss of NIS 6,923,000 for the year ended December 31, 2014.

Financial expense and income

Financial expense and income consist of revaluation of a liability for IIA grants, bank fees and other transactional costs and exchange rate differences.

We recognized financial expenses net, for the year ended December 31, 2016, of NIS 26,000 (approximately $6,000), representing an increase of NIS 8,000 (approximately $2,000), or 53.3 %, as compared to financial expenses of NIS 15,000, for the year ended December 31, 2015. The increase was primarily due to exchange rate valuation losses on dollar balances.

We recognized financial income net, for the year ended December 31, 2015, of NIS 15,000, representing a decrease of NIS 11,000, or 42%, as compared to financial income of NIS 26,000 for the year ended December 31, 2014. The decrease was primarily due to revaluation of a liability for IIA grants.

Total Comprehensive Loss

Our total comprehensive loss for the year ended December 31, 2016 was NIS 7,728,000 (approximately $2,010,000), representing a decrease of NIS 2,436,000 (approximately $633,000), or 24%, as compared to NIS 10,164,000 for the year ended December 31, 2015.

As a result of the foregoing, our loss for the year ended December 31, 2015 was NIS 10,164,000, representing an increase of NIS 2,882,000, or 40%, as compared to NIS 7,282,000 for the year ended December 31, 2014.

Critical Accounting Policies and Estimate

We describe our significant accounting policies more fully in Note 2 to our financial statements for the year ended December 31, 2016. We believe that the accounting policies below are critical in order to fully understand and evaluate our financial condition and results of operations.

We prepare our financial statements in accordance with IFRS. At the time of the preparation of the financial statements, our management is required to use estimates, evaluations, and assumptions which affect the application of the accounting policy and the amounts reported for assets, obligations, income, and expenses. Any estimates and assumptions are continually reviewed. The changes to the accounting estimates are credited during the period in which the change to the estimate is made.

Contingent Liabilities

The evaluations of provisions and contingent liabilities are based on best professional judgment, taking into consideration the stage of the proceedings, as well as cumulative legal experience in the various topics. Whereas the results of the lawsuits shall be determined by the courts, these results may differ from these evaluations.

Share-Based Compensation

Employees and other service providers of the Company are entitled to benefits by way of share-based compensation settled with company options to shares. The cost of transactions with employees settled with capital instruments is measured based on the fair value of the capital instruments on the granting date. The fair value is determined using an accepted options pricing model. The model is based on share price, grant date and on assumptions regarding expected volatility, expected lifespan, expected dividend, and a no risk interest rate.

The cost of the transactions settled with capital instruments is recognized in profit or loss together with a corresponding increase in the equity over the period in which the performance and/or service takes place, and ending on the date on which the relevant employees are entitled to the benefits, or the Vesting Period. The aggregate expense recognized for transactions settled with capital instruments at the end of each reporting date and until the Vesting Period reflects the degree to which the Vesting Period has expired and our best estimate regarding the number of options that have ultimately vested. The expense or income in profit or loss reflects the change of the aggregate expense recognized as of the end of the reported period.

We selected the Black-Scholes option-pricing model as a fair value method for our options awards. The option-pricing model requires a number of assumptions:

Expected dividend yield - The expected dividend yield assumption is based on our historical experience and expectation of no future dividend payouts. We have historically not paid cash dividends and have no foreseeable plans to pay cash dividends in the future.

Volatility - The expected volatility of the share prices reflects the assumption that the historical volatility of the share prices on the TASE is reasonably indicative of expected future trends.

Risk free interest rate - The risk free interest rate is based on the yield of governmental bonds with equivalent terms.

Contractual term - An option's contractual term must at least include the Vesting Period and the employees' historical exercise and post-vesting employment termination behavior for similar grants. If the amount of past exercise data is limited, that data may not represent a sufficiently large sample on which to base a robust conclusion on expected exercise behavior.

Share price on the TASE - The price of our Ordinary Shares on the TASE used in determining the grant date fair value of options is based on the price on the grant date.

Government Grants from the IIA

Research and development grants received from the IIA are recognized upon receipt as a liability if future economic benefits are expected from the project that will result in royalty-bearing sales. The amount of the liability for the grant is first measured at fair value using a discount rate that reflects a market rate of interest that reflects the appropriate degree of risks inherent in our business. If no economic benefits are expected from the research activity, the grant receipts are recognized as a reduction of the related research and development expenses. In that event, the royalty obligation is treated as a contingent liability in accordance with IAS 37, "Provisions, Contingent Liabilities and Contingent Assets."

At the end of each reporting period, we evaluate whether there is reasonable assurance that the received grants will not be repaid based on its best estimate of future sales and, if so, no liability is recognized and the grants are recorded against a corresponding reduction in other incomes.

B. Liquidity and Capital Resources

Overview

Since our inception in 2004, and through December 31, 2016, we have funded our operations principally with NIS 102,970,000 (approximately $26,780,000) from the issuance of Ordinary Shares (including ADSs) and warrants. As of December 31, 2016, we had NIS 2,598,000 (approximately $676,000) in cash and cash equivalents, and an additional amount of NIS 44,000 (approximately $11,000) in short-term bank deposits.

The table below presents our cash flows for the periods indicated:

	December 31,			December 31,
	2014	2015	2016	2016
	(in thousands of NIS)			(in thousands of USD-convenience translation)
Operating activities	(7,358)	(5,162)	(5,690)	(1,480)
Investing activities	(369)	(2)	(17)	(4)
Financing activities	3,219	10,686	2,169	564
Net increase (decrease) in cash and cash equivalents	(4,508)	5,522	(3,538)	(920)

Operating Activities

Net cash used in operating activities was NIS 5,690,000 (approximately $1,480,000) during 2016 in comparison to NIS 5,162,000 (approximately $1,323,000) during 2015. The increase of NIS 528,000 (approximately $137,000) was primarily attributable to an increase in research and development.

Net cash used in operating activities was NIS 5,162,000 during the year ended December 31, 2015 in comparison to NIS 7,358,000 during 2014. The decrease of NIS 2,196,000 was primarily attributable to a decrease in research and development activities.

Investing Activities

Net cash used in investing activities of NIS 17,000 (approximately $4,000) during the year ended December 31, 2016 primarily reflected purchasing of equipment.

Net cash used in investing activities of NIS 2,000 during 2015 primarily reflected proceeds from sale of property, plant and equipment.

Net cash used in investing activities of NIS 369,000 during 2014 primarily reflected an investment in Lara Pharm, proceeds from the sale of property, plant and equipment.

Financing Activities

Net cash provided by financing activities of 2,169,000 (approximately $564,000) in the year ended December 31, 2016 consisted mainly of NIS 3,509,000 (approximately $913,000) of net proceeds from the exercise of warrants, offset by expenses relating to our U.S. initial public offering and listing on NASDAQ in March 2017, of NIS 1,340,000 (approximately $349,000).

Net cash provided by financing activities in the year ended December 31, 2015 consisted of NIS 10,686,000 of net proceeds from issuance of Ordinary Shares and exercise of share options. Net cash provided by financing activities in the year ended December 31, 2014 consisted of NIS 3,219,000 of net proceeds from issuance of Ordinary Shares.

In March 2017, we issued 5,357,143 Ordinary Shares in a private placement, at a price per share of NIS 0.70 (approximately $0.19).

On March 27, 2017, we issued an aggregate of 2,000,000 ADSs and on April 3, 2017, we issued an aggregate of 300,000 ADSs, pursuant to our U.S. initial public offering, at a price of $6.00 per ADS.

Current Outlook

We have financed our operations to date primarily through proceeds from sales of our Ordinary Shares and options. We have incurred losses and generated negative cash flows from operations since August 2004. Since August 2004, we have not generated any revenue from the sale of product candidates and we do not expect to generate revenues from sale of our product candidates in the next few years.

As of December 31, 2016, our cash and cash equivalents including short-term bank deposits were NIS 2,598,000 (approximately $676,000). We believe that our existing cash resources, including the funds that we raised in our March 2017 offering, will be sufficient to fund our current operations at least until June 30, 2018; however, we expect that we will require substantial additional capital to complete the development of, and to commercialize, our product candidates. In addition, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future capital requirements will depend on many factors, including:

- the progress and costs of our research and development activities;
- the costs of manufacturing our product candidates;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the potential costs of contracting with third parties to provide marketing and distribution services for us or for building such capacities internally; and
- the magnitude of our general and administrative expenses.

Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through equity financings (such as our March 2017 offering of ADSs) and sales of technology. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate research or development plans for, or commercialization efforts with respect to our product candidates. This may raise substantial doubts about our ability to continue as a going concern.

E. Off-Balance Sheet Arrangements

We currently do not have any off-balance sheet arrangements.

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2016:

	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
		(in thousands of U.S. dollars)			
Operating leases:					
Facility	29	29			
License agreements (1)	465	465			

(1) As of December 31, 2016, we had contractual obligations with respect to (i) our license agreement with Dekel, in the amount of $25,000 relating to milestone payments due to Dekel, (ii) our license agreement with Ramot, in the amount of $40,000 to fund research at the Tel-Aviv University and (iii) our term sheet with Belvit relating to the development of a sublingual tablet and a phase I PK/ bioavailability study, in the amount of $400,000.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth information regarding our executive officers, key employees and directors as of April 27, 2017:

Name	Age	Position
Dr. Ascher Shmulewitz	60	Chairman of the Board of Directors
Dr. Elran Haber	36	Chief Executive Officer
Guy Goldin	45	Chief Financial Officer
Doron Ben Ami	54	Chief Strategy Officer
Dr. Adi Zuloff-Shani	48	Chief Technologies Officer
Abraham (Avi) Meizler	65	Director
Amit Berger [(1) (2) (3) (4)]	52	Director
Dr. Yafit Stark [(1) (2) (3) (4)]	63	Director
Micha Jesselson	31	Director
Zohar Heiblum [(1) (2) (3) (4)]	62	Director
Stephen M. Simes [(4)]	65	Director
Mark E. Groussman [(4)]	44	Director
Donald P. Dizon [(4)]	53	Director
M. David Silverman [(4)]	49	Director

(1) Member of the Compensation Committee
(2) Member of the Audit Committee
(3) Independent Director (as defined under Israeli law)
(4) Independent Director (as defined under NASDAQ Stock Market rules)

Dr. Ascher Shmulewitz has served as our Chairman since January 2014 and on our Board of Directors since February 2013. Dr. Shmulewitz is an inventor, investor and serial entrepreneur in biomedical technologies. Dr. Shmulewitz has founded and invested in over two dozen life science companies including NeoVision Corp, Labcoat Medical Ltd. Arteria Corp, Circulation Inc. and X-Cardia Inc., and has led multiple of these companies to successful exits, including through merger and acquisition transactions with large medical device companies. Dr. Shmulewitz has vast experience in the venture capital arena as an investor, manager and entrepreneur in dozens of companies and ventures. In 1995, Dr. Shmulewitz co-founded San Francisco Science and the Incumed Group, companies that provide seed funding, and is the founder of Medgenesis Partners Ltd., an Israeli private investment firm and incubator that has invested in over a dozen ventures. Dr. Shmulewitz previously held senior executive positions at Advanced Technology Laboratories Inc. (from 1988 to 1992). Dr. Shmulewitz received an M.D. degree from The Technion Medical School and a Ph.D. degree in Engineering from Tel Aviv University, Israel.

Dr. Elran Haber has served as our Chief Executive Officer since November 2015. Prior to that, and from March 2014, Dr. Haber served as our Vice President of Business Strategy and Innovation. Dr. Haber served more than 10 years as Chairman and board member of several publicly traded and privately held companies, including Issta Lines Ltd. (TASE: “ISTA”) from 2007 to 2012, American Express Global Business Travel – Israel (Histour-Eltive Ltd.) from 2010 to 2012, and has been a member of various board committees and has served in senior executive roles in various life science companies. Dr. Haber holds a Ph.D. in Pharmaceutical Science and an M.B.A. in Finance & Financial Engineering, both from The Hebrew University of Jerusalem, Israel.

Mr. Guy Goldin, CPA, has served as our Chief Financial Officer since November 2015. Mr. Goldin has over 20 years of experience in a wide variety of managerial, financial, tax and accounting related positions. Since 2012, Mr. Goldin has served as the chief financial offer of Biological Signal Processing Ltd. From 2010 until July 2016, Mr. Goldin served as the chief financial officer of Petro-Group Ltd. Prior to that, Mr. Goldin served as a chief financial officer at Critisence Ltd., and as a CPA at KPMG. Mr. Goldin holds a B.A. degree (with honors) in Accounting and Economics and an M.B.A. (finance) both from Tel- Aviv University, Israel.

Mr. Doron Ben Ami has served as our Chief Strategy Officer since December 2015. Mr. Ben Ami is a seasoned executive with more than 20 years of management experience holding various leadership roles in the multinational pharmaceutical industry. Among Mr. Ben Ami's previous roles were Associate Vice President of the Eastern Europe and Israel region at Merck (from 2010 to 2015), managing director of Merck subsidiary in Israel (from 2008 to 2010) and the General Manager of Lundbeck Israel (from 2002 to 2008). Since 2015, Mr. Ben Ami has served as a Senior Consultant at The Harel Group Inc., a U.S. based business development advisory firm that connects innovative pharmaceutical companies with strategic partners. Mr. Ben Ami holds a Master of Health Systems Administration degree (M.H.A.) from Tel Aviv University, Israel.

Dr. Adi Zuloff-Shani has served as our Chief Technologies Officer since February 2016. Dr. Zuloff-Shani has more than 15 years of experience as an R&D executive. Prior to joining us, and from 2012 to 2016, Dr. Zuloff-Shani served as a vice president development at Macrocure Ltd. (NASDAQ: "MCUR") where besides leading all research and development activities, she interacted and was involved with the activities of all departments including clinical, operations, quality assurance, quality control, finance, and regulatory affairs. Dr. Zuloff-Shani holds a Ph.D. in human biology and immunology from Bar- Ilan University, Israel.

Mr. Avi Meizler has served on our Board of Directors since February 2013. Mr. Meizler founded Meizler Biopharma SA. in 1990 and served as its president from 1990 to 2012 when it was merged with the Belgian Pharma multinational UCB SA. From June 2012 to December 2014, Mr. Meizler served as the Chairman of the board and Vice President Business Development of Meizler UCB Biopharma SA. In January 2011, Mr. Meizler co-founded Advantech Bioscience Pharmaceutical Ltd., and has served as its Chief Executive Officer since that time. In 2002, Mr. Meizler founded ATME Comercio e Serviços Ltda. (ATME Eco Solutions) currently specialized in energy and water efficiency. Mr. Meizler holds a degree in architecture and an M.B.A. from Fundação Getulio Vargas, Brazil.

Mr. Amit Berger has served on our Board of Directors since August 2014. Mr. Berger has significant expertise in financial markets, where he has held management and board positions for over twenty-five years. Since 2009, Mr. Berger has served as the Chief Executive Officer of Dolphin 1 Investment Ltd. From 2002 to 2004, Mr. Berger served as the Chairman of Dash Investments Ltd., and from 2005 to 2009, as the Chairman and a director of Enter Holdings 1 Ltd. Mr. Berger has also served on the boards of Mega Or Holdings Ltd., N.R. Spuntech Industries Ltd., Itay Financial A.A. Investments Ltd., Ortam-Sahar Engineering Ltd., Hamashbir 365 Ltd. and Polar Investments Ltd. Mr. Berger holds a B.A. degree in Economics from Tel Aviv University, Israel.

Dr. Yafit Stark has served on our Board of Directors since June 2015. Since 2006, Dr. Stark has served as Vice President Global Clinical Advisor at Teva Pharmaceutical Ltd. Dr. Stark has established the Global Innovative Clinical Research Infrastructures at Teva and was responsible for the clinical development of significant products, among them the Copaxone® for Multiple Sclerosis. Dr. Stark is a pioneer in incorporating innovation and new technologies in clinical development. During her 29 years of work in large pharma, she has built up expertise in multiple therapeutic areas and different types of medicinal products technologies. Dr. Stark serves as a director of several biotechnology companies and associations. Dr. Stark holds a Ph.D. degree in Pathology from Tel Aviv University and a Post-Doctorate in Immuno-Histopathology from Tel Aviv University and the Weizmann Institute of Science, Israel.

Mr. Micha Jesselson has served on our Board of Directors since June 2015. Since 2011, Mr. Jesselson has held various leadership roles in Jesselson Investments Ltd. Mr. Jesselson oversees the family's broad based investments in the U.S. and Israel. Mr. Jesselson manages Jesselson Investments Ltd. which is involved in a variety of sectors including venture capital investments, private equity transactions and real estate development in New York. Mr. Jesselson holds a Bachelor of Business degree from The Interdisciplinary Center (IDC), Herzliya, Israel.

Mr. Zohar Heiblum has served on our Board of Directors since August 2013. In 1983, Mr. Heiblum co-founded Tefen IL (Israel) Ltd., a leading consulting firm in Israel. Since then, Mr. Heiblum has been involved in various companies as an investor, consultant, board member and active Chairman. From 2001, Mr. Heiblum has been an active board member and manager at Momentum Management LLP, which specializes in management and investments in turnaround and special situation activities, and in his capacity served mostly in High-Tech companies. From 1998 to 2001, Mr. Heiblum served as the a director and Chairman of the board at of Orex Computed Radiography Ltd., which was later sold to Eastern Kodak Company. From 1998 to 2001, Mr. Heiblum served as a director of Biosonix Ltd. which executed a reverse merger with Neoprobe (today Navidea Biopharmaceutical Inc.) in 2002. From 2002 to 2004, Mr. Heiblum served as the general manager of the Israeli subsidiary of MobileAccess Networks Inc. (formally Foxcom) which was sold to Corning Inc. (U.S.A) in 2011. From 2013 to 2014, Mr. Heiblum served as the acting chief executive officer of Alvarion (in receivership) Ltd. and as chairman to Z. Roth Industries Ltd, which is a leading metal designer & producer of products designed to be situated in the public areas, and as of March 2016 acts as the manager of the pre research and development plan on MATIMOP – The Israeli industry center for R&D, which acts as the executive agency of the Israeli Office of the Chief Scientist. Mr. Heiblum has a B.Sc. degree in Industrial Engineering and an M.B.A., both from Tel Aviv University, Israel.

Mr. Stephen M. Simes has served on our Board of Directors since December 2016. From March 2014 until January 2016, Mr. Simes served as Chief Executive Officer and a member of the Board of Directors of RestorGenex Corporation, a publicly listed company with a focus on oncology (acquired through merger by Diffusion Pharmaceuticals, Inc.). Prior to such time, Mr. Simes served as Vice Chairman, President and Chief Executive Officer and a member of the Board of Directors of BioSante Pharmaceuticals, Inc. from 1998 until June 2013 when BioSante merged with and renamed to ANI Pharmaceuticals, Inc. BioSante, whose common stock was listed on The NASDAQ Global Market, was a specialty pharmaceutical company focused on developing products for women's and men's health. From 1994 to 1997, Mr. Simes was President and Chief Executive Officer and a member of the Board of Directors of Unimed Pharmaceuticals, Inc. (currently a wholly owned subsidiary of AbbVie, Inc.), a company with a product focus on infectious diseases, AIDS, endocrinology and oncology. From 1989 to 1993, Mr. Simes was Chairman, President and Chief Executive Officer of Gynex Pharmaceuticals, Inc., a company which concentrated on the AIDS, endocrinology, urology and growth disorders markets. In 1993, Gynex was acquired by Savient Pharmaceuticals Inc. (formerly Bio-Technology General Corp.), and from 1993 to 1994, Mr. Simes served as Senior Vice President and director of Savient Pharmaceuticals Inc. Mr. Simes's career in the pharmaceutical industry started with G.D. Searle& Co. (now a part of Pfizer Inc.). Mr. Simes has a B.Sc. degree in Chemistry at Brooklyn College of the City University of New York and an M.B.A. in Marketing and Finance from New York University.

Mr. Donald P. Dizon joined our board in March 2017. For the past five years, Mr. Dizon's principal occupation has been investing in private and public companies. Prior to that, and from December 2008 to October 2010, Mr. Dizon served as the Director of High Yield and Distressed Bond Sales at Knight Capital Group. From June 2000 to December 2008, Mr. Dizon was a Senior Vice President at Jefferies High Yield Trading, LLC. Mr. Dizon studied Economics at the University of Southern California.

Mr. Mark E. Groussman joined our board in March 2017. Mr. Groussman has been the President of Melechdavid, Inc. since 2006. In addition, Mr. Groussman has been an investor in both private and public companies for the past ten years. He served as a director of Muscle Pharm Corp. from July 2012 to October 2012. Mr. Groussman also served as the Chief Executive Officer of American Strategic Minerals Corporation from June 2012 to November 2012. Mr. Groussman holds a B.A. from George Washington University and an M.S. in Real Estate Finance from New York University.

Mr. M. David Silverman joined our board in March 2017. In 1998, Mr. Silverman founded NFM, Inc. (now NFM Lending), and has served as its Chief Executive Officer since that time. Prior to that, Mr. Silverman owned and operated several small businesses. Mr. Silverman holds a B.Sc. from the University of Maryland.

Scientific Advisory Board

We have a Scientific Advisory Board of seven researchers in the field(s) of: psychiatry, TS, neurology, Alzheimer's, psychology and pediatrics, neurobiology, pharmacology, organic and medicinal chemistry, cannabinoids and drug discovery. We consult with the members of our Scientific Advisory Board on a regular basis.

Prof. Raphael Mechoulam is a Professor Emeritus of the Department of Natural Products of the School of Pharmacy at the Faculty of Medicine of the Hebrew University of Jerusalem, and a member of the Israel Academy of Sciences and Humanities. Prof. Mechoulam's research in the field of cannabis has led to his the discovery of the endocannabinoid system. Additionally, Prof. Mechoulam was among the first to complete the total synthesis of the major plant cannabinoids, THC, cannabidiol, cannabigerol, and others, and also played a key role in the isolation of the first described endocannabinoid anandamid. Prof. Mechoulam's research interests are in the chemical and biological activity of natural products and medicinal agents, of which his primary contributions are in the field of the constituents of cannabis, about which Prof. Mechoulam has published extensively. Prof. Mechoulam has received amongst others, the Israel Prize in 2000, the European College of Neuropsychopharmacology Lifetime Achievement Award in 2006 and the Rothschild Prize in 2012.

Prof. James Leckman, M.D. is the Neison Harris Professor of Child Psychiatry, Psychiatry, Psychology and Pediatrics at Yale University. Prof. Leckman has served as Director of Research for the Yale Child Study Center for more than twenty years. Prof. Leckman's current research involves exploring whether the strengthening of families and the enhancement of childhood development leads to peaceful results and the prevention of violence. Additionally, Prof. Leckman has a longstanding interest in TS and OCD. Prof. Leckman is the author or co-author of over 430 original articles published in peer-reviewed journals, twelve books, and 140 book chapters.

Prof. Michael Davidson currently serves, among other things, as Chairman of the Stuckinski Centre for Alzheimer's Disease Research in Ramat Gan. Prof. Davidson is also the editor of European Neuropsychopharmacology. Prof. Davidson served as Chief Psychiatrist at the Department of Psychiatry of the Sheba Medical Centre in Tel-Hashomer for six years. Prof. Davidson holds a professorship at the Sackler School of Medicine of Tel Aviv University and a secondary appointment at the Mount Sinai School of Medicine in New York. Prof. Davidson is considered an international expert on Alzheimer's and is the author of approximately 300 publications in scientific literature.

Prof. Daniele Piomelli serves as the Louise Turner Arnold Chair in Neurosciences and Professor of Anatomy and Neurobiology, Pharmacology, and Biological Chemistry at University of California, Irvine. Prof. Piomelli is also the founding director of the drug discovery and development unit (D3) at the Italian Institute of Technology in Genoa, Italy, as well as the Editor in Chief of Cannabis and Cannabinoid Research of Cannabis and Cannabinoid Research. Prof. Piomelli's research has resulted in several contributions to the pharmacology of lipid based signaling molecules including endocannabinoid substances and lipid amides. Prof. Piomelli is the author of more than 400 peer reviewed articles and books and has received several awards and honors. Prof. Piomelli studied Pharmacology and Neuroscience at Columbia University, and the Rockefeller University, and earned his degree of Doctor of Pharmacy from University of Naples.

Prof. Kirsten Müller-Vahl is a Professor of Psychiatry at the Department of Psychiatry, Socialpsychiatry and Psychotherapy at the Hanover Medical School, Germany. Prof. Müller-Vahl specialist in both neurology and adult psychiatry and has worked extensively at a specialized movement disorder clinic. For six years, Prof. Müller-Vahl was a grant-holder for the German Government for scientific research related to TS. Over the past eighteen years, Dr. Müller-Vahl has investigated more than 12000 patients with TS, both children and adults, and has served as the head of the TS outpatient department for over twenty years. Additionally, Prof. Müller-Vahl served on the scientific advisory Board of the German Tourette Syndrome Association, and, in 2011, she became the president of the German Society for the Study of Tourette Syndrome. Furthermore, Prof. Müller-Vahl is a German representative member of the management committee and coordinator of the COST Action BM0905, which is involved the study of TS, and the leader of Working Group 4, which is involved in outreach activities. Prof. Müller-Vahl is a full partner in the EU funded FP7 program, the "European Multicentre Tics in Children Studies."

Prof. Avi Weizman is a Professor of Child and Adult Psychiatry at the Sackler Faculty of Medicine of Tel Aviv University, a Director of the Felsentein Medical Research Center and the head of a Laboratory for Biological Psychiatry and the head of a Research Unit at the Geha Mental Health Center. Prof. Weizman's research involves the investigation of brain mechanisms of mental disorders, and currently focuses on neurodevelopmental disorders, development of new strategies for the treatment of psychotic disorders and the psychopharmacology of mental disorders. Prof. Weizman is the author of more than 760 original papers, 5 full books, 28 book chapters and 60 review articles. After completing his residency in Psychiatry, Prof. Weizman spent two years as a visiting scientist at the National Institute of Mental Health in Bethesda, MD.

Dr. Michael H. Bloch, M.D., M.S. is the associate training director of the Child Study Center's Solnit Integrated Program, which provides psychiatrists-in-training with the opportunity to integrate general, child and research psychiatry during many stages of their career. Dr. Bloch's research interests focus on studying TS, OCD, and trichotillomania. Dr. Bloch's current research involves developing superior treatments for children and adults diagnosed with the aforementioned indications and examining predictors of long-term outcomes with an emphasis on neuroimaging. Dr. Bloch has over 100 peer-reviewed publications and has received the Keese Prize (Best Research Thesis by graduating medical student at Yale University), the Lustman Award (Best Research performed by Psychiatry Resident at Yale University) and the AACAP Norbert and Charlotte Rieger Award for Scientific Achievement (Best Manuscript Published in JAACAP by Child Psychiatrist). Dr. Bloch graduated from Yale School of Medicine, where he completed training in both child and adult psychiatry.

Family Relationships

There are no family relationships between any members of our executive management and our directors.

Arrangements for Election of Directors and Members of Management

We are not a party to, and there are no arrangements or voting agreements that we are aware of for the election of our directors and members of management.

B. Compensation

Compensation

The following table presents in the aggregate all compensation we paid to all of our directors and senior management, as a group for the year ended December 31, 2016. The table does not include any amounts we paid to reimburse any of such persons for costs incurred in providing us with services during this period.

All amounts reported in the tables below reflect the cost to the Company, in thousands of U.S. Dollars, for the year ended December 31, 2016. Amounts paid in NIS are translated into U.S. dollars at the rate of NIS 3.84 = U.S.$1.00, based on the average representative rate of exchange between the NIS and the U.S. dollar as reported by the Bank of Israel in the year ended December 31, 2016.

	Salary/ Fee and Related Benefits	Pension, Retirement and Other Similar Benefits	Share Based Compensation
All directors and senior management as a group, consisting of 10 persons	$ 592,000	-	$ 232,000

In accordance with the Companies Law, the table below reflects the compensation granted to our five most highly compensated officers during or with respect to the year ended December 31, 2016.

Annual Compensation (in USD)

Executive Officer	Salary/ Fee and Related Benefits	Pension, Retirement and Other Similar Benefits	Share Based Compensation	Total
Dr. Elran Haber	$ 190,000	$ -	$ 91,000	$ 281,000
Dr. Ascher Shmulewitz	$ 159,000	$ -	$ 24,000	$ 184,000
Dr. Adi Zuloff-Shani	$ 117,000	$ -	$ 58,000	$ 176,000
Guy Goldin	$ 62,000	$ -	$ 38,000	$ 101,000
Doron Ben Ami	$ 25,000	$ -	$ 11,000	$ 36,000

Employment and Services Agreements with Executive Officers

We have entered into written employment agreements and/or consulting agreements with each of our executive officers (including with our Chairman). All of these agreements contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable law. Most of these agreements are terminable by either party upon 30 days' prior written notice. However, a longer 90 day notice period is required with respect to our Chief Executive Officer and Chairman. In addition, we have entered into agreements with each executive officer and director pursuant to which we have agreed to indemnify each of them up to a certain amount and to the extent that these liabilities are not covered by directors and officers insurance. Members of our senior management are eligible for bonuses each year. The bonuses are payable upon meeting objectives and targets that are set by our Chief Executive Officer and compensation committee and approved annually by our Board of Directors that also set the bonus targets for our Chief Executive Officer and our Chairman.

Upon the consummation of our March 2017 U.S. initial public offering and based on quantitative targets achieved and met pursuant to our Targets Plan for the year 2016, our compensation committee and Board of Directors approved that, each of our Chief Executive Officer and Chairman was entitled to an annual one-time bonus equal to three monthly fees, or approximately NIS 150,000 (approximately $40,000), each. Accordingly, Our Chief Executive Officer was paid NIS 135,000 equal to three month's salary (NIS 45,000 per month) and Our Chairman was paid NIS 150,000 equal to three month's salary (NIS 50,000 per month). Additionally, upon the consummation of the March 2017 offering, options to purchase 700,000 Ordinary Shares previously granted to our Chief Executive Officer were vested immediately.

The aggregate compensation we paid to our current executive officers and directors, including share-based compensation, for the year ended December 31, 2016, was approximately NIS 3.2 million (approximately $0.8 million). This amount includes any amounts set aside or accrued to provide pension, severance, retirement, annual leave, and recuperation or similar benefits or expenses. It does not include any business travel, relocation, professional, and business association dues and expenses reimbursed to office holders, and other benefits commonly reimbursed or paid by companies in Israel. The above also includes the estimated fair value of share-based compensation (share options to purchase Ordinary Shares) in the amount of approximately NIS 893,000 (approximately $232,000). In addition, as of December 31, 2016, share options to purchase an aggregate of 3,449,279 Ordinary Shares granted to our executive officers were outstanding under our Israeli Share Option Plan (2005), or the 2005 Plan, at a weighted average exercise price of approximately NIS 0.89 (approximately $0.23) per share.

Since our inception, we have granted options to purchase our Ordinary Shares to our officers and certain of our directors. Such option agreements may contain acceleration provisions upon certain merger, acquisition, or change of control transactions. We describe our option plans under "Equity Incentive Plan." If the relationship between us and an executive officer or a director is terminated, except for cause (as defined in the various option plan agreements), options that are vested will generally remain exercisable for 90 days after such termination.

For a description of the terms of our options and option plans, see Item 6.E. "Share Ownership" below.

Directors' Service Contracts

Other than with respect to our directors that are also executive officers, namely, our Chairman, we do not have written agreements with any director providing for benefits upon the termination of his employment with our company.

C. Board Practices

Our Board of Directors presently consists of ten members. We believe that Mr. Berger, Mr. Heiblum, Dr. Stark, Mr. Simes, Mr. Groussman, Mr. Dizon and Mr. Silverman are "independent" for purposes of the NASDAQ Stock Market rules. Our articles of association provide that the number of directors shall be set by the general meeting of the shareholders provided that it will consist of not less than three and not more than 12 directors. Pursuant to the Companies Law, the management of our business is vested in our Board of Directors. Our Board of Directors may exercise all powers and may take all actions that are not specifically granted to our shareholders or to management. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our Board of Directors. Our Chief Executive Officer is appointed by, and serves at the discretion of, our Board of Directors, subject to the employment agreement that we have entered into with him (whose terms are approved with the prior review and approval of our compensation committee, the Board of Directors and the general meeting of our shareholders). All other executive officers are appointed by the Board of Directors or by our Chief Executive Officer, provided that he was authorized by the Board of Directors to do so. Their terms of employment are subject to the approval of the Board of Directors' compensation committee (see "—Compensation Committee") and of the Board of Directors, and are subject to the terms of any applicable employment agreements that we may enter into with them.

Each director, except external directors, to the extent required under applicable law (see the description of the External Directors Relief Resolution below, under "—External Directors"), and whose term is set for a three-years term, will hold office until the annual general meeting of our shareholders for the year in which his or her term expires, unless he or she is removed by a majority vote of our shareholders at a general meeting of our shareholders or upon the occurrence of certain events, in accordance with the Companies Law and our articles of association.

In addition, our articles of association allows our Board of Directors to appoint directors to fill vacancies on our Board of Directors or in addition to the acting directors (subject to the limitation on the number of directors and their qualifications), until the next general meeting in which directors may be appointed or such appointment terminated.

Under the Companies Law, nominations for directors may be made by any shareholder holding at least 1% of our outstanding voting power. However, any such shareholder may make such a nomination only if a written notice of such shareholder's intent to make such nomination has been given to our Board of Directors. Any such notice must include certain information, a description of all arrangements between the nominating shareholder and the proposed director nominee(s) and any other person pursuant to which the nomination(s) are to be made by the nominating shareholder, the consent of the proposed director nominee(s) to serve as our director(s) if elected and a declaration signed by the nominee(s) declaring that there is no limitation under the Companies Law preventing their election and that all of the information that is required to be provided to us in connection with such election under the Companies Law has been provided.

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

Our Board of Directors is required to elect one director to serve as the Chairman of the Board of Directors to preside at the meetings of the Board of Directors, and may also remove that director as Chairman. Pursuant to the Companies Law, neither the Chief Executive Officer nor any of his or her relatives is permitted to serve as the Chairman of the Board of Directors, and a company may not vest the Chairman or any of his or her relatives with the Chief Executive Officer's authorities. In addition, a person who reports, directly or indirectly, to the Chief Executive Officer may not serve as the Chairman of the Board of Directors; the Chairman may not be vested with authorities of a person who reports, directly or indirectly, to the Chief Executive Officer; and the Chairman may not serve in any other position in the company or a controlled company, but he or she may serve as a director or Chairman of a controlled company. However, the Companies Law permits the company's shareholders to determine, for a period not exceeding three years from each such determination, that the Chairman or his or her relative may serve as Chief Executive Officer or be vested with the Chief Executive Officer's authorities, and that the Chief Executive Officer or his or her relative may serve as Chairman or be vested with the Chairman's authorities. Such determination of a company's shareholders requires either: (1) the approval of at least the majority of the shares of those shareholders present and voting on the matter (other than controlling shareholders and those having a personal interest in the determination); or (2) that the total number of shares opposing such determination does not exceed 2% of the total voting power in the company. Currently, we have a separate Chairman and Chief Executive Officer.

The Board of Directors may, subject to the provisions of the Companies Law, delegate any or all of its powers to committees of the board, and it may, from time to time, revoke such delegation or alter the composition of any such committees, subject to certain limitations. Unless otherwise expressly provided by the Board of Directors, the committees shall not be empowered to further delegate such powers. The composition and duties of our audit committee, compensation committee, the R&D and clinical trials committee are described below. See "—Committees of the Board of Directors" below.

Prior to the consummation of our U.S. initial public offering and listing on NASDAQ, our Board of Directors was the only formal body that reviews our financial statements as permitted under the Companies Law, and in such capacity oversaw and monitored: our accounting and financial reporting processes and controls, audits of the financial statements, compliance with legal and regulatory requirements as they relate to financial statements or accounting matters and the independent registered public accounting firm's qualifications, independence and performance. Under Israeli law and regulations, we were exempted from appointing a financial statement examination committee, following our Board of Directors' ascertainment that certain requirements under the regulations exists, so to allow us to use said exemption. In lieu of the committee, our Board of Directors was required to comply with certain conditions and its composition had to meet certain requirements when had approved our financial statements. Following the consummation of our U.S. initial public offering and listing on NASDAQ our audit committee charter came into effect, and is currently also responsible, among others, to oversee our accounting and financial reporting processes and our audits of the financial statements, including considering and making recommendations to our board with respect to the financial statements, reviewing and discussing the financial statements and presenting its recommendations with respect to the financial statements to our board prior to the approval of the financial statements by our board. See "— Committees of the Board of Directors – Audit Committee" below.

Role of Board of Directors in Risk Oversight Process

The Board of Directors oversees how management monitors compliance with our risk management policies and procedures, and reviews the adequacy of the risk management framework in relation to the risks faced by us. Our Board of Directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings, and conducts specific strategic planning and review sessions that include a focused discussion and analysis of the risks we face. Senior management reviews these risks with the Board of Directors focusing on particular business functions, operations or strategies, and presents the steps taken by management to mitigate or eliminate such risks. The Board of Directors is assisted in its oversight role by an internal auditor. The internal auditor undertakes both regular and ad hoc reviews of risk management controls and procedures, the results of which are reported to our audit committee. See "—Committees of the Board of Directors—Internal Auditor" below.

Leadership Structure of the Board of Directors

In accordance with the Companies Law and our articles of association, our Board of Directors is required to appoint one of its members to serve as Chairman of the Board of Directors. Our Board of Directors has appointed Dr. Shmulewitz to serve as Chairman of the Board of Directors. The terms of services as an active Chairman were approved by our compensation committee, the Board of Directors and the general meeting of our shareholders.

Alternate Directors

Our articles of association provide, consistent with the Companies Law, that any director, and with respect to external directors (to the extent required under applicable law – see the description of the External Directors Relief Resolution under "—External Directors" below) – only subject to certain preconditions, may appoint another person to serve as his alternate director, provided such person has the qualifications prescribed under the Companies Law to be appointed and to serve as a director and is not already serving as a director or an alternate director of the company. The term of an alternate director may be terminated at any time by the appointing director and automatically terminates upon the termination of the term of the appointing director. An alternate director has the same rights and responsibilities as a director. To date there are no alternate director appointments in effect.

External Directors

Under the Companies Law, an Israeli company whose shares have been offered to the public or whose shares are listed for trading on a stock exchange in or outside of Israel is required to appoint at least two external directors to serve on its Board of Directors. Such external directors are not required to be Israeli residents in case of a company listed on a foreign stock exchange (such as NASDAQ). External directors must meet stringent standards of independence.

Notwithstanding the foregoing, in accordance with the exemption available to certain Israeli public companies whose shares are traded on the NASDAQ, we chose as of April 27, 2017 and for as long the required conditions precedent are met (unless otherwise decided by our Board of Directors), not to follow the requirements of the Companies Law with regard to the appointment of "external directors" as defined in the Companies Law, and instead, we will follow the NASDAQ rules applicable to U.S. domestic companies with respect to the appointment of independent directors, provided that when we appoint a director, both genders shall have representation in our Board.

In addition, in practice, the provisions of our articles of association referring to nominating our external directors according to Israeli law shall have no impact for as long as the External Directors Relief Resolution is in effect.

The definition of "independent director" under NASDAQ Listing Rules and the definition of "external director" under the Companies Law overlap to a significant degree such that we would generally expect any director serving as external directors under the Companies Law (if and to the extent applicable) to satisfy the requirements to be independent under NASDAQ Listing Rules. The definition of "external director" under the Companies Law includes a set of statutory criteria that must be satisfied, including criteria whose aim is to ensure that there is no factor that would impair the ability of the external director to exercise independent judgment. The definition of "independent director" under NASDAQ Listing Rules specifies similar, if slightly less stringent, requirements in addition to the requirement that the Board of Directors consider any factor which would impair the ability of the independent director to exercise independent judgment. In addition, external directors serve for a period of three years (and for no more than two additional three-year terms) pursuant to the requirements of the Companies Law. However, a special majority of shareholders must elect "external directors" while "independent directors" may be elected by an ordinary majority.

With respect to the committees of the Board, see "—Committees of the Board of Directors" below.

Fiduciary Duties of Office Holders

The Companies Law imposes a duty of care and a duty of loyalty on all office holders of a company. "Office holders" includes the Chief Executive Officer, general manager, chief business manager, deputy general manager, vice general manager, any other person assuming the responsibilities of any of the above positions regardless of that person's title, and a director, or a manager directly subordinate to the Chief Executive Officer or general manager.

The duty of care requires an office holder to act with the level of care with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care of an office holder includes a duty to use reasonable means to obtain:

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

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

- refrain from any conflict of interest between the performance of his duties in the company and his performance of his other duties or personal affairs;
- refrain from any action that constitutes competition with the company's business;
- refrain from exploiting any business opportunity of the company to receive a personal gain for himself or others; and
- disclose to the company any information or documents relating to the company's affairs which the office holder has received due to his position as an office holder.

Approval of Related Party Transactions under Israeli Law

General

Under the Companies Law, we may approve an action by an office holder from which the office holder would otherwise have to refrain, as described above, if:

- the office holder acts in good faith and the act or its approval does not cause harm to the company; and
- the office holder disclosed the nature of his or her interest in the transaction (including any significant fact or document) to the company at a reasonable time before the company's approval of such matter.

Disclosure of Personal Interests of an Office Holder

The Companies Law requires that an office holder disclose to the company, promptly, and, in any event, not later than the board meeting at which the transaction is first discussed, any direct or indirect personal interest that he or she may have and all related material information known to him or her relating to any existing or proposed transaction by the company.

A "personal interest" includes the personal interest of a person for whom the office holder holds a voting proxy or the personal interest of the office holder with respect to his or her vote on behalf of a person for whom he or she holds a proxy even if such shareholder has no personal interest in the matter.

If the transaction is an extraordinary transaction, the office holder must also disclose any personal interest held by:

- the office holder's relatives; or
- any corporation in which the office holder or his or her relatives holds 5% or more of the shares or voting rights, serves as a director or general manager or has the right to appoint at least one director or the general manager.

An office holder is not, however, obliged to disclose a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction.

Under the Companies Law, an extraordinary transaction is a transaction:

- not in the ordinary course of business;
- not on market terms; or
- that is likely to have a material effect on the company's profitability, assets or liabilities.

The Companies Law does not specify neither to who within us nor the manner in which required disclosures are to be made. We require our office holders to make such disclosures to our Board of Directors.

Under the Companies Law, once an office holder complies with the above disclosure requirement, the Board of Directors may approve a transaction between the company and an office holder, or a third party in which an office holder has a personal interest, unless the articles of association provide otherwise and provided that the transaction is in the company's interest and is performed by the office holder in good faith. If the transaction is an extraordinary transaction, first the audit committee and then the Board of Directors, in that order, must approve the transaction. Under specific circumstances, shareholder approval may also be required. Any director (and any person, in general) who has a personal interest in an extraordinary transaction, which is considered at a meeting of the Board of Directors or the audit committee, may not be present at this meeting or vote on this matter, unless the Chairman of the relevant committee or Board of Directors determines that he or she should be present in order to present the transaction that is subject to approval. If a majority of the Board of Directors or the audit committee, as the case may be, has a personal interest in the approval of a transaction, then all directors may participate in discussions of the audit committee or the Board of Directors (as applicable) on such transaction and the voting on approval thereof, but shareholder approval is also required for such transaction.

Under the Companies Law, all arrangements as to compensation and indemnification or insurance of office holders require approval of the compensation committee and Board of Directors, and compensation of office holders who are directors must be also approved, subject to certain exceptions, by the shareholders, in that order. If shareholders of a company do not approve the compensation terms of office holders, other than directors, the compensation committee and Board of Directors may override the shareholders' decision, subject to certain conditions.

Disclosure of Personal Interests of a Controlling Shareholder

Under the Companies Law, the disclosure requirements that apply to an office holder also apply to a "controlling shareholder" of a public company. Extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, including a private placement in which a controlling shareholder has a personal interest, as well as transactions for the provision of services whether directly or indirectly by a controlling shareholder or his or her relative, or a company such controlling shareholder controls, and transactions concerning the terms of engagement of a controlling shareholder or a controlling shareholder's relative, whether as an office holder or an employee, require the approval of the audit committee or the compensation committee, as the case may be, the Board of Directors and a majority of the shares voted by the shareholders of the company participating and voting on the matter in a shareholders' meeting. In addition, the shareholder approval must fulfill one of the following requirements:

- at least a majority of the shares held by shareholders who have no personal interest in the transaction and are voting at the meeting must be voted in favor of approving the transaction, excluding abstentions; or

- the shares voted by shareholders who have no personal interest in the transaction who vote against the transaction represent no more than 2% of the voting rights in the company.

In addition, any extraordinary transaction with a controlling shareholder or in which a controlling shareholder has a personal interest with a term of more than three years requires the abovementioned approval every three years; however, such transactions not involving the receipt of services or compensation can be approved for a longer term, provided that the audit committee determines that such longer term is reasonable under the circumstances.

Pursuant to regulations promulgated under the Companies Law, certain transactions with a controlling shareholder or his or her relative, or with directors, that would otherwise require approval of a company's shareholders may be exempt from shareholder approval upon certain determinations of the audit or compensation committee and Board of Directors.

The Companies Law requires that every shareholder that participates, in person, by proxy or by voting instrument, in a vote regarding a transaction with a controlling shareholder, must indicate in advance or in the ballot whether or not that shareholder has a personal interest in the vote in question. Failure to so indicate will result in the invalidation of that shareholder's vote.

The term "controlling shareholder" is defined in the Companies Law as a shareholder with the ability to direct the activities of the company, other than by virtue of being an office holder. A shareholder is presumed to be a controlling shareholder if the shareholder holds 50% or more of the voting rights in a company or has the right to appoint the majority of the directors of the company or its general manager. The definition a "controlling shareholder" is deemed to include any shareholder that holds 25% or more of the voting rights in a company if no other shareholder holds more than 50% of the voting rights in the company. For the purpose of determining the holding percentage stated above, two or more shareholders who have a personal interest in a transaction that is brought for the company's approval are deemed as joint holders.

With respect to approving transactions, to which Dr. Shmulewitz and/or Mr. Meizler are a party to and/or has or might have personal interest in, we have taken upon ourselves since February 2013 (pursuant to the ISA's request) that so long as no substantial changes are made with respect to our shareholders composition, following Dr. Shmulewitz's and Mr. Meizler's investment in us, any material transaction that we intend to pursue, which one of them is, directly or indirectly, a party to or has or might have personal interest in (except for transactions and decisions on indemnity, directors' fees, insurance, etc., which apply uniformly to all directors) will be examined in coordination with the ISA as to the manner of which such transaction should be approved prior to its approval.

Duties of Shareholders

Under the Companies Law, a shareholder has a duty to refrain from abusing its power in the company and to act in good faith and in an acceptable manner in exercising its rights and performing its obligations to the company and other shareholders, including, among other things, voting at general meetings of shareholders on the following matters:

- amendment of the articles of association;
- increase in the company's authorized share capital;
- merger; and
- the approval of "related party" transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from oppressing and discriminating against other shareholders.

The remedies generally available upon a breach of contract will also apply to a breach of the above mentioned duties, and in the event of oppression of other shareholders, additional remedies are available to the injured shareholder.

In addition, any controlling shareholder, any shareholder that knows that its vote can determine the outcome of a shareholder vote and any shareholder that, under a company's articles of association, has the power to appoint or prevent the appointment of an office holder, or has another power with respect to a company, is under a duty to act with fairness towards the company. The Companies Law does not describe the substance of this duty except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness, taking the shareholder's position in the company into account.

Committees of the Board of Directors

Our Board of Directors has established three standing committees: the audit committee and the compensation committee (which are mandatory) and an R&D and clinical trials committee.

Audit Committee

Under the Companies Law, we are required to appoint an audit committee. Notwithstanding the foregoing, in accordance with the exemption available to certain Israeli public companies whose shares are traded on NASDAQ, we chose as of April 27, 2017 and for as long the required conditions precedent are met (unless otherwise decided by our Board of Directors), not to follow the requirements of the Companies Law with regard to the composition of the audit committee (with respect to directorship of external directors) as provided for under the Companies Law, and instead, we will follow the NASDAQ rules applicable to U.S. domestic companies with respect to the appointment and composition of the audit committee.

In addition, in practice, the provisions of our articles of association referring to the audit committee according to Israeli law should be referred to and read based on the abovementioned exemption for as long as the External Directors Relief Resolution is in effect.

Our audit committee, acting pursuant to a written charter, is comprised of Mr. Heiblum (chair), Mr. Berger and Dr. Stark.

Under the Companies Law, our audit committee is responsible for:

- determining whether there are deficiencies in the business management practices of our company, and making recommendations to the Board of Directors to improve such practices;
- determining whether to approve certain related party transactions (including transactions in which an office holder has a personal interest and whether such transaction is extraordinary or material under Companies Law) (see Item 6.C. "Board Practices—Board Practices—Approval of Related Party Transactions under Israeli Law");
- examining our internal controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of its responsibilities;
- examining the scope of our auditor's work and compensation and submitting a recommendation with respect thereto to our Board of Directors or shareholders, depending on which of them is considering the appointment of our auditor;
- establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees;
- determining whether certain acts of an office holder not in accordance with his or her fiduciary duty owed to the company are extraordinary or material and to approve such acts and certain related party transactions (including transactions in which an office holder has a personal interest) and whether such transaction is extraordinary or material under the Companies Law (see Item 6.C. "Board Practices— Approval of Related Party Transactions Under Israeli Law");
- deciding whether to approve and to establish the approval process (including by tender or other competitive proceedings) for certain transactions with a controlling shareholder or in which a controlling shareholder has a personal interest; and
- determining the process of approving of transactions that are not negligible, including determining the types of transactions that will be subject to the approval of the audit committee.

We have adopted an audit committee charter setting forth among others, the responsibilities of the audit committee consistent with the rules of the SEC and NASDAQ Listing Rules (in addition to the requirements for such committee under the Companies Law), including, among others, the following:

- considering and making recommendations to the Board of Directors on our financial statements, reviewing and discussing the financial statements and presenting its recommendations with respect to the financial statements to the Board of Directors prior to the approval of the financial statements by our Board of Directors;
- oversight of our independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of our independent registered public accounting firm to the Board of Directors in accordance with Israeli law;
- recommending the engagement or termination of the person filling the office of our internal auditor, reviewing the services provided by our internal auditor and reviewing effectiveness of our system of internal control over financial reporting;
- recommending the terms of audit and non-audit services provided by the independent registered public accounting firm for pre-approval by our Board of Directors; and
- reviewing and monitoring, if applicable, legal matters with significant impact, finding of regulatory authorities' findings, receive reports regarding irregularities and legal compliance, acting according to "whistleblower policy" and recommend to our Board of Directors if so required, and oversee our policies and procedures regarding compliance to applicable financial and accounting related standards, rules and regulations.

NASDAQ Stock Market Requirements for Audit Committee

Under the NASDAQ Stock Market rules, we are required to maintain an audit committee consisting of at least three members, all of whom are independent and are financially literate and one of whom has accounting or related financial management expertise.

As noted above, currently the members of our audit committee include Mr. Berger, Mr. Heiblum and Dr. Stark. All of the members of our audit committee are "independent," as such term is defined in under NASDAQ Stock Market rules. Mr. Heiblum serves as the Chairman of our audit committee. All members of our audit committee meet the requirements for financial literacy under the NASDAQ Stock Market rules. Our Board of Directors has determined that each member of our audit committee is an audit committee financial expert as defined by the SEC rules and has the requisite financial experience as defined by the NASDAQ Stock Market rules.

Compensation Committee

Under the Companies Law, the Board of Directors of any public company must establish a compensation committee. The compensation committee must be comprised of at least three directors, including all of the external directors (if any), who must constitute a majority of the members of the compensation committee, and one of whom must serve as Chairman of the committee. However, subject to certain exceptions, Israeli companies whose securities are traded on stock exchanges such as the NASDAQ Stock Market, and who do not have a shareholder holding 25% or more of the company's share capital, do not have to meet this majority requirement; provided, however, that the compensation committee meets other Companies Law composition requirements, as well as the requirements of the jurisdiction where the company's securities are traded. In accordance with the exemption available to certain Israeli public companies, whose shares are traded on NASDAQ, we chose as of April 27, 2017 and for as long the required conditions precedent are met (unless otherwise decided by our Board of Directors), not to follow the requirements of the Companies Law with regard to the composition of and the legal quorum required for the discussion and adoption of resolution by the compensation committee (with respect to directorship of external directors) as provided for under the Companies Law, and instead, we will follow the NASDAQ rules applicable to U.S. domestic companies with respect to the appointment and composition of the compensation committee.

In addition, in practice, the provisions of our articles of association referring to the compensation committee according to Israeli law should be referred to and read based on the abovementioned exemption for as long as the External Directors Relief Resolution is in effect.

Our compensation committee is acting pursuant to a written charter, and consists of Mr. Heiblum (chair), Mr. Berger and Dr. Stark, each of whom is "independent," as such term is defined under the NASDAQ Stock Market rules. Our compensation committee complies with the provisions of the Companies Law, the regulations promulgated thereunder, and our articles of association (insofar as the provisions of our articles of association referring to the compensation committee according to Israeli law should be referred to and read based on said exemption), on all aspects referring to its independence, authorities and practice.

Our compensation committee reviews and recommends to our Board of Directors: (1) the annual base compensation of our executive officers and directors; (2) annual incentive bonus, including the specific goals and amount; (3) equity compensation; (4) employment agreements, severance arrangements, and change in control agreements/provisions; (5) retirement grants and/or retirement bonuses; and (6) any other benefits, compensation, compensation policies or arrangements.

The duties of the compensation committee include the recommendation to the company's Board of Directors of a policy regarding the terms of engagement of office holders, to which we refer as a "Compensation Policy". The compensation policy must be adopted by the company's Board of Directors, after considering the recommendations of the compensation committee. The compensation policy is then brought for approval by our shareholders and is subject to special majority requirements. On March 24, 2014, our shareholders approved our compensation policy. We intend to present a new compensation policy to our shareholders at our next general meeting of shareholders, which has not yet been convened.

Compensation Policy

The compensation policy must serve as the basis for decisions concerning the financial terms of employment or engagement of executive officers and directors, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The compensation policy must be approved (or reapproved) not longer than every three years, and relate to certain factors, including advancement of the company's objectives, the company's business and its long-term strategy, and creation of appropriate incentives for executives. It must also consider, among other things, the company's risk management, size and the nature of its operations. The compensation policy must furthermore consider the following additional factors:

- the knowledge, skills, expertise and accomplishments of the relevant office holder (director or executive);
- the director's or executive's roles and responsibilities and prior compensation agreements with him or her;
- the relationship between the terms offered and the average and median compensation of the other employees of the company, including those employed through manpower companies;
- the impact of disparities in salary upon work relationships in the company;
- the possibility of reducing variable compensation at the discretion of the Board of Directors; and the possibility of setting a limit on the exercise value of non-cash variable compensation; and
- as to severance compensation, the period of service of the director or executive, the terms of his or her compensation during such service period, the company's performance during that period of service, the person's contribution towards the company's achievement of its goals and the maximization of its profits, and the circumstances under which the person is leaving the company.

The compensation policy must also include the following principles:

- the link between variable compensation and long-term performance and measurable criteria;
- the relationship between variable and fixed compensation, and the ceiling for the value of variable compensation;

- the conditions under which a director or executive would be required to repay compensation paid to him or her if it was later shown that the data upon which such compensation was based was inaccurate and was required to be restated in the company's financial statements;
- the minimum holding or vesting period for variable, equity-based compensation; and
- maximum limits for severance compensation.

The compensation policy must also consider appropriate incentives from a long-term perspective and maximum limits for severance compensation.

The compensation committee is responsible for (1) recommending the compensation policy to a company's Board of Directors for its approval (and subsequent approval by our shareholders) and (2) duties related to the compensation policy and to the compensation of a company's office holders as well as functions previously fulfilled by a company's audit committee with respect to matters related to approval of the terms of engagement of office holders, including:

- recommending whether a compensation policy should continue in effect, if the then-current policy has a term of greater than three years (approval of either a new compensation policy or the continuation of an existing compensation policy must in any case occur every three years);
- recommending to the Board of Directors periodic updates to the compensation policy;
- assessing implementation of the compensation policy; and
- determining whether the compensation terms of the Chief Executive Officer of the company need not be brought to approval of the shareholders.

Under the regulations promulgated under the Companies Law, certain exemptions and reliefs with respect to the compensation committee are granted to companies whose securities are traded outside of Israel. We may use these exemptions and reliefs after the listing of the ADSs on the NASDAQ Capital Market.

Internal Auditor

Under the Companies Law, the Board of Directors must also appoint an internal auditor nominated and supervised by the audit committee. Our internal auditor is Mr. Daniel Shapira, who has been serving as our Internal Auditor since March 2006. Mr. Shapira is a Certified Public Accountant and holds a B.A. degree in Economics and Accounting from Bar-Ilan University, Israel. The role of the internal auditor is to examine whether a company's actions comply with the law and proper business procedure. Our Chairman acts as the internal auditor's organizational supervisor. The internal auditor will submit his internal auditor's work plan for the approval of our audit committee. The internal auditor may not be an "interested party" or office holder, or a relative of any interested party or office holder, and may not be a member of the company's independent accounting firm or its representative. The Companies Law defines an interested party as a holder of 5% or more of the shares or voting rights of a company, any person or entity that has the right to nominate or appoint at least one director or the general manager of the company or any person who serves as a director or as the general manager of a company. Our internal auditor is not our employee, but the managing partner of a firm which specializes in internal auditing.

Remuneration of Directors

Under the Companies Law, remuneration of directors is subject to the approval of the compensation committee, thereafter by the Board of Directors and thereafter by the general meeting of the shareholders. In case the remuneration of the directors is in accordance with regulation applicable to remuneration of the external directors then such remuneration shall be exempt from the approval of the general meeting. See – "Board Practices - External Directors".

Insurance

Under the Companies Law and our articles of association, a company may obtain insurance for any of its office holders for:

- a breach of his or her duty of care to the company or to another person, including a breach arising out of the negligent conduct of the office holder;

- a breach of his or her duty of loyalty to the company, provided that the office holder acted in good faith and had reasonable cause to assume that his or her act would not prejudice the company's interests;
- a financial liability imposed upon him or her in favor of another person concerning an act performed by such office holder in his or her capacity as an officer holder;
- any other insurable action in accordance with the Companies Law;
- expenses incurred by an office holder relating to an administrative enforcement proceeding conducted with respect to such office holder including reasonable litigation expenses and attorneys' fees; and
- payments to the party injured by the violation, in accordance with the Securities Law.

We have approved a five year framework, where the yearly premium will not exceed the sum of $200,000 (allowing an annual increase of 15%), with a liability limit of up to $25,000,000 per event per annum, and additional side A DIC liability limit of up to $10,000,000, and including a 84 months run-off insurance under reasonable customary terms. This framework entered in effect following the consummation of our U.S. initial public offering in March 2017.

We currently have liability insurance, providing total coverage of $15,000,000 per claim and in the aggregate for the benefit of all of our directors and officers and company coverage for securities claim. In addition, we have total coverage of $5,000,000 Side A DIC only for our directors and officers.

Indemnification

The Companies Law and our articles of association provide that the company may indemnify an office holder against:

- a financial liability imposed on him or her in favor of another person by any judgment concerning an act performed in his or her capacity as an office holder, including a settlement or arbitrator's award approved by a court; However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the Board of Directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the Board of Directors as reasonable under the circumstances, and such undertaking must detail the abovementioned foreseen events and amount or criteria;
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder: (i) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (a) no indictment (as defined in the Companies Law) was filed against such office holder as a result of such investigation or proceeding; and (b) no financial liability as a substitute for the criminal proceeding (as defined in the Companies Law) was imposed upon him or her as a result of such investigation or proceeding, or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (ii) in connection with a monetary sanction;
- reasonable litigation expenses, including attorneys' fees, expended by the office holder or charged to him or her by a court relating to an act performed in his or her capacity as an office holder, in connection with: (1) proceedings that the company institutes, or that another person institutes on the company's behalf, against him or her; (2) a criminal charge of which he or she was acquitted; or (3) a criminal charge for which he or she was convicted for a criminal offense that does not require proof of criminal thought;
- expenses incurred by an office holder relating to an administrative enforcement proceeding conducted with regard to such office holder, including reasonable litigation expenses and including attorneys' fees;
- payment to the party injured by the violation; and
- liability or expense otherwise permitted as an indemnification by the Companies Law.

Our articles of association allow us to indemnify our office holders up to a certain amount. The Companies Law also permits a company to undertake in advance to indemnify an office holder, provided that if such indemnification relates to financial liability imposed on him or her, as described above, then the undertaking should be limited:

- to categories of events that the Board of Directors determines are likely to occur in light of the operations of the company at the time that the undertaking to indemnify is made; and
- in amount or criterion determined by the Board of Directors, at the time of the giving of such undertaking to indemnify, to be reasonable under the circumstances.

We have entered into indemnification agreements, which have been amended following the consummation of our U.S. initial public offering and listing on NASDAQ, with each of our directors and with certain members of our senior management. Each such indemnification agreement provides the office holder with indemnification to the fullest extent permitted under applicable law and up to a certain amount, and including with respect to liabilities resulting from our March 2017 initial public offering in the United States, and to the extent that the directors and officers insurance do not cover these liabilities.

Exculpation

Under the Companies Law, an Israeli company may not exculpate an office holder from liability for a breach of his or her duty of loyalty, but may exculpate in advance an office holder from his or her liability to the company, in whole or in part, and for damages caused to the company as a result of a breach of his or her duty of care (other than in relation to distributions), but only if a provision authorizing such exculpation is included in its articles of association. A company may not exculpate a director from liability arising out of a prohibited dividend or distribution to shareholders. Our articles of association provide that we may exculpate any office holder from liability to us to the fullest extent permitted by law.

We have entered into exculpation agreements with each of our current directors and executive officers undertaking to exculpate and release our office holders from any and all liability to us related to any breach by them of their duty of care to us to the fullest extent permitted by law and including with respect to liabilities resulting from our March 2017 initial public offering in the United States.

Limitations

The Companies Law provides that we may not exculpate or indemnify an office holder nor enter into an insurance contract that would provide coverage for any liability incurred as a result of any of the following: (1) a breach by the office holder of his or her duty of loyalty unless (in the case of indemnity or insurance only, but not exculpation) the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice us; (2) a breach by the office holder of his or her duty of care if the breach was carried out intentionally or recklessly (as opposed to merely negligently); (3) any action taken or omission committed with the intent to derive an illegal personal benefit; or (4) any fine or forfeit levied against the office holder.

D. Employees.

As of April 27, 2017, we have five members of senior management (including our Chairman), of which two are full-time employees, and three are service providers providing their services on a part-time basis. In addition, we have three other full-time employees, all located in Israel. None of our employees is represented by labor unions or covered by collective bargaining agreements. We believe that we maintain good relations with all of our employees. However, in Israel, we are subject to certain Israeli labor laws, regulations and national labor court precedent rulings, as well as certain provisions of collective bargaining agreements applicable to us by virtue of extension orders issued in accordance with relevant labor laws by the Israeli and Industry of Economy and which apply such agreement provisions to our employees even though they are not part of a union that has signed a collective bargaining agreement.

All of our employment and consulting agreements include employees' and consultants' undertakings with respect to non-competition and assignment to us of intellectual property rights developed in the course of employment and confidentiality. The enforceability of such provisions is limited by Israeli law.

E. Share Ownership.

The following table lists as of April 27, 2017, the number of our shares beneficially owned by each of our directors, our executive officers and our directors and executive officers as a group:

	Number of Ordinary Shares Beneficially Owned (1)	Percent of Class (2)
Executive Officers and Directors		
Dr. Ascher Shmulewitz	3,502,254(3)	2.5%
Mr. Abraham (Avi) Meizler	2,226,063(4)	1.6%
Dr. Elran Haber	993,015(5)	*
Guy Goldin	150,000(6)	*
Doron Ben Ami	50,000(7)	*
Dr. Adi Zuloff-Shani	208,333(8)	*
Stephen M. Simes	111,667(9)	*
Amit Berger	-	-
Dr. Yafit Stark	-	-
Micha Jesselson	-	-
Zohar Heiblum	-	-
Mark E. Groussman	-	-
Donald P. Dizon	-	-
M. David Silverman	-	-
All directors and executive officers as a group (14 persons)	7,241,332	5.2%

* Less than 1%.

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Ordinary Shares relating to options currently exercisable or exercisable within 60 days of the date of this table are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person. Except as indicated by footnote, and subject to community property laws where applicable, the persons named in the table above have sole voting and investment power with respect to all shares shown as beneficially owned by them.
(2) The percentages shown are based on 138,355,614 Ordinary Shares issued and outstanding as of April 27, 2017 plus Ordinary Shares relating to options currently exercisable or exercisable within 60 days of the date of this table, which are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person.
(3) Includes (i) 669,703 Ordinary Shares and options to purchase 423,037 Ordinary Shares at an exercise price of NIS 0.79 (approximately $0.21) per share, held directly by Dr. Shmulewitz , (ii) 2,242,846 Ordinary Shares, held by Dekel, which is an Israel company controlled by Dr. Shmulewitz; and (iii) options to purchase 166,667 Ordinary Shares at an exercise price of NIS 0.50 (approximately $0.13) per share, held by Medgenesis Partners Ltd., which, to the best of our knowledge, is an Israeli company controlled by Dr. Shmulewitz.
(4) Includes (i) 2,192,730 Ordinary Shares held by Gillbood Trading SA, a Panamanian company controlled by Mr. Meizler, and (ii) options to purchase 33,333 Ordinary Shares at an exercise price of NIS 0.50 (approximately $0.13).
(5) Includes (i) options to purchase 199,682 Ordinary Shares at an exercise price of NIS 0.99 (approximately $0.26) per share, (ii) options to purchase 93,333 Ordinary Shares at an exercise price of NIS 0.50 (approximately $0.13) per share, and (iii) options to purchase 700,000 Ordinary Shares at an exercise price of NIS 0.99 (approximately $0.26) per share.
(6) Includes (i) options to purchase 100,000 Ordinary Shares at an exercise price of NIS 0.99 (approximately $0.26) per share, and (ii) options to purchase 50,000 Ordinary Shares at an exercise price of NIS 1.011 (approximately $0.26) per share.
(7) Includes options to purchase 50,000 Ordinary Shares at an exercise price of NIS 0.99 (approximately $0.26) per share.
(8) Includes options to purchase 208,333 Ordinary Shares at an exercise price of NIS 1.06 (approximately $0.27) per share.
(9) Includes options to purchase 111,667 Ordinary Shares at an exercise price of NIS 0.86 (approximately $0.23) per share.

Equity Incentive Plans

Israeli Share Option Plan (2015); Israeli Share Option Plan (2005)

In July 2005, we adopted the 2005 Plan, which was in force for a period of 10 years. Upon the expiration of the 2005 Plan, we adopted the Israeli Share Option Plan (2015), or the 2015 Plan. Some of the options previously granted under the 2005 Plan remain outstanding, and new options are granted under the 2015 Plan.

Under the plans, we grant options to purchase our Ordinary Shares to our officers, employees, consultants and other service providers. As of April 27, 2017, 5,000,000 Ordinary Shares were reserved for issuance under the plans, of which options to purchase 4,365,279 Ordinary Shares were issued and outstanding thereunder. Of such outstanding options, options to purchase 2,386,248 Ordinary Shares were vested as of April 30, 2017, with a weighted average exercise price of NIS 0.87 (approximately $0.24) per share.

The plans were designed to reflect the provisions of the Israeli Income Tax Ordinance (New Version) 5721-1961, or the Ordinance, mainly Sections 102 and 3(i), which afford certain tax advantages to Israeli employees, officers, and directors who are granted share options in accordance with its terms. Section 102 of the Ordinance allows employees, directors, and officers, who are not controlling shareholders and who are Israeli residents, to receive favorable tax treatment for compensation in the form of shares or share options. Section 102 of the Ordinance includes two alternatives for tax treatment involving the issuance of share options or shares to a trustee for the benefit of the grantees and also includes an additional alternative for the issuance of share options or shares directly to the grantee. Sections 102(b)(2) and 102(b)(3) of the Ordinance, which provide the most favorable tax treatment for grantees, permit the issuance to a trustee under the "capital gain" tax regime. In order to comply with the terms of the "capital gain" tax regime, all share options granted under a specific plan and subject to the provisions of Section 102 of the Ordinance, as well as the shares issued upon exercise of such share options and other shares received following any realization of rights with respect to such share options, such as share dividends and share splits, must be registered in the name of a trustee selected by the Board of Directors and held in trust for the benefit of the relevant employee, director, officer or service provider. The trustee may not release these share options or shares to the relevant grantee before the second anniversary of the registration of the share options in the name of the trustee. However, under this regime, our ability to deduct an expense with respect to the issuance of the share options or shares might be limited. Section 3(i), which permits the issuance of share options under the "income from labor" tax regime, does not provide for similar tax benefits.

The 2015 Plan may be administered by our Board of Directors either directly or upon the recommendation of a committee appointed by our Board of Directors. Our compensation committee recommends to the Board of Directors, and the Board of Directors determines or approves the eligible individuals who receive share options under the 2015 Plan, the number of Ordinary Shares covered by those share options, the terms under which such share options may be exercised, and other terms and conditions of the share options, all in accordance with the provisions of the 2015 Plan. Share option holders may not transfer their share options except in the event of death or transfer in accordance with law and the provisions of the 2015 Plan. Our compensation committee or Board of Directors may at any time amend or terminate the 2015 Plan; however, any amendment or termination may not adversely affect any share options or shares granted under such 2105 Plan prior to such action. The share option exercise price is determined by the Board of Directors, following the recommendation of the compensation committee, and specified in each option award agreement.

Awards under the 2015 Plan may be granted until December, 2025, ten years from December 2015. Share options granted under the 2005 and the 2015 Plans generally vest over 3 years commencing on the date of grant such that the options shall vest on a quarterly basis in equal portions, unless otherwise provided in a specific share option grant agreement. Share options, other than certain incentive share options, that are not exercised within the term set forth under each award agreement shall expire, unless otherwise determined by our Board of Directors. Except as otherwise determined by the Board of Directors or as set forth in an individual's award agreement, in the event of termination of employment or services for reasons of disability or death, the grantee, or in the case of death - his or her legal successor, may exercise share options that have vested prior to termination within a period of twenty four months from the date of disability or death. If we terminate a grantee's employment or service for cause (as this term is defined under the Plan), all of the grantee's unvested share options will expire on the date of termination, yet share options which by that date the offeree's eligibility to exercise has already been formed shall remain exercisable. If a grantee's employment or service is terminated for any other reason other than for cause, the grantee may exercise his or her vested share options within 90 days of the date of termination, unless otherwise provided in a specific share option grant agreement. In the event of (i) a sale of all or substantially all of our assets or (ii) our consolidation or merger in which we are not the ongoing or surviving corporation, then, and unless otherwise determined in the agreement or by the board, we shall be entitled to determine that all of the outstanding unexercised share options held by or for the benefit of any grantee shall be assumed or substituted for an appropriate number of share options of the successor company, provided that the aggregate amount of the exercise price for such share options shall be equal to the aggregate amount of the exercise price of our unexercised share options held by each grantee at such time. In addition, and unless otherwise determined by our board, upon the occurrence of certain events, as further described in the plans (among others, a merger transaction (or the like), liquidation and/or dissolution, recapitalization, rights offering, distribution of bonus shares, dividends and capital reorganization), a grantee's rights to purchase shares under either of the plans shall be adjusted as provided therein.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table presents as of April 27, 2017 (unless otherwise noted below), the beneficial ownership of our Ordinary Shares by each person who is known by us to be the beneficial owner of 5% or more of our outstanding Ordinary Shares (to whom we refer as our Major Shareholders). The data presented are based on information provided to us by the Major Shareholders or disclosed in public regulatory filings.

Except as indicated in footnotes to this table, we believe that the shareholders named in this table have sole voting and investment power with respect to all Ordinary Shares shown to be beneficially owned by them. Unless otherwise noted below, each beneficial owner's address is: c/o Therapix Biosciences Ltd., 5 Azrieli Center (Square Tower), 27th Floor, Tel-Aviv 6702501, Israel. The shareholders listed below do not have any different voting rights from any of our other shareholders. We know of no arrangements that would, at a subsequent date, result in a change of control of our Company.

Name	Number of Ordinary Shares Beneficially Owned(1)	Percent of Class(2)
Jay's Thera Ltd. (3)	8,504,958	6.1%
John Stetson	7,464,000	5.4%

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Ordinary Shares relating to options currently exercisable or exercisable within 60 days of the date of this table are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person.
(2) The percentages shown are based on 138,355,614 Ordinary Shares issued and outstanding as of April 27, 2017.
(3) To the best of our knowledge, Jay's Thera Ltd. is a private company which is controlled (indirectly) by Mr. Benjamin Jesselson, the father of Micha Jesselson, one of our directors.

Changes in Percentage Ownership by Major Shareholders

There were no changes in percentage ownership by MajorShareholders (i.e., of or more than 5% of our issued and outstanding share capital) except as detailed below:

- Equity investment in the Company as of April 3, 2013 by Incumed SPV, a company controlled by Dr. Ascher Shmulewitz, and by Gilbood Trading S.A., a company controlled by Mr. Avi Meizler, in return of 4,000,000 Ordinary Shares, constituting approximately 45% of our issued share capital after the investment.

- Public offering by the Company as of July 18, 2013 of 3,593,750 Ordinary Shares, constituting approximately 33% of our issued share capital after the offering, which reduced the percentages of our Major Shareholders.

- Equity investment in the Company as of April 29, 2015 by Jesselson Investments Ltd., a company controlled by Mr. Benjamin Jesselson, the father of Micha Jesselson, one of our directors, in return for 4,400,000 Ordinary Shares which were later transferred to its subsidiary Jay's Thera Ltd., one of our current principal shareholders, constituting approximately 20% of our issued share capital after the investment, which reduced the percentages of our Major Shareholders.

- Equity investment in the Company, including by exercise of warrants, as of August 29, 2016 by Dorigol 31 Corp., and other of its affiliated entities, in return for an aggregate of 1,139,998 Ordinary Shares, constituting approximately 6.32% of our issued share capital after their investments, which reduced the percentages of our Major Shareholders.

- Equity investment in the Company as of March 1, 2017, by Dr. Haim Amir, in return for 5,357,143 Ordinary Shares, constituting approximately 11.6% of our issued share capital after the investment, which reduced the percentages of our Major Shareholders.

- Public offering by the Company as of March 27, 2017 and April 3, 2017 of 2,000,000 ADSs and 300,000 ADSs, respectively, constituting approximately 65.8% (in the aggregate) of our issued share capital after the offering, which reduced the percentages of our Major Shareholders.

Record Holders

As of April 27, 2017, there were 3 holders of record of our Ordinary Shares. The number of record holders is not representative of the number of beneficial holders of our Ordinary Shares, as the shares of most our shareholders who hold Ordinary Shares that are traded on the TASE are recorded in the name of our Israeli share registrar, Mizrahi-Tefahot Nominees Company Ltd. As of April 27, 2017, there were no record holders of our Ordinary Shares in the United States.

The Company is not controlled by another corporation, by any foreign government or by any natural or legal persons except as set forth herein, and here are no arrangements known to the Company which would result in a change in control of the Company at a subsequent date.

B. Related Party Transactions

Employment Agreements

We have entered into written employment agreements with each of our executive officers. All of these agreements contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable law. Most of these agreements are terminable by either party upon 30 days' prior written notice. However, a longer 90 day notice period is required with respect to our Chief Executive Officer and Chairman. In addition, we have entered into agreements with each executive officer and director pursuant to which we have agreed to indemnify each of them up to a certain amount and to the extent that these liabilities are not covered by directors and officers insurance. Members of our senior management are eligible for bonuses each year. The bonuses are payable upon meeting objectives and targets that are set by our Chief Executive Officer and approved annually by our Board of Directors that also set the bonus targets for our Chief Executive Officer. See Item 6.B. "Compensation—Employment and Service Agreements with Executive Officers" and see the descriptions of exculpation and indemnification agreements and directors and officers insurance arrangements in Item 6.A. "Directors and Senior Management" and Item 6.C. "Board Practices—Insurance," — "Indemnification" and "—Exculpation".

Options

Since our inception, we have granted options to purchase our Ordinary Shares to our officers and certain of our directors. Such option agreements may contain acceleration provisions upon certain merger, acquisition, or change of control transactions. We describe our option plans under Item 6.E. "Share Ownership—Equity Incentive Plans." If the relationship between us and an executive officer or a director is terminated, except for cause (as defined in the various option plan agreements), options that are vested will generally remain exercisable for 90 days after such termination.

Dekel License Agreement

In May 2015, we entered into a license agreement, which became effective in August 2015, with Dekel, an Israeli private company controlled by Dr. Ascher Shmulewitz, the Chairman of our Board of Directors, under which we were granted an irrevocable, worldwide, exclusive, royalty-bearing license to certain of Dekel's technology. See Item 4.B. "Business Overview—Intellectual Property" for additional information. Pursuant to the license agreement, we granted options to purchase 3,876,000 of our Ordinary Shares at an exercise price per share of NIS 0.50 and additional options to purchase 11,926,154 of our Ordinary Shares at an exercise price per share of NIS 0.65. Dekel subsequently transferred options to purchase 3,352,458 Ordinary Shares to Jay's Thera Ltd., one of our Major Shareholders. As of the date hereof, Jay's Thera has exercised all of the options for aggregate consideration of NIS 1,923,000.

In May 2016, we issued Dekel 200,000 Ordinary Shares in consideration of an NIS 100,000 future royalty payment under the license agreement. Pursuant to the license agreement, we are obligated to pay Dekel certain payments subject to a completion of milestones. During November 2016, we achieved the first milestone under the license agreement, success of pre-clinical studies with Dekel's technology. Therefore, as of November 2016, we had an obligation to pay a milestone payment of $25,000 (approximately NIS 94,000). This payment was paid in cash in March 2017.

Private Placements of Ordinary Shares

On March 29, 2015 , we issued to Jesselson Investments Ltd., an Israeli company controlled by Benjamin Jesselson who is the father of our director Micha Jesselson, 4,400,000 Ordinary Shares, at a price per share of NIS 0.50 (approximately $0.12). As part of this transaction, Jesselson Investments Ltd. is entitled to indemnification in case of breach or falsity of any representation or warranty by us contained in the purchase agreement; and/or any fine or monetary sanction imposed on us by the ISA in connection with the administrative proceedings conducted by the ISA. See Item 4.B. "Business Overview—Legal Proceedings". The indemnification is capped at the lesser of the amount actually invested by the Jesselson Investments Ltd. or the loss as may be finally determined by competent court as a result of a claim filed by Jesselson Investments Ltd. in connection with such liability. Furthermore, we would only be liable in the event that any claims asserted against us regarding misrepresentation are brought before April 29, 2017 and exceed a sum of $50,000, and/or claims in connection with a monetary sanction pursuant to administrative proceedings are brought before April 29, 2020 and exceed a sum of $20,000.

In June 2015, we issued to Universal Link Ltd., a private company in control of our then director, Mr. Ahmad Alimi, 500,000 Ordinary Shares pursuant to the exercise of warrants at a price per share of NIS 0.50 (approximately $0.13), and between October and December 2015 we issued to Mr. Alimi an additional 500,000 Ordinary Shares pursuant to the exercise of warrants at a price per share of NIS 0.65 (approximately $0.16).

In October 2015, as part of a private placement to several investors, we issued Jay's Thera Ltd. 752,500 Ordinary Shares, at a price per share of NIS 1.05 (approximately $0.27).

In March 2017, as part of a private placement, we issued to Dr. Haim Amir 5,357,143 Ordinary Shares, at a price per share of NIS 0.70 (approximately $0.19). Pursuant to the agreement, in the event that we raise additional funds by means of a private placements (excluding public offerings) upon less favorable terms relating to the price per share, then we would be required to issue to Dr. Amir, for no additional consideration, such number of Ordinary Shares reflecting the difference between the new price per share and the price per share actually paid by Dr. Amir. In addition, in the event that we raise additional funds by means of a public offering of our Ordinary Shares of ADSs upon less favorable terms relating to the price per share, then immediately following the closing of such public offering, we would be required to pay Dr. Amir an amount, calculated as the number of his purchased shares (5,357,143 Ordinary Shares) multiplied by the difference between NIS 0.70 and the future public offering price per share. Pursuant to our sole discretion, we may choose to pay this sum in cash and/or in Ordinary Shares (at a price per share of such public offering). In addition, Dr. Amir is entitled to preemptive rights to participate in our future private placements upon the same terms offered to future investors, on a pro-rata basis to his holdings. The foregoing anti-dilution rights have expired. Since we issued our ADSs in our initial public offering on Nasdaq at a public offering price of $6.00 per ADS, which is less than $7.71 per ADS, we are planning to issue 1,529,910 Ordinary Shares to the investor according to the anti-dilution provision mentioned above.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION.

A. Consolidated Statements and Other Financial Information.

See Item 18. “Financial Statements”.

Legal Proceedings

In the past we were subject to an administrative inquiry relating to our reports (quality and scope of disclosure) to the ISA and the TASE with respect to the termination of a license agreement we had with Ramot for certain technology covering the BBS Technology, which was terminated in the beginning of 2014. In April 2017 we settled the administrative inquiry and admitted to the following breaches: (i) failure to submit an immediate report about a material event (the license agreement termination) in a timely and lawful manner; (ii) inclusion of a misleading detail in an immediate report; and (iii) misleading the ISA in connection with such actions. We were required to pay a monetary sanction of NIS 150,000 (approximately $40,000) (and potentially an additional equal sum if we are found to have committed the same breaches in the next 24 months). In addition, our Chairman will be subject to a one year probationary condition, whereby if he is found to commit a similar violation, he will be prevented from serving as an officer or director of a public company.

On February 3, 2016, we received a notice of opposition filed anonymously with the European Patent Office, in connection with a divisional European application for a patent relating to our Anti-CD3 technology, which we are currently in the process of selling in connection with a sale of our former subsidiary, Orimmune, to Karma Link. Additional patents covering this technology in other territories were not challenged. Karma Link is currently bearing the costs of the proceedings. On October 31, 2016, we received an invitation to attend oral proceedings. We are required to submit a response to such invitation by the end of May 2017. We do not foresee any material effect on our business should the opposition succeed, unless Karma Link will refuse to continue to bear the costs of the proceedings. In such an event, we will need to consider whether to abandon the technology, which would have no material relevance to our current business activities, or bear the costs of the proceeding. Furthermore, we do not believe that the sale of the technology nor the sale of our holdings in Orimmune will be effected should the opposition succeed.

Dividends

We have never declared or paid any cash dividends on our Ordinary Shares and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our Board of Directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our Board of Directors may deem relevant.

The distribution of dividends may also be limited by the Companies Law, which permits the distribution of dividends only out of retained earnings or earnings derived over the two most recent fiscal years, whichever is higher, provided that there is no reasonable concern that payment of a dividend will prevent a company from satisfying its existing and foreseeable obligations as they become due.

Payment of dividends may be subject to Israeli withholding taxes. See Item 10.E. “Taxation” for additional information.

B. Significant Changes

No significant change, other than as otherwise described in this annual report on Form 20-F, has occurred in our operations since the date of our consolidated financial statements included in this annual report on Form 20-F.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our Ordinary Shares have been trading on the TASE under the symbol “ THXBY” since December 26, 2005. Our ADSs commenced trading on the OTC Markets on October 6, 2014 under the symbol “ THXBY”. On March 22, 2017, our ADSs, each of which represents forty of our Ordinary Shares, commenced trading on the NASDAQ Capital Market under the symbol “TRPX.”

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

	NIS Price Per Ordinary Share		U.S.$ Price Per Ordinary Share	
	High	Low	High	Low
Annual:				
2016	1.04	0.62	0.26	0.16
2015	0.99	0.37	0.26	0.09
2014	1.13	0.38	0.33	0.10
2013	1.77	0.55	0.49	0.15
2012	14.21	1.31	3.70	0.35
Quarterly:				
Fourth Quarter 2016	0.83	0.62	0.21	0.16
Third Quarter 2016	0.93	0.77	0.24	0.21
Second Quarter 2016	1.01	0.82	0.27	0.21
First Quarter 2016	1.04	0.85	0.26	0.22
Fourth Quarter 2015	0.99	0.82	0.26	0.21
Third Quarter 2015	0.93	0.72	0.24	0.19
Second Quarter 2015	0.86	0.39	0.23	0.10
First Quarter 2015	0.49	0.37	0.12	0.09
Most Recent Six Months:				
March 2017	0.88	0.73	0.24	0.20
February 2017	0.81	0.66	0.22	0.18
January 2017	0.68	0.59	0.18	0.15
December 2016	0.76	0.63	0.20	0.16
November 2016	0.83	0.77	0.21	0.20
October 2016	0.80	0.72	0.21	0.19

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

	U.S.$ Price Per ADS	
	High	Low
Annual:		
2016	8.02	7.80
2015	7.80	4.30
2014 (from October 6, 2014)	6.00	4.30
Quarterly:		
Fourth Quarter 2016	8.02	8.02
Third Quarter 2016	8.02	8.02
Second Quarter 2016	8.02	7.80
First Quarter 2016	7.80	7.80
Fourth Quarter 2015	7.80	7.80
Third Quarter 2015	7.80	7.80
Second Quarter 2015	6.50	4.30
First Quarter 2015	4.30	4.30
Most Recent Six Months:		
March 2017	8.02	8.02
February 2017	8.02	8.02
January 2017	8.02	8.02
December 2016	8.02	8.02
November 2016	8.02	8.02
October 2016	8.02	8.02

B. Plan of Distribution

Not applicable.

C. Markets

Our Ordinary Shares are listed on the TASE. Our ADSs are listed on the NASDAQ Capital Market.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Our registration number with the Israeli Registrar of Companies is 513581652.

Purposes and Objects of the Company

Our purpose is set forth in Section 2 of our articles of association and includes every lawful purpose.

The Powers of the Directors

Our Board of Directors shall direct our policy and shall supervise the performance of our Chief Executive Officer and his actions. Pursuant to the Companies Law and our articles of association, our Board of Directors may exercise all powers and take all actions that are not required under the Companies Law or our articles of association to be exercised or taken by our shareholders, including the power to borrow money for Company purposes.

Rights Attached to Shares

Our Ordinary Shares shall confer upon the holders thereof:

- equal right to attend and to vote at all of our general meetings, whether regular or special, with each Ordinary Share entitling the holder thereof, which attend the meeting and participate at the voting, either in person or by a proxy or by a written ballot, to one vote;
- equal right to participate in distribution of dividends, if any, whether payable in cash or in bonus shares, in distribution of assets or in any other distribution, on a per share pro rata basis; and
- equal right to participate, upon our dissolution, in the distribution of our assets legally available for distribution, on a per share pro rata basis.

All Ordinary Shares have identical voting and other rights in all respects.

Dividend and Liquidation Rights and Bonus Shares

We may declare a dividend to be paid to the holders of our Ordinary Shares in proportion to their respective shareholdings. Under the Companies Law, dividend distributions are determined by the Board of Directors and do not require the approval of the shareholders of a company unless the company's articles of association provide otherwise. Our articles of association do not require shareholder approval of a dividend distribution and/or issuance of bonus shares and provide that our Board of Directors may, on its sole discretion, determine dividend distributions and/or issuance of bonus shares. We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future.

Pursuant to the Companies Law, the distribution amount is limited to the greater of retained earnings or earnings generated over the previous two years, according to our then last reviewed or audited financial statements, provided that the date of the financial statements is not more than six months prior to the date of the distribution, or we may otherwise distribute dividends that do not meet such criteria only with court approval. In each case, we are only permitted to distribute a dividend if our Board of Directors and the court, if applicable, determines that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

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

Access to Corporate Records

Under the Companies Law, shareholders are provided access to: minutes of our general meetings; our shareholders register and principal shareholders register, articles of association and financial statements; and any document that we are required by law to file publicly with the Israeli Companies Registrar or the ISA. In addition, shareholders may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interest or protect a trade secret or patent.

Transfer of Shares

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

Election of Directors

Our Ordinary Shares do not have cumulative voting rights for the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors. Pursuant to our articles of association, our directors are elected at an annual general meeting and/or a special meeting of our shareholders and serve on the Board of Directors until the next annual general meeting, except for external directors or until they resign or until they cease to act as board members pursuant to the provisions of our articles of association or any applicable law, upon the earlier. Pursuant to our articles of association, the vote required to appoint a director is a simple majority vote of holders of our voting shares, participating and voting at the relevant meeting. A director whose tenure has ended may be reelected. In addition, our articles of association allow our Board of Directors to appoint directors to fill vacancies or as an addition to the Board of Directors (subject to the maximum number of directors) to serve until the next general meeting where directors are elected or earlier if required by our articles of association or applicable law, upon the earlier. External directors are elected for an initial term of three years and may be removed from office pursuant to the terms of the Companies Law (but see above the External Directors Relief Resolution, regarding adoption of reliefs concerning the necessity of appointing external directors under Israeli law, for as long as our shares are listed on NASDAQ). See Item 6.C. "Board Practices –External Directors."

Annual and Special Meetings

Under the Companies Law, we are required to hold an annual general meeting of our shareholders once every calendar year, at such time and place which shall be determined by our Board of Directors, that must be no later than 15 months after the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to as special general meetings. Our Board of Directors may call special meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine, and upon the written request of: (a) any two of our directors or such number of directors equal to one quarter of the directors present at such a meeting; and/or (b) one or more shareholders holding, in the aggregate, either (a) 5% or more of our outstanding issued shares and 1% of our outstanding voting power or (b) 5% of our outstanding voting power. One or more shareholders, holding 1% or more of the outstanding voting power, may ask the board to add an item to the agenda of a prospective meeting, if the proposal merits discussion at the general meeting.

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

- amendments to our articles of association;
- the exercise of our Board of Director's powers if our Board of Directors is unable to exercise its powers and the exercise of any of its powers is required for our proper management;
- appointment or termination of our auditors;
- appointment of directors, including external directors (to the extent applicable) (see the above description of the External Directors Relief Resolution, regarding adoption of reliefs concerning the necessity of appointing external directors under Israeli law, for as long as our shares are listed on NASDAQ);
- approval of acts and transactions requiring general meeting approval (namely certain related party transactions) pursuant to the provisions of the Companies Law and any other applicable law;
- increases or reductions of our authorized share capital; and
- a merger (as such term is defined in the Companies Law).

Notices

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

Under the regulations of the Companies Law, certain exemptions and reliefs with respect to the manner of announcing the convening of the general meeting of shareholders are granted to companies whose securities are traded outside of Israel.

Under our articles of association, shareholders are not permitted to take action via written consent in lieu of a meeting.

Quorum

As permitted under the Companies Law, and our articles of association, the quorum required for our general meetings consists of at least three shareholders present in person, by proxy or written ballot, who hold or represent between them at least thirty percent of the total outstanding voting rights (instead of 33 1/3% of the issued share capital required under the NASDAQ Listing Rules). If within half an hour of the time appointed for the general meeting a quorum is not present, the general meeting shall stand adjourned the same day of the following week, at the same hour and in the same place, or to such other date, time and place as prescribed in the notice to the shareholders and in such adjourned meeting, if no quorum is present within half an hour of the time arranged, any number of shareholders participating in the meeting, shall constitute a quorum.

If a general meeting was summoned following the request of a shareholder, then a quorum required in an adjourned general meeting, shall consist of at least one or more shareholders, which holds and represents at least 5% of the company's issued and outstanding share capital and at least 1% of the company voting rights, or one or more shareholder, which holds at least 5% of the Company’s voting rights.

Adoption of Resolutions

Our articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required under the Companies Law or our articles of association. A shareholder may vote in a general meeting in person, by proxy or by a written ballot. Under the Companies Law, each of (i) the approval of an extraordinary transaction with a controlling shareholder, (ii) the terms of employment or other engagement of the controlling shareholder of the company or such controlling shareholder’s relative (even if not extraordinary) requires, the approval described above under “Board Practices — Approval of Related Party Transactions under Israeli Law — Disclosure of Personal Interests of Controlling Shareholders,” and (iii) the approval of certain compensation-related matters require the approval described above under “Board Practices — Committees of the Board of Directors — Compensation Committee”. Under our articles of association, the alteration of the rights, privileges, preferences, or obligations of any class of our shares requires a simple majority vote of the class so affected (or such other percentage of the relevant class that may be set forth in the governing documents relevant to such class), in addition to the ordinary majority vote of all classes of shares voting together as a single class at a shareholder meeting. An exception to the simple majority vote requirement is a resolution for the voluntary winding up, or an approval of a scheme of arrangement or reorganization, of the company pursuant to Section 350 of the Companies Law, which requires the approval of holders of 75% of the voting rights represented at the meeting, in person, by proxy, or by voting deed and voting on the resolution. In addition, the general meeting of our shareholders can decide to alter our articles of association, which decision requires - in addition to any other majority requirement and except as expressly provided otherwise on our articles of association - a simple majority vote of the shareholders attending such general meeting (without counting abstentions).

Changing Rights Attached to Shares

Unless otherwise provided by the terms of the shares and subject to any applicable law, in order to change the rights attached to any class of shares, such change must be adopted at a general meeting of the affected class or by a written consent of all the shareholders of the affected class.

The enlargement of an existing class of shares or the issuance of additional shares thereof, shall not be deemed to modify the rights attached to the previously issued shares of such class or of any other class, unless otherwise provided by the terms of the shares.

Registration Rights

None of our shareholders is entitled to registration rights.

Provisions Restricting Change in Control of Our Company - Acquisitions under Israeli Law

Merger

The Companies Law includes provisions that allow a merger transaction and requires that each company that is a party to the merger have the transaction approved by its Board of Directors and a vote of the majority of its shares (unless certain requirements described under the Companies Law are met) and, in the case of the target company, a majority vote of each class of its shares, voted on the proposed merger at a shareholders meeting.

For purposes of the shareholder vote of each party, unless a court rules otherwise, the merger will not be deemed approved if shares representing a majority of the voting power present at the shareholders meeting and which are not held by the other party to the merger (or by any person who holds 25% or more of the voting power or the right to appoint 25% or more of the directors of the other party) vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same special majority approval that governs all extraordinary transactions with controlling shareholders (as described under "Board Practices — Approval of Related Party Transactions under Israeli Law — Disclosure of Personal Interests of a Controlling Shareholder").

If the transaction would have been approved by the shareholders of a merging company but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value of the parties to the merger and the consideration offered to the shareholders of the target company.

Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that as a result of the merger the surviving company will be unable to satisfy the obligations of any of the parties to the merger and may further give instructions to secure the rights of creditors. In addition, a merger may not be completed unless at least (1) 50 days have passed from the time that the requisite proposals for approval of the merger were filed with the Israeli Registrar of Companies by each merging company and (2) 30 days have passed since the merger was approved by the shareholders of each merging company.

Special Tender Offer

The Companies Law also provides that an acquisition of shares in a public company must be made by means of a special tender offer if as a result of the acquisition (i) the purchaser would become a 25% or greater shareholder of the company, unless there is already another 25% or greater shareholder of the company or (ii) the purchaser would become a more than 45% shareholder of the company, unless there is already a shareholder holding more than 45% of the company, subject to certain exceptions. These requirements do not apply if, in general, the acquisition (i) was made in a private placement that received shareholder approval, (ii) was from a 25% or greater shareholder of the company which resulted in the acquirer becoming a 25% or greater shareholder of the company, or (iii) was from a shareholder holding more than 45% of the company's issued and outstanding share capital which resulted in the acquirer becoming a holder of more than 45% of the company's issued and outstanding share capital.

A special tender offer must be extended to all shareholders, but the offeror is not required to purchase more than 5% of the company's outstanding shares, regardless of how many shares are tendered by shareholders. In general, the tender offer may be consummated only if (i) at least 5% of the company's outstanding shares will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer (excluding the purchaser, controlling shareholders, holders of 25% or more of the voting rights in the company or any person having a personal interest in the acceptance of the tender offer). If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

If a tender offer is not accepted in accordance with the requirements set forth above, the acquirer may not acquire shares (either alone or together with others) that will increase its holdings to 25% or more or above 45% (as may be the case) of the company's issued and outstanding share capital or of the applicable class and such shares shall not bestow upon such acquirer any rights and shall become treasury shares for as long as the acquirer holds said shares. In addition, if a shareholder's holding in a company increases to 25% or greater of the company's issued and outstanding share capital or above 45% of the company's issued and outstanding share capital, among others, as a result of the company's shares becoming treasury shares following a distribution event, then such excess shares shall not bestow upon their holder any voting rights for as long as the holder holds said excess shares.

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold (either alone or together with others) over 90% of the target company's issued and outstanding share capital is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would as a result hold (either alone or together with others) over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the relevant class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition an Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may include in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If a tender offer is not accepted in accordance with the requirements set forth above, the acquirer may not acquire shares from shareholders who accepted the tender offer that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class.

If a tender offer is not accepted in accordance with the requirements set forth above, the acquirer may not acquire shares (either alone or together with others) that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class and such shares shall not bestow upon such acquirer any rights and shall become treasury shares for as long as the acquirer holds said shares.

Anti-Takeover Provisions under Israeli Law

For as long as our securities are traded on the TASE, the Securities Law does not allow us, to create and issue shares having rights different from those attached to our Ordinary Shares, including shares providing certain preferred rights with respect to voting, distributions, or other matters and shares having preemptive rights. The authorization and designation of a class of preferred shares will require an amendment to our articles of association, which requires the prior approval of the holders of a majority of the voting power attaching to our issued and outstanding shares at a general meeting. The convening of the meeting, the shareholders entitled to participate and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Companies Law as described above in "Description of Share Capital" and "Management."

Lastly, Israeli tax law treats some acquisitions, such as stock-for-stock exchanges between an Israeli company and a foreign company, less favorably than U.S. tax laws. For example, Israeli tax law may, under certain circumstances, subject a shareholder who exchanges his Ordinary Shares for shares in another corporation to taxation prior to the sale of the shares received in such stock-for-stock swap.

Changes in Our Capital

Our articles of association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Companies Law and must be approved by a resolution duly passed by our shareholders at a general meeting. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings or profits, require the approval of both our Board of Directors and an Israeli court.

The general meeting may, by a simple majority vote of the shareholders attending the general meeting:

- increase our registered share capital by the creation of new shares from the existing class or a new class, as determined by the general meeting;
- cancel any registered share capital which have not been taken or agreed to be taken by any person;
- consolidate and divide all or any of our share capital into shares of larger nominal value than our existing shares;
- subdivide our existing shares or any of them, our share capital or any of it, into shares of smaller nominal value than is fixed;
- reduce our share capital subject to approval required by the Companies Law; and
- modify, cancel, convert, extend, add to or otherwise modify the rights, privileges, advantages, limitations and instructions related or unrelated to the Company's shares at the time.

C. Material Contracts

We have not entered into any material contract within the two years prior to the date of this annual report on Form 20-F, other than contracts entered into in the ordinary course of business, or as otherwise described herein in "Item 4.A. History and Development of the Company" above, "Item 4.B. Business Overview" above, or "Item 7.A. Major Shareholders" above.

D. Exchange Controls

There are currently no Israeli currency control restrictions on remittances of dividends on our Ordinary Shares, proceeds from the sale of the shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of countries that are, or have been, in a state of war with Israel.

E. Taxation.

ISRAELI TAX CONSIDERATIONS AND GOVERNMENT PROGRAMS

The following is a description of the material Israeli income tax consequences of the ownership of our Ordinary Shares or ADSs. The following also contains a description of material relevant provisions of the current Israeli income tax structure applicable to companies in Israel, with reference to its effect on us. To the extent that the discussion is based on new tax legislation which has not been subject to judicial or administrative interpretation, there can be no assurance that the tax authorities will accept the views expressed in the discussion in question. The discussion is not intended, and should not be taken, as legal or professional tax advice and is not exhaustive of all possible tax considerations.

The following description is not intended to constitute a complete analysis of all tax consequences relating to the ownership or disposition of our Ordinary Shares and ADSs. Shareholders should consult their own tax advisors concerning the tax consequences of their particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign or other taxing jurisdiction.

General Corporate Tax Structure in Israel

Israeli resident companies are generally subject to corporate tax, currently at the rate of 25% of a company's taxable income (under a proposed legislation the corporate tax rate will be reduced to 24% and 23% in the years 2017 and 2018, respectively). However, the effective tax rate payable by a company that derives income from a Preferred Enterprise (as discussed below) may be considerably less. Capital gains derived by an Israeli resident company are subject to tax at the prevailing corporate tax rate. Under Israeli tax legislation, a corporation will be considered as an "Israeli resident company" if it meets one of the following: (i) it was incorporated in Israel; or (ii) the control and management of its business are exercised in Israel.

Law for the Encouragement of Industry (Taxes), 5729-1969

The Law for the Encouragement of Industry (Taxes), 5729-1969, generally referred to as the Industry Encouragement Law, provides several tax benefits for "Industrial Companies."

The Industry Encouragement Law defines an "Industrial Company" as an Israeli resident-company, of which 90% or more of its income in any tax year, other than income from defense loans, is derived from an "Industrial Enterprise" owned by it. An "Industrial Enterprise" is defined as an enterprise whose principal activity in a given tax year is industrial production.

The following corporate tax benefits, among others, are available to Industrial Companies:

- amortization of the cost of purchased a patent, rights to use a patent, and know-how, which are used for the development or advancement of the company, over an eight-year period and certain other intangible property rights (other than goodwill), commencing on the year in which such rights were first exercised;
- under limited conditions, an election to file consolidated tax returns with related Israeli Industrial Companies; and
- expenses related to a public offering are deductible in equal amounts over three years.

Eligibility for benefits under the Industry Encouragement Law is not contingent upon approval of any governmental authority. There is no assurance that we qualify as an Industrial Company or that the benefits described above will be available in the future.

The Encouragement of Research, Development and Technological Innovations in the Industry Law, 5744-1984

Under the Research Law, research and development programs which meet specified criteria and are approved by the IIA are eligible for grants of up to 50% of the project's expenditure, as determined by the research committee, in exchange for the payment of royalties from the revenues generated from the sale of products and related services developed, in whole or in part pursuant to, or as a result of, a research and development program funded by the IIA. The royalties are generally at a range of 3.0% to 5.0% of revenues until the entire IIA grant is repaid, together with an annual interest generally equal to the 12 month London InterBank Offered Rate, or the LIBOR, applicable to dollar deposits that is published on the first business day of each calendar year.

The terms of the Research Law also require that the manufacture of products developed with government grants be performed in Israel. The transfer of manufacturing activity outside Israel may not be transferred outside of Israel, unless the prior approval of the IIA is received, however, this does not restrict the export of products that incorporate the funded technology. Under the regulations of the Research Law, assuming we receive approval from the IIA to manufacture our IIA-funded products outside Israel, we may be required to pay increased royalties. The increase in royalties depends upon the manufacturing volume that is performed outside of Israel as follows:

Manufacturing Volume Outside of Israel	**Royalties to the IIA as a Percentage of Grant**
Up to 50%	120%
between 50% and 90%	150%
90% and more	300%

If the manufacturing is performed outside of Israel by us, the rate of royalties payable by us on revenues from the sale of products manufactured outside of Israel will increase by 1% over the regular rates. If the manufacturing is performed outside of Israel by a third party, the rate of royalties payable by us on those revenues will be equal to the ratio obtained by dividing the amount of the grants received from IIA and our total investment in the project that was funded by these grants. The transfer of no more than 10% of the manufacturing capacity in the aggregate outside of Israel is exempt under the Research Law from obtaining the prior approval of the IIA. A company requesting funds from the IIA also has the option of declaring in its IIA grant application an intention to perform part of its manufacturing outside Israel, thus avoiding the need to obtain additional approval. On January 6, 2011, the Research Law was amended to clarify that the potential increased royalties specified in the table above will apply even in those cases where the IIA approval for transfer of manufacturing outside of Israel is not required, namely when the volume of the transferred manufacturing capacity is less than 10% of total capacity.

The know-how developed within the framework of the IIA plan may not be transferred to third parties outside Israel without the prior approval of a governmental committee charted under the Research Law. The approval, however, is not required for the export of any products developed using grants received from the IIA. The IIA approval to transfer know-how created, in whole or in part, in connection with an IIA-funded project to third party outside Israel where the transferring company remains an operating Israeli entity is subject to payment of a redemption fee to the IIA calculated according to a formula provided under the Research Law that is based, in general, on the ratio between the aggregate IIA grants to the company's aggregate investments in the project that was funded by these IIA grants, multiplied by the transaction consideration. The transfer of such know-how to a party outside Israel where the transferring company ceases to exist as an Israeli entity is subject to a redemption fee formula that is based, in general, on the ratio between the aggregate IIA grants to the total R&D expenses of the company, multiplied by the transaction consideration. According to regulations promulgated following the 2011 amendment, the maximum amount payable to the IIA in case of transfer of know how outside Israel, and in the event that the receiver of the grants ceases to be an Israeli corporation, shall not exceed 6 times the value of the grants received plus interest, with a possibility to reduce such payment to up to 3 times the value of the grants received plus interest if the R&D activity remains in Israel for a period of three years after payment to the IIA, subject to additional conditions specified in the regulations.

Transfer of know-how within Israel is subject to the IIA approval and to an undertaking of the recipient Israeli entity to comply with the provisions of the Research Law and related regulations, including the restrictions on the transfer of know-how and the obligation to pay royalties, as further described in the Research Law and related regulations.

The restrictions under the Research Law will continue to apply even after we will repay the full amount of royalties payable pursuant to the grants. In addition, the government of the State of Israel may from time to time audit sales of product candidates which it claims incorporate technology funded via IIA programs and this may lead to additional royalties being payable on additional product candidates.

These restrictions may impair our ability to outsource manufacturing or otherwise transfer our know-how outside Israel and may require us to obtain the approval of the IIA for certain actions and transactions and pay additional royalties or other payments to the IIA. If we fail to comply with the Research Law, we may be subject to criminal charges.

In August 2015, a new amendment to the Research Law was enacted, or Amendment Seven, which came into effect on January 1, 2016 and has made it unclear whether the transfer of manufacturing rights and transfer of know-how will continue to be subject to the same limitations and obligations as described above. Amendment Seven abolishes, inter alia, the sections in the Research Law allowing for the transfer of know-how and transfer of manufacturing rights overseas. However, there are certain savings provisions under Amendment Seven, which provide that until new regulations are adopted by IIA (to be constituted by virtue of Amendment Seven), the Research Law as it was in effect before the effective date of Amendment Seven and certain regulations, including inter alia, the regulations relating to royalty rates and transfer of know-how overseas, will remain in effect. IIA should be fully constituted no later than August 10, 2018. New regulations should be adopted by IIA no more than one year after the council is constituted. It is not possible to assess at this time the effect of Amendment Seven until implementing regulations will be promulgated.

Tax Benefits for Research and Development under the Encouragement of Industrial Research and Development Law, 5744-1984

Israeli tax law allows, under certain conditions, a tax deduction for expenditures, including capital expenditures, for the year in which they are incurred. Expenditures are deemed related to scientific research and development projects, if:

- The expenditures are approved by the relevant Israeli government ministry, determined by the field of research;
- The research and development must be for the promotion of the company; and
- The research and development is carried out by or on behalf of the company seeking such tax deduction.

The amount of such deductible expenses is reduced by the sum of any funds received through government grants for the finance of such scientific research and development projects. No deduction under these research and development deduction rules is allowed if such deduction is related to an expense invested in an asset depreciable under the general depreciation rules of the Ordinance. Expenditures not so approved are deductible in equal amounts over three years.

From time to time we may apply the IIA for approval to allow a tax deduction for all research and development expenses during the year incurred. There can be no assurance that such application will be accepted.

Law for the Encouragement of Capital Investments, 5719-1959

The Law for the Encouragement of Capital Investments, 5719-1959, generally referred to as the Investment Law, provides certain incentives for capital investments in production facilities (or other eligible assets) under certain conditions. In specific, the Investment Law, currently provides certain tax benefits for income generated by "Preferred Companies" from their "Preferred Enterprises." The definition of a Preferred Company includes, inter alia, a company incorporated in Israel that is not wholly owned by a governmental entity, which:

- owns a Preferred Enterprise, which is defined as an "Industrial Enterprise" (as defined under the Investment Law) that is classified as either a "Competitive Enterprise" (as defined under the Investment Law) or a "Competitive Enterprise in the Field of Renewable Energy" (as defined under the Investment Law);
- is controlled and managed from Israel;
- is not a "Family Company," a "Home Company," or a "Kibbutz" (collective community) as defined under the Ordinance;
- keeps acceptable books of account and files reports in accordance with the provisions of the Investment Law and the Ordinance; and
- was not, and certain officers of which were not, convicted of certain crimes in the 10 years prior to the tax year with respect to which benefits are being claimed.

As of January 1, 2014, a Preferred Company is entitled to a reduced corporate tax rate of 16% with respect to its income derived from its Preferred Enterprise, unless the Preferred Enterprise is located in development area A, in which case the rate will be 9% (our operations are currently not located in development area A).

In December 2016, the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years), 2016, which includes Amendment 73 to the Law for the Encouragement of Capital Investments was published. According to such amendment, a preferred enterprise located in development area A will be subject to a tax rate of 7.5% instead of 9%, effective from January 1, 2017, and thereafter. The tax rate applicable to preferred enterprises located in other areas remains at 16%.

If in the future we generate taxable income, to the extent that we qualify as a "Preferred Company," the benefits provided under the Investment Law could potentially reduce our corporate tax liabilities.

Taxation of our Shareholders

Capital Gains

Capital gain tax is imposed on the disposal of capital assets by an Israeli resident, and on the disposal of such assets by a non-Israeli resident if those assets are either (i) located in Israel; (ii) are shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel. The Israeli Income Tax Ordinance of 1961 (New Version) (the "Ordinance") distinguishes between "Real Gain" and the "Inflationary Surplus." Real Gain is the excess of the total capital gain over Inflationary Surplus computed generally on the basis of the increase in the Israeli CPI between the date of purchase and the date of disposal. Inflationary Surplus is not subject to tax in Israel.

Real Gain accrued by individuals on the sale of our ordinary shares will be taxed at the rate of 25%. However, if the individual shareholder is a "Controlling Shareholder" (i.e., a person who holds, directly or indirectly, alone or together with another, 10% or more of one of the Israeli resident company's means of control) at the time of sale or at any time during the preceding 12 months period, such gain will be taxed at the rate of 30%.

Real Gain derived by corporations will be generally subject to the regular corporate tax rate (24% in 2017, and 23% in 2018).

Individual and corporate shareholder dealing in securities are taxed at the tax rates applicable to business income– 24% for corporations in 2017 and a marginal tax rate of up to 50% in 2017 for individuals.

Capital Gains Taxes is Applicable also to Non-Israeli Resident Shareholders. A non-Israeli resident who derives capital gains from the sale of shares in an Israeli resident company may be exempt from Israeli tax so long as the following cumulative conditions are met: (i) the shares were purchased upon or after the registration of the securities on the stock exchange, (ii) the seller does not have a permanent establishment in Israel to which the derived capital gain is attributed, and (iii) if the seller is a corporation, less than 25% of its means of control are held, directly and indirectly, by Israeli resident shareholders. In addition, such exemption would not be available to a person whose gains from selling or otherwise disposing of the securities are deemed to be business income.

Additionally, a sale of shares by a non-Israeli resident may be exempt from Israeli capital gains tax under the provisions of an applicable tax treaty. For example, under Convention Between the Government of the United States of America and the Government of the State of Israel with respect to Taxes on Income, as amended, or the United States-Israel Tax Treaty, the sale, exchange or other disposition of shares by a shareholder who is a United States resident (for purposes of the treaty) holding the shares as a capital asset and is entitled to claim the benefits afforded to such a resident by the U.S.-Israel Tax Treaty, or a Treaty U.S. Resident, is generally exempt from Israeli capital gains tax unless: (i) the capital gain arising from such sale, exchange or disposition is attributed to real estate located in Israel; (ii) the capital gain arising from such sale, exchange or disposition is attributed to royalties; (iii) the capital gain arising from the such sale, exchange or disposition is attributed to a permanent establishment in Israel, under certain terms; (iv) such Treaty U.S. Resident holds, directly or indirectly, shares representing 10% or more of the voting capital during any part of the 12-month period preceding the disposition, subject to certain conditions; or (v) such Treaty U.S. Resident is an individual and was present in Israel for 183 days or more during the relevant taxable year.

In some instances where our shareholders may be liable for Israeli tax on the sale of their Ordinary Shares or ADSs, the payment of the consideration may be subject to the withholding of Israeli tax at source. Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale.

Either the purchaser, the Israeli stockbrokers or financial institution through which the shares are held is obliged, subject to the above mentioned exemptions, to withhold tax upon the sale of securities from the Real Gain at the rate of 25%.

At the sale of securities traded on a stock exchange, a detailed return, including a computation of the tax due, must be filed and an advance payment must be made on January 31 and July 31 of every tax year in respect of sales of securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Ordinance and regulations promulgated thereunder, the aforementioned return need not be filed and no advance payment must be paid. Capital gain is also reportable on the annual income tax return.

Dividends

A distribution of dividends from income, which is not attributed to a Preferred Enterprise to an Israeli resident individual, will generally be subject to income tax at a rate of 25%. However, a 30% tax rate will apply if the dividend recipient is a "Controlling Shareholder" (as defined above) at the time of distribution or at any time during the preceding 12 months period. If the recipient of the dividend is an Israeli resident corporation, such dividend will be exempt from income tax provided the income from which such dividend is distributed was derived or accrued within Israel.

Non-Israeli residents are generally subject to Israeli income tax on the receipt of dividends paid on our Ordinary Shares or ADSs at the rate of 25%, which tax will be withheld at source, unless relief is provided in a treaty between Israel and the shareholder's country of residence. With respect to a person who is a controlling shareholder at the time of receiving the dividend or on any time during the preceding twelve months, the applicable tax rate is 30%, unless a reduced tax rate is provided under an applicable tax treaty. For example, under the United States-Israel Tax Treaty, the maximum rate of tax withheld at source in Israel on dividends paid to a holder of our Ordinary Shares or ADSs who is a Treaty U.S. Resident is 25%. However, generally, the maximum rate of withholding tax on dividends, not generated by a Preferred Enterprise, that are paid to a United States corporation holding 10% or more of the outstanding voting capital throughout the tax year in which the dividend is distributed as well as during the previous tax year, is 12.5%, provided that not more than 25% of the gross income for such preceding year consists of certain types of dividends and interest. Notwithstanding the foregoing, dividends distributed from income attributed to an Preferred Enterprise are not entitled to such reduction under the tax treaty but are subject to a withholding tax rate of 15% for a shareholder that is a U.S. corporation, provided that the condition related to our gross income for the previous year (as set forth in the previous sentence) is met. If the dividend is attributable partly to income derived from a Preferred Enterprise, and partly to other sources of income, the withholding rate will be a blended rate reflecting the relative portions of the two types of income. We cannot assure you that we will designate the profits that we may distribute in a way that will reduce shareholders' tax liability.

A distribution of dividend by our company from income attributed to a Preferred Enterprise will generally be subject to withholding tax in Israel at the following tax rates: Israeli resident individuals - 20% Israeli resident companies – 0%, Non-Israeli residents – 20%, subject to a reduced rate under the provisions of any applicable double tax treaty.

Excess Tax

Individuals who are subject to tax in Israel are also subject to an additional tax at a rate of 3% as of 2017 on annual income exceeding a certain threshold (NIS 640,000 for 2017 and thereafter), including, but not limited to income derived from dividends, interest and capital gains.

Foreign Exchange Regulations

Non-residents of Israel who hold our ordinary shares are able to receive any dividends, and any amounts payable upon the dissolution, liquidation and winding up of our affairs, repayable in non-Israeli currency at the rate of exchange prevailing at the time of conversion. However, Israeli income tax is generally required to have been paid or withheld on these amounts. In addition, the statutory framework for the potential imposition of currency exchange control has not been eliminated, and may be restored at any time by administrative action.

Estate and Gift Tax

Israeli law presently does not impose estate or gift taxes.

U.S. FEDERAL INCOME TAX CONSIDERATIONS

THE FOLLOWING SUMMARY IS INCLUDED HEREIN FOR GENERAL INFORMATION AND IS NOT INTENDED TO BE, AND SHOULD NOT BE CONSIDERED TO BE, LEGAL OR TAX ADVICE. EACH U.S. HOLDER SHOULD CONSULT WITH HIS OR HER OWN TAX ADVISOR AS TO THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND SALE OF ORDINARY SHARES AND AMERICAN DEPOSITORY SHARES, INCLUDING THE EFFECTS OF APPLICABLE STATE, LOCAL, FOREIGN OR OTHER TAX LAWS AND POSSIBLE CHANGES IN THE TAX LAWS.

Subject to the limitations described in the next paragraph, the following discussion summarizes the material U.S. federal income tax consequences to a "U.S. Holder" arising from the purchase, ownership and sale of the Ordinary Shares, ADSs. For this purpose, a "U.S. Holder" is a holder of Ordinary Shares or ADSs that is: (1) an individual citizen or resident of the United States, including an alien individual who is a lawful permanent resident of the United States or meets the substantial presence residency test under U.S. federal income tax laws; (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) or a partnership (other than a partnership that is not treated as a U.S. person under any applicable U.S. Treasury regulations) created or organized under the laws of the United States or the District of Columbia or any political subdivision thereof; (3) an estate, the income of which is includable in gross income for U.S. federal income tax purposes regardless of source; (4) a trust if a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust; or (5) a trust that has a valid election in effect to be treated as a U.S. person to the extent provided in U.S. Treasury regulations.

This summary is for general information purposes only and does not purport to be a comprehensive description of all of the U.S. federal income tax considerations that may be relevant to a decision to purchase our Ordinary Shares or ADSs. This summary generally considers only U.S. Holders that will own our Ordinary Shares or ADSs as capital assets. Except to the limited extent discussed below, this summary does not consider the U.S. federal tax consequences to a person that is not a U.S. Holder, nor does it describe the rules applicable to determine a taxpayer's status as a U.S. Holder. This summary is based on the provisions of the Internal Revenue Code of 1986, as amended, or the Code, final, temporary and proposed U.S. Treasury regulations promulgated thereunder, administrative and judicial interpretations thereof, and the U.S./Israel Income Tax Treaty, all as in effect as of the date hereof and all of which are subject to change, possibly on a retroactive basis, and all of which are open to differing interpretations. We will not seek a ruling from the U.S. IRS with regard to the U.S. federal income tax treatment of an investment in our Ordinary Shares or ADSs by U.S. Holders and, therefore, can provide no assurances that the IRS will agree with the conclusions set forth below.

This discussion does not address all of the aspects of U.S. federal income taxation that may be relevant to a particular U.S. holder based on such holder's particular circumstances and in particular does not discuss any estate, gift, generation-skipping, transfer, state, local, excise or foreign tax considerations. In addition, this discussion does not address the U.S. federal income tax treatment of a U.S. Holder who is: (1) a bank, life insurance company, regulated investment company, or other financial institution or "financial services entity"; (2) a broker or dealer in securities or foreign currency; (3) a person who acquired our Ordinary Shares or ADSs in connection with employment or other performance of services; (4) a U.S. Holder that is subject to the U.S. alternative minimum tax; (5) a U.S. Holder that holds our Ordinary Shares or ADSs as a hedge or as part of a hedging, straddle, conversion or constructive sale transaction or other risk-reduction transaction for U.S. federal income tax purposes; (6) a tax-exempt entity; (7) real estate investment trusts or grantor trusts; (8) a U.S. Holder that expatriates out of the United States or a former long-term resident of the United States; or (9) a person having a functional currency other than the U.S. dollar. This discussion does not address the U.S. federal income tax treatment of a U.S. Holder that owns, directly or constructively, at any time, Ordinary Shares or ADSs representing 10% or more of our voting power. Additionally, the U.S. federal income tax treatment of persons who hold Ordinary Shares or ADSs through a partnership or other pass-through entity are not considered.

Each prospective investor is advised to consult his or her own tax adviser for the specific tax consequences to that investor of purchasing, holding or disposing of our Ordinary Shares or ADSs, including the effects of applicable state, local, foreign or other tax laws and possible changes in the tax laws.

Taxation of Dividends Paid on Ordinary Shares or ADSs

We do not intend to pay dividends in the foreseeable future. In the event that we do pay dividends, and subject to the discussion under the heading "Passive Foreign Investment Companies" below, a U.S. Holder will be required to include in gross income as ordinary income the amount of any distribution paid on Ordinary Shares or ADSs (including the amount of any Israeli tax withheld on the date of the distribution), to the extent that such distribution does not exceed our current and accumulated earnings and profits, as determined for U.S. federal income tax purposes. The amount of a distribution which exceeds our earnings and profits will be treated first as a non-taxable return of capital, reducing the U.S. Holder's tax basis for the Ordinary Shares to the extent thereof, and then capital gain. Corporate holders generally will not be allowed a deduction for dividends received.

In general, preferential tax rates for "qualified dividend income" and long-term capital gains are applicable for U.S. Holders that are individuals, estates or trusts. For this purpose, "qualified dividend income" means, inter alia, dividends received from a "qualified foreign corporation." A "qualified foreign corporation" is a corporation that is entitled to the benefits of a comprehensive tax treaty with the United States which includes an exchange of information program. The IRS has stated that the Israel/U.S. Tax Treaty satisfies this requirement and we believe we are eligible for the benefits of that treaty.

In addition, our dividends will be qualified dividend income if our Ordinary Shares or ADSs are readily tradable on the NASDAQ Capital Market or another established securities market in the United States. Dividends will not qualify for the preferential rate if we are treated, in the year the dividend is paid or in the prior year, as a PFIC, as described below under "Passive Foreign Investment Companies." A U.S. Holder will not be entitled to the preferential rate: (1) if the U.S. Holder has not held our Ordinary Shares or ADSs for at least 61 days of the 121 day period beginning on the date which is 60 days before the ex-dividend date, or (2) to the extent the U.S. Holder is under an obligation to make related payments on substantially similar property. Any days during which the U.S. Holder has diminished its risk of loss on our Ordinary Shares or ADSs are not counted towards meeting the 61-day holding period. Finally, U.S. Holders who elect to treat the dividend income as "investment income" pursuant to Code section 163(d)(4) will not be eligible for the preferential rate of taxation.

The amount of a distribution with respect to our Ordinary Shares or ADSs will be measured by the amount of the fair market value of any property distributed, and for U.S. federal income tax purposes, the amount of any Israeli taxes withheld therefrom. Cash distributions paid by us in NIS will be included in the income of U.S. Holders at a U.S. dollar amount based upon the spot rate of exchange in effect on the date the dividend is includible in the income of the U.S. Holder, and U.S. Holders will have a tax basis in such NIS for U.S. federal income tax purposes equal to such U.S. dollar value. If the U.S. Holder subsequently converts the NIS into U.S. dollars or otherwise disposes of it, any subsequent gain or loss in respect of such NIS arising from exchange rate fluctuations will be U.S. source ordinary exchange gain or loss.

Distributions paid by us will generally be foreign source income for U.S. foreign tax credit purposes and will generally be considered passive category income for such purposes. Subject to the limitations set forth in the Code, U.S. Holders may elect to claim a foreign tax credit against their U.S. federal income tax liability for Israeli income tax withheld from distributions received in respect of the Ordinary Shares or ADSs. The rules relating to the determination of the U.S. foreign tax credit are complex, and U.S. Holders should consult with their own tax advisors to determine whether, and to what extent, they are entitled to such credit. U.S. Holders that do not elect to claim a foreign tax credit may instead claim a deduction for Israeli income taxes withheld, provided such U.S. Holders itemize their deductions.

Taxation of the Disposition of Ordinary Shares or ADSs

Except as provided under the PFIC rules described below under "Passive Foreign Investment Companies," upon the sale, exchange or other disposition of our Ordinary Shares or ADSs, a U.S. Holder will recognize capital gain or loss in an amount equal to the difference between such U.S. Holder's tax basis for the Ordinary Shares or ADSs in U.S. dollars and the amount realized on the disposition in U.S. dollar (or its U.S. dollar equivalent determined by reference to the spot rate of exchange on the date of disposition, if the amount realized is denominated in a foreign currency). The gain or loss realized on the sale, exchange or other disposition of Ordinary Shares or ADSs will be long-term capital gain or loss if the U.S. Holder has a holding period of more than one year at the time of the disposition.

Gain realized by a U.S. Holder on a sale, exchange or other disposition of Ordinary Shares or ADSs will generally be treated as U.S. source income for U.S. foreign tax credit purposes. A loss realized by a U.S. Holder on the sale, exchange or other disposition of Ordinary Shares or ADSs is generally allocated to U.S. source income. The deductibility of a loss realized on the sale, exchange or other disposition of Ordinary Shares or ADSs is subject to limitations.

Passive Foreign Investment Companies

Special U.S. federal income tax laws apply to U.S. taxpayers who own shares of a corporation that is a PFIC. We will be treated as a PFIC for U.S. federal income tax purposes for any taxable year that either:

- 75% or more of our gross income (including our pro rata share of gross income for any company, in which we are considered to own 25% or more of the shares by value), in a taxable year is passive; or
- At least 50% of our assets, averaged over the year and generally determined based upon fair market value (including our pro rata share of the assets of any company in which we are considered to own 25% or more of the shares by value) are held for the production of, or produce, passive income.

For this purpose, passive income generally consists of dividends, interest, rents, royalties, annuities and income from certain commodities transactions and from notional principal contracts. Cash is treated as generating passive income.

We believe that we may be a PFIC during 2016 although we have not determined whether we will be a PFIC in 2017, or in future years. The tests for determining PFIC status are applied annually, and it is difficult to make accurate projections of future income and assets which are relevant to this determination. In addition, our PFIC status may depend in part on the market value of our Ordinary Shares. Accordingly, there can be no assurance that we currently are not or will not become a PFIC.

If we currently are or become a PFIC, each U.S. Holder who has not elected to treat us as a qualified electing fund by making a "QEF election", or who has not elected to mark the shares to market (as discussed below), would, upon receipt of certain distributions by us and upon disposition of our Ordinary Shares or ADSs at a gain: (1) have such distribution or gain allocated ratably over the U.S. Holder's holding period for the Ordinary Shares or ADSs, as the case may be; (2) 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 (3) 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, when shares of a PFIC are acquired by reason of death from a decedent that was a U.S. Holder, the tax basis of such shares would not receive a step-up to fair market value as of the date of the decedent's death, but instead would be equal to the decedent's basis if lower, unless all gain were recognized by the decedent. Indirect investments in a PFIC may also be subject to these special U.S. federal income tax rules.

The PFIC rules described above would not apply to a U.S. Holder who makes a QEF election for all taxable years that such U.S. Holder has held the Ordinary Shares or ADSs while we are a PFIC, provided that we comply with specified reporting requirements. Instead, each U.S. Holder who has made such a QEF election is required for each taxable year that we are a PFIC to include in income such U.S. Holder's pro rata share of our ordinary earnings as ordinary income and such U.S. Holder's pro rata share of our net capital gains as long-term capital gain, regardless of whether we make any distributions of such earnings or gain. In general, a QEF election is effective only if we make available certain required information. The QEF election is made on a shareholder-by-shareholder basis and generally may be revoked only with the consent of the IRS. We intend to furnish U.S. Holders upon request with information needed in order to complete IRS Form 8621 and to make and maintain a valid QEF election for any year in which we or any of our Subsidiaries are a PFIC. U.S. Holders should consult with their own tax advisors regarding eligibility, manner and advisability of making a QEF election if we are treated as a PFIC.

In addition, the PFIC rules described above would not apply if we were a PFIC and a U.S. Holder made a mark-to-market election. A U.S. Holder of our Ordinary Shares or ADSs which are regularly traded on a qualifying exchange, including the NASDAQ Capital Market, can elect to mark the Ordinary Shares or ADSs to market annually, recognizing as ordinary income or loss each year an amount equal to the difference as of the close of the taxable year between the fair market value of the Ordinary Shares or ADSs and the U.S. Holder's adjusted tax basis in the Ordinary Shares or ADSs. Losses are allowed only to the extent of net mark-to-market gain previously included income by the U.S. Holder under the election for prior taxable years. The mark-to-market election is made on a shareholder-by-shareholder basis and generally may be revoked only with the consent of the IRS.

U.S. Holders 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. U.S. Holders are strongly urged to consult their tax advisors about the PFIC rules, including tax return filing requirements and the eligibility, manner, and consequences to them of making a QEF or mark-to-market election with respect to our Ordinary Shares or ADSs in the event that we are a PFIC.

Tax on Net Investment Income

For taxable years beginning after December 31, 2013, U.S. Holders who are individuals, estates or trusts will generally be required to pay a new 3.8% Medicare tax on their net investment income (including dividends on and gains from the sale or other disposition of our Ordinary Shares or ADSs), or in the case of estates and trusts on their net investment income that is not distributed. In each case, the 3.8% Medicare tax applies only to the extent the U.S. Holder's total adjusted income exceeds applicable thresholds.

Tax Consequences for Non-U.S. Holders of Ordinary Shares or ADSs

Except as provided below, an individual, corporation, estate or trust that is not a U.S. Holder referred to below as a non-U.S. Holder, generally will not be subject to U.S. federal income or withholding tax on the payment of dividends on, and the proceeds from the disposition of, our Ordinary Shares or ADSs.

A non-U.S. Holder may be subject to U.S. federal income tax on a dividend paid on our Ordinary Shares or ADSs or gain from the disposition of our Ordinary Shares or ADSs if: (1) such item is effectively connected with the conduct by the non-U.S. Holder of a trade or business in the United States and, if required by an applicable income tax treaty is attributable to a permanent establishment or fixed place of business in the United States; (2) in the case of a disposition of our Ordinary Shares or ADSs, the individual non-U.S. Holder is present in the United States for 183 days or more in the taxable year of the disposition and other specified conditions are met.

In general, non-U.S. Holders will not be subject to backup withholding with respect to the payment of dividends on our Ordinary Shares or ADSs if payment is made through a paying agent, or office of a foreign broker outside the United States. However, if payment is made in the United States or by a U.S. related person, non-U.S. Holders may be subject to backup withholding, unless the non-U.S. Holder provides an applicable IRS Form W-8 (or a substantially similar form) certifying its foreign status, or otherwise establishes an exemption.

The amount of any backup withholding from a payment to a non-U.S. Holder will be allowed as a credit against such holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Information Reporting and Withholding

A U.S. Holder may be subject to backup withholding at a rate of 28% with respect to cash dividends and proceeds from a disposition of Ordinary Shares or ADSs. In general, backup withholding will apply only if a U.S. Holder fails to comply with specified identification procedures. Backup withholding will not apply with respect to payments made to designated exempt recipients, such as corporations and tax-exempt organizations. Backup withholding is not an additional tax and may be claimed as a credit against the U.S. federal income tax liability of a U.S. Holder, provided that the required information is timely furnished to the IRS.

Pursuant to the Foreign Account Tax Compliance Act (FATCA), a U.S. Holder with interests in "specified foreign financial assets" (including, among other assets, our Ordinary Shares or ADSs, unless such Ordinary Shares or ADSs are held on such U.S. Holder's behalf through a financial institution) may be required to file an information report with the IRS if the aggregate value of all such assets exceeds $50,000 on the last day of the taxable year or $75,000 at any time during the taxable year (or such higher dollar amount as may be prescribed by applicable IRS guidance); and may be required to file a Report of Foreign Bank and Financial Accounts, if the aggregate value of the foreign financial accounts exceeds $10,000 at any time during the calendar year. You should consult your own tax advisor as to the possible obligation to file such information report.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to certain information reporting requirements of the Exchange Act, applicable to foreign private issuers and under those requirements will file reports with the SEC. You may read and copy the annual report on Form 20-F, including the related exhibits and schedules, and any document we file with the SEC without charge at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, DC 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains an Internet website that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC will also available to the public through the SEC's website at www.sec.gov.

As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act. However, we will file with the SEC, within 120 days after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and may submit to the SEC, on a Form 6-K, unaudited quarterly financial information.

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

We maintain a corporate website at http://therapixbio.com. Information contained on, or that can be accessed through, our website and the other websites referenced above do not constitute a part of this annual report on Form 20-F. We have included these website addresses in this annual report on Form 20-F solely as inactive textual references.

I. Subsidiary Information.

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In the ordinary course of our operations, we are exposed to certain market risks, primarily changes in foreign currency exchange rates and interest rates.

Quantitative and Qualitative Disclosure About Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our current investment policy is to invest available cash in bank deposits with banks that have a credit rating of at least A-minus. However, a substantial majority of our cash and cash equivalents is held in current bank accounts that do not bear interest. In the near future, we intend to hold most of our cash and cash equivalents in deposits that bear interest. Given the current low rates of interest we receive, once we begin to hold most of our cash and cash equivalents in deposits that bear interest, we do not expect to be adversely affected if such rates are reduced. Our market risk exposure is primarily a result of NIS/U.S. dollar exchange rates, which is discussed in detail in the following paragraph.

Foreign Currency Exchange Risk

Our results of operations and cash flow are subject to fluctuations due to changes in NIS/U.S. dollar currency exchange rates. As of December 31, 2016, approximately half of our liquid assets is held in U.S. dollars, and the majority of our expenses is denominated in NIS. Changes of 5% and 10% in the U.S. Dollar/NIS exchange rate would decrease/increase our loss for 2016 by 2% and 1%, respectively. However, these historical figures may not be indicative of future exposure, as we expect that the percentage of our NIS denominated expenses will materially decrease in the near future, therefore reducing our exposure to exchange rate fluctuations.

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

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities.

Not applicable.

B. Warrants and rights.

Not applicable.

C. Other Securities.

Not applicable.

D. American Depositary Shares

Fees and Expenses

The following table shows the fees and expenses that a holder of our ADSs may have to pay, either directly or indirectly:

***Persons depositing or withdrawing shares or ADS holders must pay*:**	***For:***
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs).	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property.
	Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates.
$.05 (or less) per ADS.	Any cash distribution to ADS holders.
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs.	Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to ADS holders.
$.05 (or less) per ADS per calendar year.	Depositary services.
Registration or transfer fees.	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares.
Expenses of the depositary.	Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement).
	Converting foreign currency to U.S. dollars.
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes.	As necessary.
Any charges incurred by the depositary or its agents for servicing the deposited securities.	As necessary.

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

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

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

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

There are no material modifications to the rights of security holders.

Use of Proceeds

Initial Public Offering

The effective date of the registration statement (File no. 333-214458) for our initial U.S. public offering of our ADSs was March 21, 2017. The offering with respect to our ADSs commenced on March 21, 2017 and was closed on March 27, 2017 and April 3, 2017. Laidlaw & Company (UK) Ltd. was the book-running manager for the offering. We registered 2,000,000 American Depository Shares (ADSs), each representing 40 of our ordinary shares, and granted the underwriters a 45-day option to purchase up to an additional 300,000 ADSs, at the public offering price, less underwriting discount, to cover over-allotments, if any. The over-allotment was exercised in full by the underwriters.

The gross proceeds received by us from this offering were approximately $13,800,000, prior to deducting underwriting discounts, commissions and other estimated offering expenses. Under the terms of the offering, we incurred aggregate underwriting discounts of approximately $911,000 and expenses of approximately $889,000 in connection with the offering, resulting in net proceeds to us of approximately $12,000,000. None of the expenses was paid directly or indirectly to any director, officer, general partner of ours or to their associates, persons owning ten percent or more of any class of our equity securities, or to any of our affiliates.

The primary purposes of this offering were to advance the formulation and clinical development efforts in our Joint Pharma program (THX-TS01 product candidate); to advance the formulation and clinical development efforts in our BrainBright Pharma program (THX- ULD01 product candidate); and the remainder for working capital and general corporate purposes, and possible in-licensing of additional intellectual property and product candidates.

As of April 27, 2017, we still have not used the net proceeds of this offering. We expect to use the net proceeds from this offering as follows:

(i) Approximately $8 million for R&D activities; and

(ii) Approximately $4 million for business development, G&A expenses and working capital.

We believe that the net proceeds from the offering, together with our cash reserves preceding the offering, should be sufficient at least until June 30, 2018, for the following purposes:

(i) Approximately $3.9 million to advance the formulation and clinical development efforts in our Joint Pharma program (THX-TS01 product candidate), allocated as follows:

- approximately $600,000 to complete a POC, Phase IIa clinical trial in the United States;
- approximately $1.3 million to complete Phase IIb clinical trial in Europe; and
- the remainder to fund general formulation development and product manufacturing for clinical trials.

(ii) Approximately $3.5 million to advance the formulation and clinical development efforts in our BrainBright Pharma program (THX- ULD01 product candidate), allocated as follows:

- approximately $400,000 to complete a Phase I clinical trial in Canada or the United States;
- approximately $1 million to initiate a POC, Phase IIa clinical trial in Israel or Europe; and
- the remainder to fund general formulation development and product manufacturing for clinical trials.

(iii) The remainder for working capital and general corporate purposes, and possible in-licensing of additional intellectual property and product candidates.

Our expected use of net proceeds from the offering represents our current intentions based upon our present plans and business condition. As of the date of this annual report, we cannot predict with certainty any or all of the particular uses for the net proceeds we received upon the completion of the offering, or the amounts, if any, that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including the progress of our clinical development and regulatory efforts, the status and results of the clinical trials, the pace of our partnering efforts in regards to manufacturing and commercialization and the overall regulatory environment.. As a result, our management will have broad discretion in the application of the net proceeds, which may include uses not set forth above, and investors in our securities will be relying on our judgment regarding the application of the net proceeds from the offering.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2016, or the Evaluation Date. Based on such evaluation, those officers have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be included in periodic filings under the Exchange Act and that such information is accumulated and communicated to management, including our principal executive and financial officers, as appropriate to allow timely decisions regarding required disclosure.

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

This annual report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

(c) Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to an exemption for emerging growth companies provided in the JOBS Act.

(d) Changes in Internal Control over Financial Reporting

During the year ended December 31, 2016, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

All of the members of our audit committee are "independent," as such term is defined in under NASDAQ Stock Market rules. In addition, our board of directors has determined that each member of our audit committee is an audit committee financial expert, as defined under the rules under the Exchange Act.

ITEM 16B. CODE OF ETHICS

We have adopted a written code of ethics that applies to our officers and employees, including our principal executive officer, principal financial officer, principal controller and persons performing similar functions as well as our directors. Our Code of Business Conduct and Ethics is posted on our website at http://therapixbio.com. Information contained on, or that can be accessed through, our website does not constitute a part of this annual report on Form 20-F and is not incorporated by reference herein. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the code, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC including the instructions to Item 16B of Form 20-F. We have not granted any waivers under our Code of Business Conduct and Ethics.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Kost Forer Gabbay & Kasierer (a member of EY Global), has served as our principal independent registered public accounting firm for each of the two years ended December 31, 2015 and 2016.

The following table provides information regarding fees paid by us to Kost Forer Gabbay & Kasierer and/or other member firms of EY Global for all services, including audit services, for the years ended December 31, 2015 and 2016:

	Year Ended December 31,	
	2015	2016
Audit fees [(1)]	$ 243,384	$ 70,700
Audit-related fees	-	-
Tax fees [(2)]		$ 3,385
All other fees	-	-
Total	$ 243,384	$ 74,085

(1) Includes professional services rendered in connection with the audit of our annual financial statements, review of our interim financial statements, tax returns, and fees relating to our public offering of ADSs.
(2) Includes on going tax consultation.

Pre-Approval of Auditors' Compensation

Pursuant to our audit committee's charter, the audit committee, among others, is required to recommend to our Board of Directors to recommend to our shareholders to appoint and approve the compensation of the independent registered public accounting firm, engaged to audit our financial statements, including oversight of the independent registered public accounting firm and recommend to our Board of Directors, in accordance with the Israeli law, the engagement, compensation or termination of engagement of the independent registered public accounting firm.

In addition, according to such charter, the audit committee is responsible, among others, to pre-approve audit and non-audit services provided to us by the independent registered public accounting firm. The audit committee shall consult with our management but shall not delegate these responsibilities. The audit committee shall also review and approve disclosures relating to fees and non-audit services required to be included in the Securities and Exchange Commission reports. Subject to our Board of Directors and shareholders approval, if and to the extent required by applicable law, the audit committee shall have the authority to approve all audit engagement fees and terms and all non-audit engagements, as may be permissible, with the independent registered public accounting firm and to establish pre-approval policies and procedures for the engagement of independent accountants to render services to us, including a delegation of authority to one or more of its members. The pre-approval of auditing and non-auditing services can be carried out with input from, but no delegation of authority to, our management.

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

Not applicable.

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

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

The Sarbanes-Oxley Act, as well as related rules subsequently implemented by the SEC, requires foreign private issuers, such as us, to comply with various corporate governance practices. In addition, following the listing of the ADSs on the NASDAQ Capital Market, we will be required to comply with the NASDAQ Stock Market rules. Under those rules, we may elect to follow certain corporate governance practices permitted under the Companies Law in lieu of compliance with corresponding corporate governance requirements otherwise imposed by the NASDAQ Stock Market rules for U.S. domestic issuers.

In accordance with Israeli law and practice and subject to the exemption set forth in Rule 5615 of the NASDAQ Stock Market rules, we intend to follow the provisions of the Companies Law, rather than the NASDAQ Stock Market rules, with respect to the following requirements:

- *Distribution of periodic reports to shareholders; proxy solicitation.* As opposed to the NASDAQ Stock Market rules, which require listed issuers to make such reports available to shareholders in one of a number of specific manners, Israeli law does not require us to distribute periodic reports directly to shareholders, and the generally accepted business practice in Israel is not to distribute such reports to shareholders but to make such reports available through a public website. In addition to making such reports available on a public website, we currently make our audited financial statements available to our shareholders at our offices and will only mail such reports to shareholders upon request. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules.

- *Quorum*. While the NASDAQ Stock Market rules require that the quorum for purposes of any meeting of the holders of a listed company's common voting stock, as specified in the company's bylaws, be no less than 33 1/3% of the company's outstanding common voting stock, under Israeli law, a company is entitled to determine in its articles of association the number of shareholders and percentage of holdings required for a quorum at a shareholders meeting. Our articles of association provide that a quorum of three or more shareholders holding at least 30% of the voting rights in person or by proxy is required for commencement of business at a general meeting. However, the quorum set forth in our articles of association with respect to an adjourned meeting, if no quorum is present within half an hour of the time arranged, consists of any number of shareholders present in person or by proxy.

- *Compensation of officers.* Israeli law and our articles of association do not require that the independent members of our Board of Directors (or a compensation committee composed solely of independent members of our Board of Directors) determine an executive officer's compensation, as is generally required under the NASDAQ Stock Market rules with respect to the Chief Executive Officer and all other executive officers. Instead, compensation of executive officers is determined and approved by our compensation committee and our Board of Directors, and in certain circumstances by our shareholders, either consistent with our office holder compensation policy or, in special circumstances in deviation therefrom, taking into account certain considerations stated in the Companies Law.

  Shareholder approval is generally required for officer compensation in the event (i) approval by our Board of Directors and our compensation committee is not consistent with our office holder compensation policy (ii) compensation required to be approved is that of our Chief Executive Officer, or (iii) with respect to an officer that is a controlling shareholder or his or her relative. Such shareholder approval shall require a majority vote of the shares present and voting at a shareholders' meeting, provided either (i) such majority includes a majority of the shares held by non-controlling shareholders who do not otherwise have a personal interest in the compensation arrangement that are voted at the meeting, excluding for such purpose any abstentions disinterested majority, (ii) the total shares held by non-controlling and disinterested shareholders who voted against the arrangement does not exceed 2% of the voting rights in our company.

  Additionally, approval of the compensation of an executive officer who is also a director requires a simple majority vote of the shares present and voting at a shareholders meeting, if consistent with our office holder compensation policy. Our compensation committee and Board of Directors may, in special circumstances, approve the compensation of an executive officer (other than a director, a Chief Executive Officer or a controlling shareholder) or approve the compensation policy despite shareholders' objection, based on specified arguments and taking shareholders' objection into account. Our compensation committee may further exempt an engagement with a nominee for the position of Chief Executive Officer, who meets the non-affiliation requirements set forth for an external director, from requiring shareholder approval, if such engagement is consistent with our office holder compensation policy and our compensation committee determines based on specified arguments that presentation of such engagement to shareholder approval is likely to prevent such engagement. To the extent that any such transaction with a controlling shareholder is for a period exceeding three years, approval is required once every three years.

  A director or executive officer may not be present when the Board of Directors of a company discusses or votes upon a transaction in which he or she has a personal interest, except in case of ordinary transactions, unless the Chairman of the Board of Directors determines that he or she should be present to present the transaction that is subject to approval.

- *Shareholder approval.* We will seek shareholder approval for all corporate actions requiring such approval under the requirements of the Companies Law, rather than seeking approval for corporation actions in accordance with NASDAQ Listing Rule 5635. In particular, under this NASDAQ Stock Market rule, shareholder approval is generally required for: (i) an acquisition of shares/assets of another company that involves the issuance of 20% or more of the acquirer's shares or voting rights or if a director, officer or 5% shareholder has greater than a 5% interest in the target company or the consideration to be received; (ii) the issuance of shares leading to a change of control; (iii) adoption/amendment of equity compensation arrangements (although under the provisions of the Companies Law there is no requirement for shareholder approval for the adoption/amendment of the equity compensation plan); and (iv) issuances of 20% or more of the shares or voting rights (including securities convertible into, or exercisable for, equity) of a listed company via a private placement (and/or via sales by directors/officers/5% shareholders) if such equity is issued (or sold) at below the greater of the book or market value of shares. By contrast, under the Companies Law, shareholder approval is required for, among other things: (i) transactions with directors concerning the terms of their service or indemnification, exemption and insurance for their service (or for any other position that they may hold at a company), for which approvals of the compensation committee, Board of Directors and shareholders are all required, (ii) extraordinary transactions with controlling shareholders of publicly held companies (or in which such controlling shareholders have a personal interest), which require the special approval, and (iii) terms of employment or other engagement of the controlling shareholder of us or such controlling shareholder's relative, which require special approval. In addition, under the Companies Law, a merger requires approval of the shareholders of each of the merging companies.

- *Approval of Related Party Transactions*. All related party transactions are approved in accordance with the requirements and procedures for approval of interested party acts and transactions as set forth in the Companies Law, which requires the approval of the audit committee, or the compensation committee, as the case may be, the Board of Directors and shareholders, as may be applicable, for specified transactions, rather than approval by the audit committee or other independent body of our Board of Directors as required under the NASDAQ Stock Market rules.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

We have elected to provide financial statements and related information pursuant to Item 18.

ITEM 18. FINANCIAL STATEMENTS

The consolidated financial statements and the related notes required by this Item are included in this annual report on Form 20-F beginning on page F-1.

ITEM 19. EXHIBITS

Exhibit Number	Exhibit Description
1.1	Articles of Association of Therapix Biosciences Ltd. (unofficial English translation from Hebrew original) (filed as Exhibit 3.1 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on November 23, 2016, and incorporated herein by reference).
2.1	Form of Amended and Restated Depositary Agreement (filed as Exhibit 1 to the Post-Effective Amendment No. 1 to Form F-6 (File No. 333-197509) filed on December 7, 2016, and incorporated herein by reference).
2.2	Specimen American Depositary Receipt (included in Exhibit 2.1).
2.3	Form of Representative's Warrant (included in Exhibit 1.1 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on March 20, 2017, and incorporated herein by reference).
4.1^	License Agreement dated May 20, 2015, by and between the Company and Dekel Pharmaceuticals Ltd. (filed as Exhibit 10.1 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on December 6, 2016, and incorporated herein by reference).
4.2^	Research Funding and License Agreement dated January 31, 2016, by and between the Company and Ramot at Tel Aviv University Ltd. (filed as Exhibit 10.2 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on November 4, 2016, and incorporated herein by reference).
4.3†	License Agreement dated March 30, 2017, by and between the Company and Yissum Research Development Company of the Hebrew University of Jerusalem Ltd. (filed herewith).
4.4^	Term Sheet for License dated June 7, 2016 between the Company and Belvit Pharma LLC (filed as Exhibit 10.4 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on November 4, 2016, and incorporated herein by reference).
4.5	Israeli Share Option Plan (2015) (filed as Exhibit 10.5 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on November 4, 2016, and incorporated herein by reference).
4.6	Israeli Share Option Plan (2005) (filed as Exhibit 10.6 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on November 4, 2016, and incorporated herein by reference).
4.7	Employment Agreement dated February 15, 2016, as amended on April 17, 2016, by and between the Company and Dr. Elran Haber (filed as Exhibit 10.7 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on November 4, 2016, and incorporated herein by reference).
4.8	Consulting Agreement dated November 29, 2015, by and between the Company and Mr. Doron Ben-Ami (filed as Exhibit 10.8 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on November 4, 2016, and incorporated herein by reference).
4.9	Financial Services Agreement dated November 2015, and addendum dated March 22, 2016, by and between the Company and Mr. Guy Goldin (filed as Exhibit 10.9 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on November 4, 2016, and incorporated herein by reference).
4.10	Employment Agreement dated February 16, 2016, by and between the Company and Dr. Adi Zuloff-Shani (filed as Exhibit 10.10 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on November 4, 2016, and incorporated herein by reference).
4.11	Consulting Agreement dated February 16, 2016, and addendum dated April 17, 2016, by and between the Company and Dr. Ascher Shmulewitz (filed as Exhibit 10.11 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on November 4, 2016, and incorporated herein by reference).
4.12	Form of Indemnification Agreement (filed herewith).
4.13	Form of Exculpation Agreement (filed as Exhibit 10.13 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on November 4, 2016, and incorporated herein by reference).
4.14	Private Placement Agreement dated February 13, 2017, by and between the Company and Dr. Haim Amir (filed as Exhibit 10.14 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on March 3, 2017, and incorporated herein by reference).
4.15	Amendment to Private Placement Agreement dated February 28, 2017, by and between the Company and Dr. Haim Amir (filed as Exhibit 10.15 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on March 3, 2017, and incorporated herein by reference).
12.1	Certification of the Chief Executive Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934 (filed herewith).
12.2	Certification of the Principal Financial and Accounting Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934 (filed herewith).
13.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350 (furnished herewith).
13.2	Certification of the Principal Financial and Accounting Officer pursuant to 18 U.S.C. 1350 (furnished herewith).

^ Portions of this exhibit have been omitted pursuant to an order granting confidential treatment.
† Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

SIGNATURES

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

THERAPIX BIOSCIENCES LTD.

By: /s/ Elran Haber
Dr. Elran Haber
Chief Executive Officer

Date: May 1, 2017

THERAPIX BIOSCIENCES LTD.

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2016

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of

THERAPIX BIOSCIENCES LTD.

We have audited the accompanying consolidated statements of financial position of Therapix Biosciences Ltd. and its subsidiaries ("the Company") as of December 31, 2016 and 2015, and the related consolidated statements of profit or loss, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2016. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Haifa, Israel
May 1, 2017

/s/ KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

THERAPIX BIOSCIENCES LTD.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31, 2015	December 31, 2016	Convenience translation into USD (Note 1b) December 31, 2016
		NIS in thousands		USD in thousands
ASSETS				
CURRENT ASSETS:				
Cash	5	6,136	2,598	676
Restricted cash	15e	44	44	11
Accounts receivable	6	279	450	117
		6,459	3,092	804
NON-CURRENT ASSETS:				
Prepaid public offering costs	22d	-	1,652	430
Property	7	42	44	11
		42	1,696	441
		6,501	4,788	1,245

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

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31, 2015	December 31, 2016	Convenience translation into USD (Note 1b) December 31, 2016
		NIS in thousands		USD in thousands
LIABILITIES AND EQUITY				
CURRENT LIABILITIES:				
Trade payables	9	1,779	2,268	590
Other accounts payable	10	215	317	82
		1,994	2,585	672
EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:	16			
Share capital		3,540	4,100	1,066
Share premium		95,772	101,408	26,374
Share-based payment transactions		18,309	16,878	4,390
Foreign currency translation reserve		20	-	-
Transactions with non-controlling interests		941	941	245
Accumulated deficit		(113,468)	(121,124)	(31,502)
		5,114	2,203	573
Non-controlling interests		(607)	-	-
Total equity		4,507	2,203	573
Total liabilities and equity		6,501	4,788	1,245

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

THERAPIX BIOSCIENCES LTD.

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

	Note	Year ended December 31, 2014	2015	2016	Convenience translation into USD (Note 1b) December 31, 2016
		NIS in thousands (except per share data)			USD in thousands (except per share data)
Research and development expenses, net	18a	(1,800)	(931)	(2,842)	(739)
General and administrative expenses	18b	(5,238)	(5,297)	(4,870)	(1,267)
		(7,038)	(6,228)	(7,712)	(2,006)
Other income (expenses), net	18d	115	(3,734)	30	7
Operating loss		(6,923)	(9,962)	(7,682)	(1,999)
Finance income	18c	401	20	3	1
Finance expenses	18c	(427)	(35)	(29)	(7)
Company's share of losses of an associate		(343)	(197)	-	-
Net loss		(7,292)	(10,174)	(7,708)	(2,005)
Attributable to:					
Equity holders of the Company		(7,207)	(9,877)	(7,656)	(1,991)
Non-controlling interests		(85)	(297)	(52)	(14)
		(7,292)	(10,174)	(7,708)	(2,005)
Basic and diluted net loss per share attributable to equity holders of the Company	19	(0.45)	(0.43)	(0.21)	(0.05)

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

THERAPIX BIOSCIENCES LTD.

CONSOLIDATED STATEMENTS COMPREHENSIVE INCOME

	Year ended December 31,			Convenience translation into USD (Note 1b) December 31,
	2014	2015	2016	2016
	NIS in thousands			USD in thousands
Net loss	(7,292)	(10,174)	(7,708)	(2,005)
Amounts that will be or that have been reclassified to profit or loss when specific conditions are met:				
Adjustments arising from translating financial statements of foreign operations	10	10	-	-
Amounts transferred to the statement of profit or loss for sale of foreign operation	-	-	(20)	(5)
Total other comprehensive income (loss)	10	10	(20)	(5)
Total comprehensive loss	(7,282)	(10,164)	(7,728)	(2,010)
Attributable to:				
Equity holders of the Company	(7,197)	(9,867)	(7,676)	(1,996)
Non-controlling interests	(85)	(297)	(52)	(14)
	(7,282)	(10,164)	(7,728)	(2,010)

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

THERAPIX BIOSCIENCES LTD.

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Attributable to equity holders of the Company									
	Share capital	Share premium	Share-based payment transactions	Foreign currency translation reserve from associate	Warrants	Transactions with non-controlling interests	Accumulated deficit	Total	Non-controlling interests	Total equity
	NIS in thousands									
Balance at January 1, 2014	1,410	78,276	15,071	-	4,377	941	(96,384)	3,691	(225)	3,466
Loss	-	-	-	-	-	-	(7,207)	(7,207)	(85)	(7,292)
Other comprehensive income	-	-	-	10	-	-	-	10	-	10
Total comprehensive loss	-	-	-	10	-	-	(7,207)	(7,197)	(85)	(7,282)
Issuance of shares and warrants (1)	431	2,184	-	-	604	-	-	3,219	-	3,219
Share-based payments	-	-	144	-	-	-	-	144	-	144
Balance at December 31, 2014	1,841	80,460	15,215	10	4,981	941	(103,591)	(143)	(310)	(453)
Loss	-	-	-	-	-	-	(9,877)	(9,877)	(297)	(10,174)
Other comprehensive income	-	-	-	10	-	-	-	10	-	10
Total comprehensive loss	-	-	-	10	-	-	(9,877)	(9,867)	(297)	(10,164)
Issuance of shares (2)	806	4,858	-	-	-	-	-	5,664	-	5,664
Exercise of share options and warrants into shares	893	6,134	(1,344)	-	(661)	-	-	5,022	-	5,022
Expiration of warrants	-	4,320	-	-	(4,320)	-	-	-	-	-
Share-based payments	-	-	4,438	-	-	-	-	4,438	-	4,438
Balance at December 31, 2015	3,540	95,772	18,309	20	-	941	(113,468)	5,114	(607)	4,507
Loss	-	-	-	-	-	-	(7,656)	(7,656)	(52)	(7,708)
Other comprehensive loss	-	-	-	(20)	-	-	-	(20)	-	(20)
Total comprehensive loss	-	-	-	(20)	-	-	(7,656)	(7,676)	(52)	(7,728)
Deconsolidation of a subsidiary (See Note 8b)	-	-	-	-	-	-	-	-	659	659
Exercise of share options	540	4,420	(1,451)	-	-	-	-	3,509	-	3,509
Expiration of share options	-	1,136	(1,136)	-	-	-	-	-	-	-
Share-based payments	20	80	1,156	-	-	-	-	1,256	-	1,256
Balance at December 31, 2016	4,100	101,408	16,878	-	-	941	(121,124)	2,203	-	2,203

(1) Net of issuance expenses of NIS 290,000.
(2) Net of issuance expenses of NIS 84,000.

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

THERAPIX BIOSCIENCES LTD.

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Attributable to equity holders of the Company									
	Share capital	Share premium	Share-based payment transactions	Foreign currency translation reserve from associate	Warrants	Transactions with non-controlling interests	Accumulated deficit	Total	Non-controlling interests	Total equity
	Convenience translation into USD (note 1b) in thousands									
Balance at January 1, 2016	921	24,908	4,762	5	-	245	(29,511)	1,330	(158)	1,172
Loss	-	-	-	-	-	-	(1,991)	(1,991)	(14)	(2,005)
Other comprehensive loss	-	-	-	(5)	-	-	-	(5)	-	(5)
Total comprehensive loss	-	-	-	(5)	-	-	(1,991)	(1,996)	(14)	(2,010)
Deconsolidation of a subsidiary (See Note 8b)	-	-	-	-	-	-	-	-	172	172
Exercise of share options	140	1,150	(377)	-	-	-	-	913	-	913
Expiration of share options	-	295	(295)	-	-	-	-	-	-	-
Share-based payments	5	21	300	-	-	-	-	326	-	326
Balance at December 31, 2016	1,066	26,374	4,390	-	-	245	(31,502)	573	-	573

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

THERAPIX BIOSCIENCES LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,			Convenience translation into USD (Note 1b) December 31,
	2014	2015	2016	2016
	NIS in thousands			USD in thousands
Cash flows from operating activities:				
Net loss	(7,292)	(10,174)	(7,708)	(2,005)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	146	11	14	4
Loss (gain) from sale of equipment	(116)	19	-	-
Share-based payment expense	144	4,438	1,256	327
Change in liability to the Israeli National Authority for Technological Innovation ("INATI")	28	(191)	-	-
Gain from sale of investments in investees	-	-	(130)	(34)
Finance expenses (income), net	(5)	35	(20)	(5)
Company's share in losses of associate	343	197	-	-
Change in fair value of warrant liability	(396)	-	-	-
Change in fair value of financial derivatives	350	-	-	-
	494	4,509	1,120	292
Working capital adjustments:				
Decrease (increase) in accounts receivable	20	(177)	(421)	(109)
Increase (decrease) in trade payables	(374)	597	893	232
Increase (decrease) in other accounts payable	(211)	83	426	110
	(565)	503	898	233
Interest received	5	-	-	-
Net cash used in operating activities	(7,358)	(5,162)	(5,690)	(1,480)

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

THERAPIX BIOSCIENCES LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,			Convenience translation into USD (Note 1b) December 31,
	2014	2015	2016	2016
	NIS in thousands			USD in thousands
Cash flows from investing activities:				
Proceeds from sale of equipment	220	2	-	-
Decrease in restricted cash, net	283	-	-	-
Purchase of equipment	(2)	(4)	(16)	(4)
Investment in financial derivatives	(350)	-	-	-
Investment in associate	(520)	-	-	-
Proceeds from sale of an investment in previously consolidated subsidiary (a)	-	-	(1)	-
Net cash used in investing activities	(369)	(2)	(17)	(4)
Cash flows from financing activities:				
Proceeds from issuance of shares and warrants (net of issuance expenses)	3,219	5,664	-	-
Prepaid public offering costs	-	-	(1,340)	(349)
Proceeds from exercise of share options and warrants	-	5,022	3,509	913
Net cash provided by financing activities	3,219	10,686	2,169	564
Increase (decrease) in cash	(4,508)	5,522	(3,538)	(920)
Cash at the beginning of the year	5,122	614	6,136	1,596
Cash at the end of the year	614	6,136	2,598	676

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

THERAPIX BIOSCIENCES LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,			Convenience translation into USD (Note 1b) December 31,
	2014	2015	2016	2016
	NIS in thousands			USD in thousands
(a) Proceeds from sale of an investment in previously consolidated subsidiary:				
The subsidiary' assets and liabilities at date of sale:				
Non-current liabilities	-	-	(790)	(205)
Non-controlling interests	-	-	659	171
Gain from sale of subsidiary	-	-	130	34
	-	-	(1)	-
(b) Significant non-cash transactions:				
Public offering costs due to service providers	-	-	312	81

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1:- GENERAL

a. Therapix Biosciences Ltd. ("Therapix"), a pharmaceutical company, was incorporated in Israel and commenced its operations on August 23, 2004. Until March 2014, Therapix and its subsidiaries (the "Company") were mainly engaged in developing several innovative immunotherapy products and it owns patents in the immunotherapy field.

In August 2015, the Company revised its business strategy according to which it will focus on developing approved drugs based on cannabinoid molecules. The Company is presently developing a cannabinoid based drug for Tourette syndrome using the entourage technology and is preparing to develop a cannabinoid based drug for mild cognitive impairment using the low dose technology.

The Company controls one subsidiary, NasVax Inc., a private inactive company whose financial statements are consolidated with those of the Company and owns approximately 27% of Lara Pharm Ltd.'s share capital ("Lara") – see Note 8a. The headquarters of the Company are located in Tel-Aviv, Israel.

Until June, 2016 the Company also owned a subsidiary named Orimmune Bio Ltd. ("Orimmune"), which was sold during the year (see Note 8b.).

The consolidated financial statements of the Company for the year ended December 31, 2016 were authorized for issue on May 1, 2017.

b. Convenience translation into U.S. dollars ("dollars", "USD" or "$"):

For the convenience of the reader, the reported New Israeli Shekel (NIS) amounts as of December 31, 2016, and for the year then ended have been translated into dollars at the Bank of Israel's representative rate of exchange for December 31, 2016 (USD 1 = NIS 3.845). The dollar amounts presented in these financial statements should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated. The dollars amounts were rounded to whole numbers for convenience.

c. The Company incurred a net loss of NIS 7.7 million and had negative cash flows from operating activities of NIS 5.7 million for the year ended December 31, 2016. As of December 31, 2016, the Company had an accumulated deficit of NIS 121 million as a result of recurring operating losses. As discussed in Note 1a above, the Company's business strategy is to focus on developing cannabinoid based drugs to treat Tourette syndrome and mild cognitive impairment.

As the Company presently has no activities that generate revenues, the Company's continued operation is dependent on its ability to raise funding from external sources. This dependency will continue until the Company will be able to finance its operations by selling its products or commercializing its technology. In March 2017, the Company completed an Initial Public Offering ("IPO") in the United States and raised approximately USD 13.7 million (see Note 22d.). Prior to the IPO, in early March 2017, the Company also raised USD 1 million in a private placement (see Note 22c.)

The Company's management believes that the balance of cash held by the Company subsequent to the IPO will be sufficient to finance its operating activities and meet its obligations for a period of at least twelve months from the date of the statement of financial position.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The following accounting policies have been applied consistently in the financial statements for all periods presented, unless otherwise stated.

a. Basis of presentation of the financial statements:

These financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board (IASB).

The Company's financial statements have been prepared on a cost basis, unless otherwise indicated.

The Company has elected to present the profit or loss items using the function of expense method.

b. The operating cycle:

The operating cycle of the Company is one year.

c. Consolidated financial statements:

The consolidated financial statements include the financial statements of companies that are controlled by the Company (subsidiaries). Control is achieved when the Company is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. The consolidation of the financial statements commences on the date on which control is obtained and ends when such control ceases.

The financial statements of Therapix and its subsidiaries are prepared as of the same dates and periods. The accounting policies applied in the financial statements of the subsidiaries are uniform and consistent with the policies applied in the financial statements of Therapix. Significant intragroup balances and transactions and gains or losses resulting from intragroup transactions are eliminated in full in the consolidated financial statements.

Non-controlling interests in subsidiaries represent the equity in subsidiaries not attributable, directly or indirectly, to a parent. Non-controlling interests are presented in equity separately from the equity attributable to the equity holders of the Company. Losses are attributed to non-controlling interests even if they result in a negative balance of non-controlling interests in the consolidated statement of financial position.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

d. Functional currency and foreign currency:

1. Functional currency and presentation currency:

The Company determines the functional currency of each entity, including companies accounted for at equity. The functional currency of Therapix and Orimmune Bio Ltd. is the NIS while the functional currency of Lara is the USD.

2. Transactions, assets and liabilities in foreign currency:

Transactions denominated in foreign currency (other than the functional currency) are recorded upon initial recognition at the exchange rate at the date of the transaction. After initial recognition, monetary assets and liabilities denominated in foreign currency are translated at each reporting date into the functional currency at the exchange rate at that date. Exchange rate differences are recognized in profit or loss. Non-monetary assets and liabilities denominated in foreign currency and measured at cost are translated at the exchange rate at the date of the transaction. Non-monetary assets and liabilities denominated in foreign currency and measured at fair value are translated into the functional currency using the exchange rate prevailing at the date when the fair value was determined.

e. Investments in associates:

Associates are companies in which the Company has significant influence over the financial and operating policies without having control.

The Company's investment in associates is accounted for using the equity method.

Losses of an associate in amounts which exceed its equity are recognized by the Company up to the carrying amount of its investment in the associate.

Under the equity method, the investment in the associate is presented at cost with the addition of post-acquisition changes in the Company's share of net assets, including other comprehensive income of the associate. Gains and losses resulting from transactions between the Company and the associate are eliminated to the extent of the interest in the associate.

Goodwill relating to the acquisition of an associate is included in the carrying amount of the investment and is not tested for impairment separately.

The financial statements of the Company and of the associate are prepared as of the same dates and periods. The accounting policies applied in the financial statements of the associate consistent with the policies applied in the financial statements of the Company.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

g. Financial instruments:

1. Financial assets:

Financial assets within the scope of IAS 39 (accounts receivable) are initially recognized at fair value plus directly attributable transaction costs.

After initial recognition, accounts receivable are measured at amortized cost.

2. Financial liabilities:

Financial liabilities are initially recognized at fair value. Loans and other liabilities measured at amortized cost are presented net of direct transaction costs.

After initial recognition, the accounting treatment of financial liabilities is based on their classification as follows:

a) Financial liabilities at amortized cost:

After initial recognition, loans and other liabilities are measured based on their terms at amortized cost less directly attributable transaction costs using the effective interest method.

3. Offsetting of financial instruments:

Financial assets and financial liabilities are offset and the net amount is presented in the consolidated statement of financial position if there is a legal enforceable right to offset the recognized amounts and there is an intention either to settle on a net basis or to realize the asset and settle the liability simultaneously.

The right of offset must be legally enforceable not only during the ordinary course of business of the parties to the contract but also in the event of bankruptcy or insolvency of one of the parties. In order for the right of offset to be currently available, it must not be contingent on a future event, there may not be periods during which the right is not available, or there may not be any events that will cause the right to expire.

4. Issue of a unit of securities:

The issue of a unit of securities involves the allocation of the proceeds received (before issuance expenses) to the securities issued in the unit based on the following order: financial derivatives and other financial instruments measured at fair value in each period. Then fair value is determined for financial liabilities that are measured at amortized cost. The proceeds allocated to equity instruments are determined to be the residual amount. Issuance costs are allocated to each component pro rata to the amounts determined for each component in the unit.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

5. Derecognition of financial instruments:

   a) Financial assets:

      A financial asset is derecognized when the contractual rights to the cash flows from the financial asset expire or the Company has transferred its contractual rights to receive cash flows from the financial asset or assumes an obligation to pay the cash flows in full without material delay to a third party and has transferred substantially all the risks and rewards of the asset, or has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

   b) Financial liabilities:

      A financial liability is derecognized when the obligation under the liability is discharged or cancelled or expires.

6. Impairment of financial assets:

   The Company assesses at each reporting date whether there is any objective evidence of impairment of a financial asset or group of financial assets as follows:

   Financial assets carried at amortized cost:

   Objective evidence of impairment exists when one or more events that have occurred after initial recognition of the asset have a negative impact on the estimated future cash flows. The amount of the loss recorded in profit or loss is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows (excluding future credit losses that have not yet been incurred) discounted at the financial asset's original effective interest rate. If the financial asset has a variable interest rate, the discount rate is the current effective interest rate. In a subsequent period, the amount of the impairment loss is reversed if the recovery of the asset can be related objectively to an event occurring after the impairment was recognized. The amount of the reversal, up to the amount of any previous impairment, is recorded in profit or loss.

   Investment in associate or joint venture:

   After application of the equity method, the Company determines whether it is necessary to recognize any additional impairment loss with respect to the investment in associates or joint ventures. The Company determines at each reporting date whether there is objective evidence that the carrying amount of the investment in the associate or the joint venture is impaired. The test of impairment is carried out with reference to the entire investment, including the goodwill attributed to the associate or the joint venture.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

h. Leases:

The criteria for classifying leases as finance or operating leases depend on the substance of the agreements and are made at the inception of the lease in accordance with the following principles as set out in IAS 17.

The Company as lessee - operating lease:

Leases in which substantially all the risks and rewards of ownership of the leased asset are not transferred to the Company are classified as operating leases. Lease payments are recognized as an expense in profit or loss on a straight-line basis over the lease term.

i. Property:

Property is measured at cost, including direct acquisition costs, less accumulated depreciation, accumulated impairment losses and any related investment grants and excluding day-to-day servicing expenses.

Depreciation is calculated on a straight-line basis over the useful life of the assets at annual rates as follows:

	%
Lab equipment	15
Computers	33
Office furniture and equipment	6

Leasehold improvements are depreciated on a straight-line basis over the shorter of the lease term (including the extension option held by the Company and intended to be exercised) and the expected life of the improvement.

The useful life, depreciation method and residual value of an asset are reviewed at least each year-end and any changes are accounted for prospectively as a change in accounting estimate. As for testing the impairment of property, see below.

Depreciation of an asset ceases at the earlier of the date that the asset is classified as held for sale and the date that the asset is derecognized.

j. Research and development expenditures:

Research expenditures are recognized in profit or loss when incurred.

The conditions enabling capitalization of development costs as an asset have not yet been met and, therefore, all development expenditures are recognized in profit or loss when incurred.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

k. Impairment of non-financial assets:

The Company evaluates the need to record an impairment of the carrying amount of non-financial assets (property) whenever events or changes in circumstances indicate that the carrying amount is not recoverable. If the carrying amount of non-financial assets exceeds their recoverable amount, the assets are reduced to their recoverable amount. The recoverable amount is the higher of fair value less costs of sale and value in use.

l. Government grants:

Government grants are recognized when there is reasonable assurance that the grants will be received and the Company will comply with the attached conditions.

Government grants received from the Office of the Israeli National Authority for Technological Innovation at the Ministry of Industry, Trade and Labor ("INATI") are recognized upon receipt as a liability if future economic benefits are expected from the research project that will result in royalty-bearing sales.

The liability is first measured at fair value using a discount rate that reflects a market rate of interest. The difference between the amount of grant received and the fair value of the liability is accounted for as a Government grant and recognized as a reduction of research and development expenses. After initial recognition, the liability is measured at amortized cost using the effective interest method. Royalty payments are treated as a reduction of the liability. If no economic benefits are expected from the research activity, the grant receipts are recognized as a reduction of the related research and development expenses. In that event, the royalty obligation is treated as a contingent liability in accordance with IAS 37.

In each reporting date, the Company evaluates whether there is reasonable assurance that the liability recognized, in whole or in part, will not be repaid (since the Company will not be required to pay royalties) based on the best estimate of future sales and using the original effective interest method and, if so, the appropriate amount of the liability is derecognized against other income.

Amounts paid as royalties are recognized as a settlement of the liability.

m. Taxes on income:

Current or deferred taxes are recognized in profit or loss, except to the extent that they relate to items which are recognized in other comprehensive income or equity.

1. Current taxes:

The current tax liability is measured using the tax rates and tax laws that have been enacted or substantively enacted by the reporting date as well as adjustments required in connection with the tax liability in respect of previous years.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

2. Deferred taxes:

As it is presently not probable that the Company will generate taxable income in the future, no deferred tax assets have been recognized in the consolidated financial statements in respect of carryforward tax losses and other temporary differences. At each reporting date, temporary differences (such as carryforward tax losses) for which deferred tax assets had not been recognized are reviewed and a respective deferred tax asset is recognized to the extent that their utilization is probable.

n. Share-based payment transactions:

The Company's employees and other service providers are entitled to remuneration in the form of share-based payments ("equity-settled transactions").

Equity-settled transactions:

The cost of equity-settled transactions with employees is measured at the fair value of the equity instruments at grant date. The fair value is determined using an acceptable option pricing model; see additional information in Note 17. In estimating fair value, the vesting conditions (consisting of service conditions and performance conditions other than market conditions) are not taken into account. The only conditions taken into account in estimating fair value are market conditions and non-vesting conditions.

As for other service providers, when the Company is unable to reliably estimate the fair value of the services received, the cost of the transactions is measured at the fair value of the equity instruments granted.

The cost of equity-settled transactions is recognized in profit or loss together with a corresponding increase in equity, during the period in which the performance or service conditions are to be satisfied, ending on the date on which the relevant employees become fully entitled to the award ("the vesting period"). The cumulative expense recognized for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and the Company's best estimate of the number of equity instruments that will ultimately vest. No expense is recognized for awards that do not ultimately vest.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

o. Employee benefit liabilities:

The Company has several employee benefit plans:

1. Short-term employee benefits:

Short-term employee benefits are benefits that are expected to be settled less than twelve months from the end of the reporting period in which the employees render the related services. These benefits include salaries, paid annual leave, paid sick leave, recreation and social security contributions and are recognized as expenses as the services are rendered. A liability in respect of a cash bonus or a profit-sharing plan is recognized when the Company has a legal or constructive obligation to make such payment as a result of past service rendered by an employee and a reliable estimate of the amount can be made.

2. Post-employment benefits:

The plans are normally financed by contributions to insurance companies and classified as defined contribution plans or as defined benefit plans.

The Company has defined contribution plans pursuant to section 14 to the Severance Pay Law in Israel under which the Company pays fixed contributions and will have no legal or constructive obligation to pay further contributions if the fund does not hold sufficient amounts to pay all employee benefits relating to employee service in the current and prior periods. Contributions to the defined contribution plan in respect of severance or retirement pay are recognized as an expense when contributed concurrently with performance of the employee's services.

p. Revenue recognition:

The Company has not yet generated any revenues from the sale of goods or from the rendering of services.

q. Finance income and expenses:

Finance income comprises interest income on amounts invested and exchange rate gains. Interest income is recognized as it accrues using the effective interest method.

Finance expenses comprise changes in the fair value of financial liabilities measured at fair value through profit or loss and exchange rate losses. Borrowing costs are recognized in profit or loss using the effective interest method.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

r. Earnings (loss) per share:

Earnings (loss) per share is calculated by dividing the net income (loss) attributable to equity holders of the Company by the weighted number of Ordinary shares outstanding during the period.

Basic loss per share includes only shares that were outstanding during the period.

Potential Ordinary shares are included in the computation of diluted loss per share when their conversion increases loss per share from continuing operations.

NOTE 3:- SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS

In the process of applying the significant accounting policies, the Company has made the following judgments which have the most significant effect on the amounts recognized in the financial statements:

a. Judgments:

- Classification of leases:

In order to determine whether to classify a lease as a finance lease or an operating lease, the Company evaluates whether the lease transfers substantially all the risks and rewards incidental to ownership of the asset. In this respect, the Company evaluates such criteria as the existence of a bargain purchase option, the lease term in relation to the economic life of the asset and the present value of the minimum lease payments in relation to the fair value of the asset.

- Determining the fair value of share-based payment transactions:

The fair value of share-based payment transactions is determined upon initial recognition by an acceptable option pricing model. The inputs to the model include share price and exercise price and assumptions regarding expected volatility, expected life of the share option, expected dividend and risk-free interest rate.

NOTE 3:- SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS (Cont.)

b. Estimates and assumptions:

The preparation of the financial statements requires management to make estimates and assumptions that have an effect on the application of the accounting policies and on the reported amounts of assets, liabilities, revenues and expenses. Changes in accounting estimates are reported in the period of the change in estimate.

The key assumptions made in the financial statements concerning uncertainties at the reporting date and the critical estimates computed by the Company that may result in a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

- Grants from the INATI:

  Government grants received from the INATI are recognized as a liability if future economic benefits are expected from the research and development activity that will result in royalty-bearing sales. There is uncertainty regarding the estimated future cash flows and estimated discount rate used to measure the amount of the liability.

- Legal claims:

  In estimating the likelihood of outcome of legal claims filed against the Company and its investees, the companies rely on the opinion of their legal counsel. These estimates are based on the legal counsel's best professional judgment, taking into account the stage of proceedings and legal precedents in respect of the different issues. Since the outcome of the claims will be determined in courts, the results could differ from these estimates.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 4:- DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION

a. Amendments to IAS 7, "Statement of Cash Flows", regarding additional disclosures of financial liabilities:

In January 2016, the IASB issued amendments to IAS 7, "Statement of Cash Flows", ("the amendments") which require additional disclosures regarding financial liabilities. The amendments require disclosure of the changes between the opening balance and the closing balance of financial liabilities, including changes from cash flows from financing activities, changes arising from obtaining or losing control of subsidiaries, changes in foreign exchange rates and changes in fair value.

The amendments are to be applied for annual periods beginning on or after January 1, 2017. Comparative information for periods prior to the effective date of the amendments is not required. Early adoption is permitted.

The Company will include the necessary disclosures in the financial statements when applicable.

b. IFRS 16, "Leases":

In January 2016, the IASB issued IFRS 16, "Leases" ("the new Standard"). According to the new Standard, a lease is a contract, or part of a contract, that conveys the right to use an asset for a period of time in exchange for consideration.

According to the new Standard:

- Lessees are required to recognize an asset and a corresponding liability in the statement of financial position in respect of all leases (except in certain cases) similar to the accounting treatment of finance leases according to the existing IAS 17, "Leases".

- Lessees are required to initially recognize a lease liability for the obligation to make lease payments and a corresponding right-of-use asset. Lessees will also recognize interest and depreciation expenses separately.

- Variable lease payments that are not dependent on changes in the Israeli CPI or interest rates, but are based on performance or use (such as a percentage of revenues) are recognized as an expense by the lessees as incurred and recognized as income by the lessors as earned.

- In the event of change in variable lease payments that are CPI-linked, lessees are required to remeasure the lease liability and the effect of the remeasurement is an adjustment to the carrying amount of the right-of-use asset.

NOTE 4:- DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION (Cont.)

- The new Standard includes two exceptions according to which lessees are permitted to elect to apply a method similar to the current accounting treatment for operating leases. These exceptions are leases for which the underlying asset is of low value and leases with a term of up to one year.

- The accounting treatment by lessors remains substantially unchanged, namely classification of a lease as a finance lease or an operating lease.

The new Standard is to be applied for annual periods beginning on or after January 1, 2019. Early adoption is permitted provided that IFRS 15, "Revenue from Contracts with Customers", is applied simultaneously.

For leases existing at the date of transition, the new Standard permits lessees to use either a full retrospective approach, or a modified retrospective approach, with certain transition relief whereby restatement of comparative data is not required.

The Company believes that the new Standard is not expected to have a material impact on the financial statements.

c. IFRS 15, "Revenue from Contracts with Customers":

IFRS 15 ("the new Standard") was issued by the IASB in May 2014.

The new Standard replaces IAS 18, "Revenue", IAS 11, "Construction Contracts", IFRIC 13, "Customer Loyalty Programs", IFRIC 15, "Agreements for the Construction of Real Estate", IFRIC 18, "Transfers of Assets from Customers" and SIC-31, "Revenue - Barter Transactions Involving Advertising Services".

The new Standard introduces a five-step model that will apply to revenue earned from contracts with customers:

Step 1: *Identify the contract with a customer*, including reference to contract combination and accounting for contract modifications.

Step 2: *Identify the separate performance obligations in the contract*

Step 3: *Determine the transaction price*, including reference to variable consideration, financing components that are significant to the contract, non-cash consideration and any consideration payable to the customer.

Step 4: *Allocate the transaction price to the separate performance obligations* on a relative stand-alone selling price basis using observable information, if it is available, or using estimates and assessments.

NOTE 4:- DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION (Cont.)

Step 5: *Recognize revenue when a performance obligation is satisfied,* either at a point in time or over time.

The new Standard is to be applied retrospectively for annual periods beginning on January 1, 2018. Early adoption is permitted. At this stage, the Company has not started to generate revenues yet, and therefore early adoption is not relevant.

d. IFRS 9, "Financial Instruments":

In July 2014, the IASB issued the final and complete version of IFRS 9, "Financial Instruments" ("IFRS 9"), which replaces IAS 39, "Financial Instruments: Recognition and Measurement". IFRS 9 mainly focuses on the classification and measurement of financial assets and it applies to all assets in the scope of IAS 39.

According to IFRS 9, all financial assets are measured at fair value upon initial recognition. In subsequent periods, debt instruments are measured at amortized cost only if both of the following conditions are met:

- the asset is held within a business model whose objective is to hold assets in order to collect the contractual cash flows.

- the contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Subsequent measurement of all other debt instruments and financial assets should be at fair value. IFRS 9 establishes a distinction between debt instruments to be measured at fair value through profit or loss and debt instruments to be measured at fair value through other comprehensive income.

Financial assets that are equity instruments should be measured in subsequent periods at fair value and the changes recognized in profit or loss or in other comprehensive income (loss), in accordance with the election by the Company on an instrument-by-instrument basis. If equity instruments are held for trading, they should be measured at fair value through profit or loss.

According to IFRS 9, the provisions of IAS 39 will continue to apply to derecognition and to financial liabilities for which the fair value option has not been elected.

According to IFRS 9, changes in fair value s of financial liabilities which are attributable to the change in credit risk should be presented in other comprehensive income. All other changes in fair value should be presented in profit or loss.

NOTE 4:- DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION (Cont.)

IFRS 9 also prescribes new hedge accounting requirements.

IFRS 9 is to be applied for annual periods beginning on January 1, 2018. Early adoption is permitted.

The Company believes that the IFRS 9 is not expected to have a material impact on the financial statements.

NOTE 5:- CASH

	December 31,		Convenience translation into USD (Note 1b) December 31,
	2015	2016	2016
	NIS in thousands		USD in thousands
Cash for immediate withdrawal - in NIS	4,197	1,342	349
Cash for immediate withdrawal - in USD	1,939	1,256	327
	6,136	2,598	676

NOTE 6:- ACCOUNTS RECEIVABLE

	December 31,		Convenience translation into USD (Note 1b) December 31,
	2015	2016	2016
	NIS in thousands		USD in thousands
Prepaid expenses	147	34	9
Value added tax	132	166	43
Other receivables	-	250	65
	279	450	117

NOTE 7:- EQUIPMENT

2016:

	Computers	Lab equipment	Office furniture and equipment	Total
	NIS in thousands			
Cost:				
Balance at January 1, 2016	73	44	47	164
Additions during the year	16	-	-	16
Disposals during the year	-	-	-	-
Balance at December 31, 2016	89	44	47	180
Accumulated depreciation:				
Balance at January 1, 2016	70	29	23	122
Additions during the year	5	7	2	14
Disposals during the year	-	-	-	-
Balance at December 31, 2016	75	36	25	136
Depreciated cost at December 31, 2016	14	8	22	44
Depreciated cost at December 31, 2016 (convenience translation into USD) (note 1b)	4	2	5	11

NOTE 7:- EQUIPMENT (Cont.)

2015:

	Computers	Lab equipment	Office furniture and equipment	Total
	NIS in thousands			
Cost:				
Balance at January 1, 2015	212	272	66	550
Additions during the year	3	1	-	4
Disposals during the year	(142)	(229)	(19)	(390)
Balance at December 31, 2015	73	44	47	164
Accumulated depreciation:				
Balance at January 1, 2015	187	262	31	480
Additions during the year	-	7	4	11
Disposals during the year	(117)	(240)	(12)	(369)
Balance at December 31, 2015	70	29	23	122
Depreciated cost at December 31, 2015	3	15	24	42

NOTE 8:- INVESTMENT IN ASSOCIATE AND INVESTMENTS IN INVESTEES

a. Investment in Lara

Composition:

	December 31,		Convenience translation into USD (Note 1b) December 31,
	2015	2016	2016
	NIS in thousands		USD in thousands
Cost of shares	520	-	-
Post-acquisition losses	(540)	-	-
Foreign currency translation reserve	20	-	-
Balance at December 31	-	-	-

NOTE 8:- INVESTMENT IN ASSOCIATE AND INVESTMENTS IN INVESTEES (Cont.)

Additional information:

On March 12, 2014, the Company entered into a non-binding term sheet with Lara, an Israeli company that operates in the field of medical cannabis and is developing a synthesized formulation that is based on cannabinoids (active components found in the cannabis plant) to be administered through an inhaler. On June 15, 2014, a final investment agreement was signed between the parties which determined, among others, that the Company will invest in Lara up to a total of USD 1.5 million, subject to the fulfillment of several prerequisites (the "Investment Agreement").

Under the Investment Agreement the Company undertook to transfer to Lara an initial investment amount of USD 800,000 against shares that will represent about 48% of Lara's issued and outstanding share capital (approximately 27% on a fully diluted basis including options to employees and consultants). The Company transferred to Lara USD 250,000 under the Investment Agreement during 2014. Under the Investment Agreement, the Company initially recorded an investment in an associate in the net amount of NIS 520,000 and an investment in a financial derivative (option) in the amount of NIS 350,000. During 2014, the Company recorded its share in Lara's losses in the amount of NIS 343,000 and other comprehensive income related to exchange difference of NIS 10,000. As of December 31, 2014, the financial derivative was written off since its fair value was determined to be NIS 0. During 2015, the Company recorded its share in Lara's losses in the amount of NIS 197,000 and other comprehensive income related to exchange difference of NIS 10,000. Following meetings held between the Company and Lara, on August 13, 2015, the latter informed the Company of its unilateral cancellation of the Investment Agreement because Lara claimed, among others, that the Company did not plan on making additional investments in Lara. The Company explained that it was not required to invest more funds in Lara unless conditions and/or milestones that are described in the Investment Agreement had been met. Accordingly, the Company opposed the unilateral cancellation of the Investment Agreement and the Company officially informed Lara of that. As of December 31, 2015, the Company continued to hold shares of Lara representing approximately a 27% interest in the share capital of Lara and a director nominated by the Company served on Lara's board of directors.

In May 2016, the Company and Lara signed a settlement and termination agreement (the "Settlement Agreement"). Under the Settlement Agreement, the parties agreed that the Company will continue to hold approximately 27% of Lara's share capital, it will be exempt from making the remaining payments under the Investment Agreement and all other terms of the Investment Agreement will have no further binding effect. Under the Settlement Agreement, Lara's founder was granted an option, for a period of 12 months, to purchase all of the Company's holding in Lara for USD 500,000. Furthermore, pursuant to the Settlement Agreement, the Company's representative on Lara's board of directors resigned. Accordingly, the Company no longer has significant influence over Lara. As of December 31, 2016, the balance of the investment in Lara is NIS 0.

NOTE 8:- INVESTMENT IN ASSOCIATE AND INVESTMENTS IN INVESTEES (Cont.)

Sale of previously consolidated subsidiary:

b. On June 22, 2016, the Company entered into a share transfer agreement ("the Transfer Agreement") with its wholly owned subsidiary, Orimmune Bio Ltd. ("the Subsidiary") and Karma Link Ltd. ("the Buyer"), whose controlling shareholder served as a director of the Company until February 2016, whereby the Company will sell its interests in the Subsidiary to the Buyer and take steps to transfer its rights in the Anti-CD3 technology (mainly consisting of the Company's license from Hadasit Research Services & Development Ltd., the Technology Transfer Company of Hadassah Medical Organization which owns the technology) ("the License") and certain assets of the Company underlying the development of the technology, all under the terms specified below.

   The Transfer Agreement mainly consists of the following:

   1. The Company will transfer its entire interests in the Subsidiary's shares to the Buyer and exercise its best effort to assist in the assignment of the license to the Subsidiary, including certain intellectual property assets developed by the Company in connection with the license, and in obtaining all the necessary approvals.

   2. Subject to the completion of the License assignment process described above, the Company will be entitled to a predetermined rate (which is a low double-digit number) of all receipts which the Buyer (and its related parties, as defined in the Transfer Agreement) will receive from the Subsidiary or from third parties in connection with the shares and/or assets of the Subsidiary, up to an aggregate of approximately NIS 40 million. For each receipt in excess of said aggregate amount, the Company will be entitled to a lower rate determined therefrom (also a low double-digit number).

   3. The Company will assign to the Buyer its right to increase its interests in the Subsidiary's share capital according to the investment agreement of September 2, 2013 signed between the Company, the Subsidiary and Acebright Holdings Limited (another shareholder in the Subsidiary). During the interim period until the completion of the License assignment process, the Buyer will bear certain of the payments in respect of the License and/or resulting therefrom (including payments for holding the patents under the License and including payments for a pending patent opposition proceeding involving the License). These amounts are non-recoverable. During the interim period, any revenues that are received by the Company from the commercialization of the technology will be delivered to the Subsidiary, less various fees and expenses payable in respect of the License and additional payments which the Company is entitled to receive.

      In August 2016, the Transfer Agreement was executed, and no consideration was paid to the Company at such time. The Transfer Agreement included a mechanism in which the Company is entitled to receive future compensation in the event of, and based on, the Subsidiary's future sale to a third party.

NOTE 8:- INVESTMENT IN ASSOCIATE AND INVESTMENTS IN INVESTEES (Cont.)

As a result of the loss of control, the Company recorded a capital gain in the amount of NIS 130,000.

NOTE 9:- TRADE PAYABLES

	December 31,		Convenience translation into USD (Note 1b) December 31,
	2015	2016	2016
	NIS in thousands		USD in thousands
Accounts payable	433	307	80
Accrued expenses	1,346	1,961	510
	1,779	2,268	590

NOTE 10:- OTHER ACCOUNTS PAYABLE

	December 31,		Convenience translation into USD (Note 1b) December 31,
	2015	2016	2016
	NIS in thousands		USD in thousands
Employees and payroll accruals	132	169	44
Accrued vacation	83	148	38
	215	317	82

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 11:- LIABILITIES FOR GOVERNMENT GRANTS

	December 31,		Convenience translation into USD (Note 1b) December 31,
	2015	2016	2016
	NIS in thousands		USD in thousands
Balance at January 1,	156	-	-
Amounts carried to financing in the statement of profit or loss	35	-	-
Change in liability to the INATI	(191)	-	-
Balance at December 31,	-	-	-
Presented in the consolidated statements of financial position in:			
Non-current liabilities	-	-	-

The Company received research and development participation grants from INATI and, in return, undertook to pay the INATI royalties at the rates prescribed by law and the Regulations for Encouragement of Industrial Research and Development (Rate of Royalties and Tools for their Implementation), 1996 and the procedures of the Industrial Research and Development Administration (at a rate of 3% in the first three years and 3.5% from the fourth year on sales of products resulting from the sponsored research and development as above), all until the full repayment of the grant. The grant is linked to the dollar and bears interest according to the INATI's terms. As of December 31, 2016, the Company does not anticipate to repay the grant in respect of the Anti-CD3 project and, accordingly, it eliminated the balance of the liability with a corresponding credit to other income.

Total grants received from the INATI through December 31, 2016 amounted to NIS 15.4 million. No royalties have been paid yet.

NOTE 12:- FINANCIAL INSTRUMENTS

a. Classification of financial assets and financial liabilities:

The financial assets and financial liabilities in the balance sheet are classified by groups of financial instruments pursuant to IAS 39:

	December 31,		Convenience translation into USD (Note 1b) December 31,
	2015	2016	2016
	NIS in thousands		USD in thousands
Financial assets:			
Cash and restricted cash	6,180	2,642	687
Financial liabilities:			
Financial liabilities carried at amortized cost	1,994	2,585	672

b. Financial risk factors:

The Company's activities expose it to various financial risks such as market risks (foreign currency risk and interest risk), credit risk and liquidity risk. The Company's comprehensive risk management plan focuses on activities that reduce to a minimum any possible adverse effects on the Company's financial performance.

Risk management is performed by management in accordance with the policies approved by the Company's board of directors (the "Board"). The Board establishes written principles for the overall risk management activities as well as specific policies with respect to certain exposures to risks such as exchange rate risk, credit risk and the investments of surplus funds.

1. Market risks:

Foreign currency risk:

The Company is exposed to exchange rate risk resulting from the exposure to different currencies, mainly the U.S. dollar. Exchange rate risk arises from recognized liabilities that are denominated in a foreign currency other than the functional currency.

2. Credit risks:

All cash and cash equivalents are held in three banks in Israel which are considered financially solid.

NOTE 12:- FINANCIAL INSTRUMENTS (Cont.)

3. Liquidity risk:

The Company monitors the risk of a shortage of funds on a regular basis and acts to raise funds to satisfy its liabilities.

The table below presents the maturity profile of the Company's financial liabilities based on contractual undiscounted payments (including interest payments):

December 31, 2016:

	Less than one year	Over one year	Total
	NIS in thousands		
Trade payables	2,268	-	2,268
Other accounts payable	317	-	317
	2,585	-	2,585

December 31, 2015:

	Less than one year	Over one year	Total
	NIS in thousands		
Trade payables	1,779	-	1,779
Other accounts payable	215	-	215
	1,994	-	1,994

The carrying amounts of cash, accounts receivable, trade payables, and other accounts payable approximate their fair value.

NOTE 13:- EMPLOYEE BENEFIT LIABILITIES

Employee benefits consist of short-term benefits and post-employment benefits.

Post-employment benefits:

According to the labor laws and the Israeli Severance Pay Law, 1963 (the "Severance Pay Law"), the Company is required to pay compensation to an employee upon dismissal or retirement or to make current contributions in defined contribution plans pursuant to section 14 to the Severance Pay Law, as specified below. The Company's liability is accounted for as a post-employment benefit. The computation of the Company's employee benefit liability is made in accordance with a valid employment contract based on the employee's salary and employment term which establish the entitlement to receive the compensation.

The post-employment benefits are normally financed by contributions classified as defined benefit plans or as defined contribution plans as detailed below.

Defined contribution plans:

Section 14 to the Severance Pay Law applies to a substantial part of the compensation payments, pursuant to which the fixed contributions paid by the Company into pension funds and/or policies of insurance companies release the Company from any additional liability to employees for whom said contributions were made. These contributions and contributions for compensation represent defined contribution plans.

	Year ended December 31,			Convenience translation into USD (Note 1b) December 31,
	2014	2015	2016	2016
	NIS in thousands			USD in thousands
Expenses in respect of defined contribution plans	114	96	120	31

NOTE 14:- TAXES ON INCOME

a. Tax rates applicable to the Company:

The Israeli corporate income tax rate was 25% in 2016 and 26.5% in 2015 and 2014.

In January 2016, the Law for Amending the Income Tax Ordinance (No. 216) (Reduction of Corporate Tax Rate), 2016 was approved, which includes a reduction of the corporate tax rate from 26.5% to 25%, effective from January 1, 2016.

In December 2016, the Israeli Parliament approved the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years), 2016 which reduces the corporate income tax rate to 24% (instead of 25%) effective from January 1, 2017 and to 23% effective from January 1, 2018.

The change in the tax rates had no effect on the financial statements in 2016.

b. Tax assessments:

The assessments of the Company are deemed final through the 2011 tax year.

c. Carryforward tax losses and other temporary differences:

The Company has carry forward tax losses totaling approximately NIS 86 million as of December 31, 2016.

No deferred tax asset relating to carry forward losses and to other temporary differences has been recognized because its utilization in the foreseeable future is not probable.

d. Theoretical tax:

The difference between the tax benefit calculated in respect of the pre-tax loss at the regular corporate tax rate applicable to the Company and the tax benefit (zero) recorded in the statement of profit or loss in all reporting periods mainly arises from losses for tax purposes for which no deferred taxes were recognized because their utilization in the foreseeable future is not probable.

NOTE 15:- CONTINGENT LIABILITIES, COMMITMENTS AND LIENS

a. Commitments - BBS technology:

In January 2014, the Company reported that it received a letter from Ramot at Tel-Aviv University Ltd. ("Ramot"), the Tel-Aviv University's technology transfer company, in which Ramot announced its intention to terminate the license and research agreement in connection with the BBS technology (the Alzheimer's drug). The Company's position was that Ramot's announcement was illegitimate and groundless. The parties negotiated the disputes between them in order to reach an agreed solution including in matters related to the INATI, and at the beginning of October 2014, reached an agreement on an outline according to which the Company will return the license to Ramot, including the exclusive license to use and commercialize the assets and knowhow gained at the Company during the license term ("the Company's assets and knowhow") and, in return, if the Company's assets and knowhow are being commercialized, the Company will receive royalties in the future (in the scope, percentages and conditions as determined) ("the Agreed Outline"). After the Agreed Outline became effective, the parties agreed that the license agreement will become null and void and that any monetary and/or other liability between the parties will become null and void including the Company's undertaking to bear the costs of registration and/or maintaining the patents effective from the cancellation date as above and thereafter such that Ramot will be responsible for such debts.

On August 18, 2016, the Department of Administrative Enforcement of The Israel Securities Authority ("ISA") filed an administrative letter of claims against the Company, the Company's Chairman, and certain former officers of the Company. The letter of claims alleged that the Company and the named respondents carried out five different violations of the Securities Law regarding the Company's reports in respect of the above license agreement. Following discussions the Company held with the ISA, the Company agreed to pay a monetary sanction of NIS 150,000 (see Note 22a.).

NOTE 15:- CONTINGENT LIABILITIES, COMMITMENTS AND LIENS (Cont.)

b. Commitment - New Ramot Agreement:

In February 2016, the Company entered into an exclusive, irrevocable, worldwide research and license agreement with Ramot at Tel Aviv University Ltd. ("Ramot") for a patent application relating to methods for treatment of cognitive decline with low doses of tetrahydrocannabinol. Pursuant to the agreement, the Company is obligated to pay patent filing and prosecution expenses, including past expenses, and to fund further research in an amount of approximately NIS 237,630. Furthermore, the Company is obligated to pay fees (aggregating approximately $3.5 million) upon the occurrence of certain milestones, including achieving the completion of a Phase II clinical trial, pivotal clinical trial, filing a new drug application with the U.S. Food and Drug Administration, the receipt of regulatory approvals and the achievement of worldwide sales which exceed certain thresholds. Pursuant to the agreement, the Company is obligated to pay royalties at a low single digit percentage rate upon commercialization of a product based on licensed asset, and a percentage rate in the low twenties pursuant to a sublicense of the licensed assets. Pursuant to the agreement, the Company undertook to conduct technology research and the Company may terminate such obligation with no further obligation to fund it should the principal investigator cease to supervise the research and Ramot will be unable to locate an alternative scientist acceptable to the Company. The exclusivity under the license agreement expires and the agreement terminates upon expiration of all of the Company payment obligations under the agreement, after which Ramot shall be entitled to freely use, sell, and otherwise transfer the technology under the license and grant further licenses without accounting to the Company. The patent expiration date of any patent maturing from this application would likely be 2035. The Company expects the exclusivity period to end upon the earlier of the termination of the license agreement or the patent expiration date.

c. Commitment - Dekel Pharmaceuticals Ltd.:

In May 2015, the Company entered into an exclusive, irrevocable, worldwide license agreement with Dekel Pharmaceuticals Ltd. (a private company controlled by the Company's chairman, Mr. Asher Shmulewitz) ("Dekel") for certain technology and one granted U.S. patent related to compositions and methods for treating inflammatory disorders. The agreement became effective in August 2015. The Company then granted Dekel an option to purchase 3,876,000 of its Ordinary Shares at an exercise price of NIS 0.5 per share, exercisable for 90 days. The option was fully exercised as of November 2015. The Company also granted Dekel an additional option to purchase 11,926,154 of its Ordinary Shares at an exercise price of NIS 0.65 per share, exercisable for 12 months. To date, 65% of the second option (representing options to purchase 7,760,256 Ordinary Shares) has been exercised, for aggregate consideration of NIS 5 million, and the remainder of the option has expired. Pursuant to the license agreement, in May 2016 the Company issued Dekel 200,000 of its Ordinary Shares at a price per share of NIS 0.5 on account of future royalty payments. The Company also is obligated to pay Dekel fees based on specific milestones and royalties upon commercialization. The milestone payments include: (i) $25,000 upon the successful completion of preclinical trials (which milestone was met in November 2016, this payment was paid in cash in March 2017); (ii) $75,000 upon the successful completion of a Phase I/IIa trial; and (iii) $75,000 upon the earlier of generating net revenues of at least $200,000 from the commercialization of the technology or the approval of the FDA / the European Medicines Agency, or the EMA, of a drug based on the licensed assets. In each case, and subject to the Company's discretion, the respective milestone payments are payable in cash or equity based on a price per Ordinary Share of NIS 0.5. The royalty payments are 8% for commercialization and 35% pursuant to a sub-license of the licensed assets. The patent expiration dates of any patents maturing from this application would likely be 2029.

NOTE 15:- CONTINGENT LIABILITIES, COMMITMENTS AND LIENS (Cont.)

d. Operating lease commitments:

The Company signed an agreement on June 30, 2016 for one year, with a third party for the lease of offices in Azrieli towers, Tel Aviv, with area of 100 square meters for a monthly rental of approximately NIS 18,300 (approximately USD 5,000), linked to the Israeli CPI.

Future minimum lease payments under the existing lease contracts as of December 31, 2016 total NIS 112,000 (approximately USD 30,000).

e. Liens:

To secure the Company's obligation for the lease of the offices, the Company provided a bank guarantee of NIS 44,000 (approximately USD 11,000) in favor of the lessor. To secure the bank guarantee, the Company pledged such amount in a bank account.

f. On June 7, 2016 (the "Effective Date"), the Company entered into a binding term sheet-agreement with Belvit Pharma LLC ("Belvit") for certain intellectual property rights, including a provisional patent application covering the method and formulation for the sublingual administration of THC with enhanced bioavailability. The Company initially intends to exploit this technology with respect to Mild Cognitive Impairments ("MCI"). Pursuant to the term sheet, the Company will receive an exclusive, irrevocable, worldwide, license to develop, manufacture, and commercialize a drug based on a low-dose of THC and a right of first negotiation with respect to normal-dose technology within the twenty four months of the Effective Date of the term sheet. The Company agreed to pay all costs and expenses related to the development of the technology, and to conduct, at the Company expense, a Pharmacokinetics ("PK")/bioavailability study which the Company intends to conduct in the second quarter of 2017. The Company shall further pay Belvit a low single-digit royalty rate upon commercialization of a product based on the licensed assets. Furthermore, Belvit shall have the right to use the study results. Belvit shall pay the Company a low single-digit royalty rate from any income from other uses of the technology. While the Company will be responsible for the development of the technology, Belvit will be responsible for the formulation development. The term sheet further includes the development stages and estimated development costs. Filing and patent prosecution will be borne by both parties. Entry into a definitive license agreement is subject to the Company's successful completion of the abovementioned PK/bioavailability study. The patent expiration date of any patent maturing from this application would likely be 2037.

NOTE 16:- EQUITY

a. Composition of share capital:

	December 31, 2015		December 31, 2016	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
	Number of shares			
Ordinary shares of NIS 0.1 par value each	100,000,000	35,399,152	300,000,000	40,998,471

Capital consolidation:

On January 1, 2014, the shareholders approved to consolidate the authorized share capital and the issued and outstanding share capital such that 10 Ordinary shares of NIS 0.01 par value each in the authorized share capital and the issued and outstanding share capital of the Company will be consolidated into one Ordinary share of the Company of NIS 0.1 par value. The number of the outstanding share options was adjusted accordingly.

On December 12, 2016, the general meeting of the Company's shareholders approved an increase of the Company's authorized share capital to 300,000,000 ordinary shares.

b. Changes in share capital:

Issued and outstanding share capital:

	Number of shares	NIS par value
Balance at January 1, 2016	35,399,152	3,539,915
Issuance of share capital	200,000	20,000
Exercise of share options	5,399,319	539,932
Balance at December 31, 2016	40,998,471	4,099,847

c. Rights attached to shares:

Voting rights at the shareholders meeting, right to dividends, rights upon liquidation of the Company and right to nominate the directors in the Company.

NOTE 16:- EQUITY (Cont.)

d. Capital management in the Company:

The Company's capital management objectives are to preserve the Company's ability to ensure business continuity thereby creating a return for the shareholders, investors and other interested parties.

The Company is not under any minimal equity requirements nor is it required to attain a certain level of capital return.

e. Issuance of shares and warrants:

1. On May 8, 2014, the Company raised gross proceeds of approximately NIS 2.9 million (at a price per share of NIS 0.95) from the issuance of 3,009,400 Ordinary shares, 3,009,400 warrants (series 3) and 3,009,400 warrants (series 4) of the Company pursuant to a shelf offering registration that the Company published on May 8, 2014 and a shelf prospectus of August 8, 2012. On May 15, 2014, the Company issued 406,269 publicly traded warrants (series 4) to Clal Finance Underwriting Ltd. as part of the issuance costs.

2. On November 19, 2014, the Company entered into a private placement agreement according to which 1,300,000 Ordinary shares of NIS 0.1 par value each, 1,300,000 fully vested warrants and 1,300,000 conditional warrants were issued. The fully vested warrants are exercisable at a 1 to 1 ratio at an exercise price of NIS 0.5, per share from the date of issuance over a period of three months. The conditional warrants are exercisable at a 1 to 1 ratio subject to the exercise of the fully vested warrants. The fair value of the warrants was estimated at approximately NIS 3,000.
The total gross proceeds from the offered securities were NIS 650,000 (net proceeds - NIS 631,000).

3. On February 19, 2015, the Company raised NIS 250,000 in consideration for 500,000 Ordinary shares of NIS 0.1 par value each, 500,000 fully vested warrants and 500,000 conditional warrants. The immediate warrants may be exercised into shares on a 1:1 basis in consideration of the exercise price of NIS 0.65 from the date of issuance for a period of 45 days. The contingent warrants may be exercised into shares on a 1:1 basis together with and subject to the exercise of the immediate warrants in consideration of the exercise price of NIS 1.10 for a period of 24 months. Also, 40,000 warrants were granted to the Company's consultant as the investment broker. The fair value of the warrants granted to the consultant was estimated at NIS 2,000.
On April 30, 2015, the immediate and conditional warrants expired without being exercised.

4. On April 29, 2015, the Company raised NIS 2.2 million from Jesselson Investments Ltd. in a private placement. In consideration for these funds, the Company issued a total of 4,400,000 Ordinary shares of NIS 0.1 par value each at the price of NIS 0.5 per share. As a result of the issuance, Jesselson Investments holds about 18.87% of the Company's Ordinary shares.

NOTE 16:- EQUITY (Cont.)

5. On November 25, 2015, the Company completed a round of financing under which it signed investment agreements with several new and existing private investors to make private placements in consideration of the issuance of 3,159,025 Ordinary shares of the Company. The investors invested an aggregate amount of approximately NIS 3.3 million in consideration of Ordinary shares of the Company at the price per share of NIS 1.05, which constituted about 11.4% of the Company's issued and outstanding share capital immediately after the completion of the investment (approximately 6.7% on a fully diluted basis).

   Simultaneously, with the closing of the private placement agreements, Dekel informed the Company that it sold (or that it is acting to sell) to the other investors in this private placement (independently) Initial Options and Additional Options that Dekel holds by virtue of the License Agreement that will constitute about an additional 12.4% of the Company's issued and outstanding share capital (about 9.1% on a fully diluted basis). Assuming the investors exercise their options and Dekel exercises a portion of its options, the effect will be an additional equity investment of approximately NIS 2.3 million. The completion of the private placements was subject to the fulfillment of several conditions which were met within 45 days of the closing of the round of financing, as stated above, including the receipt of necessary regulatory approvals. During October 2015, the investors exercised the options purchased from Dekel. The total proceeds from the exercise of the options were approximately NIS 1.5 million.

f. Share options and warrants:

1. On February 1, 2015, the Company's warrants (series 2) expired.

2. On May 10, 2015, 3,415,669 warrants (series 4) of the Company expired, 1,850,000 warrants which had been issued in December 2013 expired and 1,000,000 immediate warrants expired.

3. On June 9 and 15, 2015, 1,300,000 warrants, which had been granted under a private placement dated November 19, 2014, were exercised into Ordinary shares of NIS 0.1 par value each at the exercise price of NIS 0.5 per share. The total proceeds from the exercise of the warrants were NIS 650,000.

4. Between October 18 and November 18, 2015, the remaining immediate share options of Dekel and some of the contingent share options were exercised (a total of 6,245,270 share options). The total proceeds from the exercise of the share options were approximately NIS 2 million.

5. On October 20, 2015, 310,000 share options were exercised into Ordinary shares of NIS 0.1 par value each at the exercise price of NIS 0.65 per share. The total proceeds from the exercise of the share options were approximately NIS 201,000.

NOTE 16:- EQUITY (Cont.)

6. On November 1, 2015, 300 share options which had been granted to the Company's employees in 2009 expired.

7. On December 6 and 13, 2015, 990,000 share options were exercised into Ordinary shares of NIS 0.1 par value each at the exercise price of NIS 0.65 per share. The total proceeds from the exercise of the share options were NIS 644,000.

8. On December 23, 2015, 40,000 share options were exercised into Ordinary shares of NIS 0.1 par value each at the exercise price of NIS 0.5 per share. The total proceeds from the exercise of the share options were NIS 20,000.

9. On December 31, 2015, 33,333 share options were exercised into Ordinary shares of NIS 0.1 par value each at the exercise price of NIS 0.5 per share. The total proceeds from the exercise of the share options were NIS 17,000.

10. Further to the matter discussed in Note 15c, on May 16, 2016 after obtaining the Tel Aviv Stock Exchange ("TASE") approval and as part of the conditions of the license agreement with Dekel, which became effective on August 19, 2015, and in order to fulfill the contingent liability of the Company to Dekel under the License Agreement, the Company issued to Dekel 200,000 Ordinary shares associated with the advance payment according to the License Agreement.

11. Further to the description in Note 15c, on August 18 and 19, 2016, the Company received exercise notices for the exercise of 5,390,986 share options which were held by Dekel, under the license agreement signed with Dekel, to purchase 5,390,986 Ordinary shares par value NIS 0.1 per share, out of which Dekel exercised 993,846 share options, while the remaining were exercised by third parties, to which, to the best of the Company's knowledge, Dekel sold its share options. The consideration from the exercise of the share options by Dekel and by third parties was NIS 3.5 million.

    It is clarified, that the remaining share options held by Dekel expired on August 20, 2016, according to their original terms.

12. In August, 2016, 8,333 share options were exercised into Ordinary shares of NIS 0.1 par value each at the exercise price of NIS 0.5 per share. The total proceeds from the exercise of the share options were NIS 4,100.

NOTE 17:- SHARE-BASED PAYMENT TRANSACTIONS

a. The expense recognized in the financial statements:

The expense recognized in the Company's financial statements for services received from employees and other service providers is shown in the following table:

	Year ended December 31,			Convenience translation into USD (Note 1b) December 31,
	2014	2015	2016	2016
	NIS in thousands			USD in thousands
Expense arising from equity-settled share-based payment transactions	144	532	1,156	300

The share-based payment transactions that the Company granted to its employees and consultants are described below. During 2015, the Company's Board adopted the 2015 Share Option Plan (the "Plan"). Under the Plan, the Company may grant its employees and other service providers share options of the Company. The Board reserved 5,000,000 shares which may be granted under the Plan, out of which 634,721 are still available for grant.

Also, during 2015, an expense of NIS 3.9 million was recognized in respect of the License Agreement with Dekel under other expenses. See additional information in Note 15c.

b. Movement during the year:

The following table lists the number of share options, the weighted average exercise prices of share options and changes in employee and consultants share options during the current and previous year:

	2016		2015	
	Number of share options	Weighted average exercise price	Number of share options	Weighted average exercise price
		NIS		NIS
Share options outstanding at beginning of year	1,337,153	4.00	1,210,443	4.39
Share options granted during the year	3,390,000	0.94	1,340,000	0.59
Share options exercised during the year	(8,333)	0.50	(33,333)	0.5
Share options forfeited or expired during the year	(353,538)	13.58	(1,179,957)	0.63
Share options outstanding at end of year	4,365,279	0.85	1,337,153	4.00
Share options exercisable at end of year	1,664,933	0.83	623,890	3.52

d. The weighted average remaining contractual life of the share options outstanding was 8.74 years and 7.89 years as of December 31, 2016 and 2015, respectively.

e. The weighted average fair value of the share options granted in 2016 was NIS 0.66 (2015 - NIS 0.23).

f. The range of exercise prices of share options outstanding at the end of the year was NIS 0.1-NIS 12 as of December 31, 2016 and NIS 0.1-NIS 44.58 as of December 31, 2015.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 18:- ADDITIONAL INFORMATION TO THE ITEMS OF PROFIT OR LOSS

	Year ended December 31,			Convenience translation into USD (Note 1b) December 31,
	2014	2015	2016	2016
	NIS in thousands			USD in thousands
a. Research and development expenses, net:				
Wages and related expenses	506	183	748	194
Materials	25	31	70	18
Share-based payment	8	6	383	100
Consultants and subcontractors	582	441	1,195	311
Depreciation	49	6	7	2
Patents	284	243	293	76
Other expenses	375	21	146	38
Grants from the INATI	(29)	-	-	-
	1,800	931	2,842	739
b. General and administrative expenses:				
Wages, salaries and related expenses	1,635	1,540	1,531	398
Share-based payment	136	526	773	201
Professional services including business development	2,508	1,907	1,841	479
Insurance and directors' fees	244	214	245	64
Depreciation	100	6	6	2
Office maintenance and rent and other	615	1,104	474	123
	5,238	5,297	4,870	1,267
c. Finance (income) expenses:				
Finance income:				
Interest income on bank deposits	(5)	-	(3)	(1)
Change in fair value of warrants	(396)	-	-	-
Exchange rate differences	-	(20)	-	-
	(401)	(20)	(3)	(1)
Finance expenses:				
Finance expenses from interest and commissions	13	-	5	1
Finance expenses from liability to the INATI	56	35	-	-
Exchange rate differences	8	-	24	6
Impairment of financial instrument	350	-	-	-
	427	35	29	7

NOTE 18:- ADDITIONAL INFORMATION TO THE ITEMS OF PROFIT OR LOSS (Cont.)

The change in fair value of warrants (accounted for as a liability in 2013) was recorded due to the expiration, during September 2014, of warrants granted on December 25, 2013, as part of the investment agreement with Acebright Holding Limited. The fair value of the warrant was originally calculated using the Black-Scholes model.

	Year ended December 31,			Convenience translation into USD (Note 1b) December 31,
	2014	2015	2016	2016
	NIS in thousands			USD in thousands
d.Other income (expenses):				
Share-based payment (see Note 15c)	-	(3,906)	(100)	(26)
Change in liability to the INATI (see Note 11)	-	(191)	-	-
Capital gain from sale of subsidiary (see Note 8b.)	-	-	130	34
Capital loss from sale of equipment	115	19	-	-
	115	3,734	30	7

NOTE 19:- LOSS PER SHARE

a. Details of the number of shares and loss used in the computation of loss per share:

	Year ended December 31,						Convenience translation into USD (Note 1b) year ended December 31,	
	2014		2015		2016		2016	
	Weighted number of shares	Loss	Weighted number of shares	Loss	Weighted number of shares	Loss	Weighted number of shares	Loss
	In thousands	NIS in thousands	In thousands	NIS in thousands	In thousands	NIS in thousands	In thousands	USD in thousands
Amounts used in the computation of basic and diluted loss per share	16,072	(7,292)	23,853	(10,174)	37,458	(7,708)	37,458	(2,005)

b. The computation of diluted loss per share did not include the following convertible securities since their inclusion would decrease the loss per share (anti-dilutive effect):

1. Share options to employees, officers and consultants.
2. Marketable warrants (series 1).
3. Non-marketable warrants (series 4).
4. Non-marketable warrants to investor.

NOTE 20:- OPERATING SEGMENTS

The Company applies the principles of IFRS 8 regarding operating segments. The segment reporting is based on internal management reports of the Company's management which are regularly reviewed by the chief operating decision maker to make decisions about resources to be allocated and assess performance ("the management approach"). According to the principles of IFRS 8, management determined that the Company has one reportable segment: development of drugs based on cannabinoid molecules to be approved by an official regulatory authority.

NOTE 21:- TRANSACTIONS AND BALANCES WITH RELATED PARTIES

a. Balances with related parties:

December 31, 2016:

	December 31, 2016			Convenience translation into USD (Note 1b) December 31, 2016
	Key management personnel	Other related parties	Key management personnel	Other related parties
	NIS in thousands		USD in thousands	
Other accounts payable	187	344	49	89

December 31, 2015:

	Key management personnel	Other related parties
	NIS in thousands	
Other accounts payable	21	308

b. Transactions with related parties (not including amounts described in Note 21c):

	Year Ended December 31,			Convenience translation into USD (Note 1b) December 31,
	2014	2015	2016	2016
	NIS in thousands			USD in thousands
General and administrative (see Note 22a)	-	250	(100)	(26)
Other expenses (see Note 15c)	-	3,906	196	51

NOTE 21:- TRANSACTIONS AND BALANCES WITH RELATED PARTIES (Cont.)

c. Benefits to key management personnel (including directors):

	Year ended December 31,			Convenience translation into USD (Note 1b) December 31,
	2014	2015	2016	2016
	NIS in thousands			USD in thousands
Short-term benefits	2,165	2,022	2,275	592
Share-based payment (see Note 17)	128	501	893	232
	2,293	2,523	3,168	824

d. Material agreements signed with related parties:

1. On January 8, 2014, the Company's Board appointed Mr. Asher Shmulewitz as active Chairman of the Company's Board.

2. On February 16, 2014, the Company and the CEO, Mr. Ari Aminetzah, reached understandings regarding the termination of his employment as the Company's CEO at the end of March 2014. During April-May 2014 Mr. Aminetzah rendered business development services to the Company.

3. On March 24, 2014, the shareholders approved payment of compensation to the Company's Chairman: (1) for September-December 2013 - monthly payment of USD 10,000 (2) from January 8, 2014 - monthly payment of NIS 50,000 and (3) issuance of 423,037 unlisted share options of the Company at exercise price of not less than the share market price in the 30 days before the issuance plus 10%. The share options vest equally on a quarterly basis over three years. Also, the Company's remuneration policy was approved by the shareholders. The share options were issued on April 1, 2014.

4. As for a license agreement with a company owned by the Company's chairman, Mr. Asher Shmulewitz, see Note 15c.

5. On April 2, 2015, the Company reported that Jonathan Berger, was appointed as the Company's CFO and on that date the Company reported that the Company's former CFO, Uri Ben-Or, and the former comptroller, Dov Weinberg, are leaving the Company.

6. On April 5, 2015, the Company reported that the Company's CEO, Mr. Jan Turek, is leaving the Company effective May 31, 2015. On May 21, 2015, the Company reported that Jonathan Berger, was appointed as the Company's CEO in addition to his role as the Company's CFO. On August 31, 2015, the Company reported that Jonathan Berger, terminated his role as the Company's CEO and CFO effective October 1, 2015.

NOTE 21:- TRANSACTIONS AND BALANCES WITH RELATED PARTIES (Cont.)

7. On November 19, 2015, the Company reported that Guy Goldin, was appointed as the Company's CFO effective November 1, 2015.

8. On November 25, 2015, the Company reported that Dr. Elran Haber was appointed as the Company's CEO. On February 14, 2016, the shareholders approved his employment contract effective November 1, 2015. According to the terms of the contract, the CEO is entitled to a monthly salary of NIS 45,000, to an annual bonus of up to 6 monthly salaries subject to a target plan set by the Board and to receive 700,000 share options at the exercise price of NIS 0.995 per share. The share options vest on a quarterly basis over three years from the date of issuance. In the event of an IPO any unvested share options granted will vest immediately (see Note 22d). Total expenses recorded in respect of these share options were approximately NIS 309,000 and approximately NIS 52,000 during the years 2016 and 2015, respectively.

NOTE 22:- EVENTS AFTER THE REPORTING DATE

a. Further to the matter discussed in Note 15a, in April 2017 the Company settled the administrative inquiry and admitted to the following breaches: (i) failure to submit an immediate report about a material event (the license agreement termination) in a timely and lawful manner; (ii) inclusion of a misleading detail in an immediate report; and (iii) misleading the ISA in connection with such actions. The Company was required to pay a monetary sanction of NIS 150,000 (approximately $40,000) (and potentially an additional equal sum if the Company is found to have committed the same breaches in the next 24 months). In addition, the Company's Chairman also agreed to admit to having made the abovementioned breaches and to pay a monetary sanction of NIS 150,000 (approximately $40,000). He will be also subject to a one year probationary condition, whereby if he is found to commit a similar violation, he will be prevented from serving as an officer or director of a public company.

   Furthermore, pursuant to the investment agreement between the Company and Jesselson Investments Ltd. (see Note 16e. (4)), if monetary sanctions by the ISA higher than $20,000 are imposed on the Company, it will be required to compensate Jesselson Investments Ltd. by way of cash payment equal to the amount of the monetary sanctions or by issuing Jesselson Investments Ltd. additional shares in an amount equal to the amount of the monetary sanctions divided by NIS 0.5.

   A provision in the sum of NIS 300,000 was recorded in the financial statements as of December 31, 2016.

NOTE 22:- EVENTS AFTER THE REPORTING DATE (Cont.)

b. In March 2017 the Company entered into an exclusive, worldwide, sublicensable, royalty-bearing license with Yissum Research Development Company of the Hebrew University of Jerusalem Ltd ("Yissum") for the grant of a license to an issued U.S. patent, including foreign counterparts, that covers nasal delivery of cannabinoids, excluding any use or exploitation of cannabinoids in conjunction or combination with Tramadol (but including exploitation of cannabinoids in conjunction or combination with other substances), all subject to a development plan to be approved by Yissum for the purpose of research, developing, and commercializing. Pursuant to the agreement, Yissum will grant the Company an exclusive, worldwide, sublicensable, royalty-bearing license to the patents and the Company will pay Yissum fees based on specific milestones (aggregating approximately $1 million) and medial single-digit royalties upon the commercialization of a product based on the licensed assets. Royalty rates will decrease to a low single-digit percentage upon commercialization of a competitive product or if the Company is required to pay a third party in order to sell the technology based product. The Company will further undertake to pay all patent filing and prosecution expenses, including past expenses. The Company will also compensate and indemnify Yissum from and against any damage, loss, cost and expenses incurred by the Company or by it subordinates by reason of any acts or omissions, or which derive from the exploitation or use of the technology or related product. Pursuant to the license agreement, the exclusivity under the license agreement expires if not terminated earlier, on a country-by-country, product-by-product basis, upon the later of: (i) the date of expiration in such country of the last to expire licensed patent included in the licensed technology; (ii) the date of expiration of any exclusivity on the product granted by a regulatory or government body in such country; or (iii) the end of a period of fifteen (15) years from the date of the first commercial sale in such country. The patent expiration dates for the patents covered by the license agreement are from 2026-2028.

c. On March 6, 2017, as part of a private placement, the Company issued to a private investor (the Investor) 5,357,143 Ordinary Shares, at a price per share of NIS 0.70 (approximately USD 0.19). Pursuant to the agreement, in the event that the Company raises additional funds by means of private placements (excluding public offerings) upon less favorable terms relating to the price per share, then the Company would be required to issue to the Investor, for no additional consideration, such number of Ordinary Shares reflecting the difference between the new price per share and the price per share actually paid by the Investor. In addition, in the event that the Company raises additional funds by means of a public offering of its Ordinary Shares of American Depository Shares ("ADSs") upon less favorable terms relating to the price per share, then immediately following the closing of such public offering, the Company would be required to pay the Investor an amount, calculated as the number of his purchased shares (5,357,143 Ordinary Shares) multiplied by the difference between NIS 0.70 and the future public offering price per share. Pursuant to the Company's sole discretion, the Company may choose to pay this sum in cash and/or in Ordinary Shares (at a price per share of such public offering). In addition, the Investor is entitled to preemptive rights to participate in its future private placements upon the same terms offered to future investors, on a pro-rata basis to his holdings. Since the Company has issued ADSs in the IPO which took place in March 2017 (see Note 22d.) at a public offering price of USD 6.00 per ADS, which is less than USD 7.71 per ADS (approximately USD 0.19 per Ordinary Share), the Company issued the Investor an additional 1,529,910 Ordinary Shares.

NOTE 22:- EVENTS AFTER THE REPORTING DATE (Cont.)

d. On March 27, 2017, the Company announced the closing of its initial public offering in the United States. The offering included 2,000,000 ADSs. Each ADS, representing 40 Ordinary shares of the Company, was issued at a price of USD 6.00. The gross proceeds from this offering was USD 12 million, prior to deducting underwriting discounts, commissions and other offering expenses of approximately USD 1.7 million. The Company granted the underwriters a 45-day option to purchase up to an additional 300,000 ADSs to cover over-allotments ("Green Shoe"), if any. The underwriters decided to exercise their Green Shoe option and invested another USD 1.8 million in the Company, prior to deducting underwriting discounts of approximately USD 0.1 million.
Further to the description in Note 21d (9), and following the completion of the Company's IPO, the unvested share options granted to the Company's CEO vested.

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