UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 20-F

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

OR

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

For the fiscal year ended December 31, 2018

OR

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

OR

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

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
(Jurisdiction of incorporation or organization)

4 Ariel Sharon Street
HaShahar Tower, 16th Floor
Givatayim 5320047, Israel
(Address of principal executive offices)

Ascher Shmulewitz, M.D, Ph.D.
Chairman of the Board and Interim Chief Executive Officer
Tel: +972-3-6167055
4 Ariel Sharon Street
HaShahar Tower, 16th Floor
Givatayim 5320047, 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	*Trading Symbol(s)*	*Name of each exchange on which registered*
American Depository Shares each representing 40 Ordinary Shares, par value NIS 0.1 per share (1)	**TRPX**	**Nasdaq Capital Market**
Ordinary Shares, par value NIS 0.1 per share (2)		

(1) Evidenced by American Depositary Receipts.

(2) Not for trading, but only in connection with the listing of the American Depositary Shares.

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.

140,252,374 Ordinary Shares, par value NIS 0.1 per share as of December 31, 2018

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 every Interactive Data File required to be submitted 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. ☐

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

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

U.S. GAAP ☐

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

Other ☐

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

☐ 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 cannabinoids pharmaceuticals. We are focusing on a drug development program that we call *Joint Pharma*, which targets the treatment of the central nervous system and related indications with our product candidate THX-110. As part of our Joint Pharma program, we are also developing THX-150 and THX-160, which target multi drug resistant bacteria and pain, respectively.

THX-110 is a combination drug candidate based on two components: (1) dronabinol, the active ingredient in the U.S. Food and Drug Administration, or FDA, approved synthetic analog of Δ9-tetrahydrocannabinol, or THC, which is the major cannabinoid molecule in the cannabis plant, and (2) pulseless electrical activity, or PEA, which is an endogenous fatty acid amide that belongs to the class of nuclear factor agonists, which are molecules that regulate the expression of genes. We believe that the combination of THC and PEA may induce a reaction known as the "entourage effect," which has strong potential to treat Tourette syndrome, obstructive sleep apnea and pain. THX-150 is a drug candidate intended for the treatment of infectious diseases. It consists of dronabinol (synthetic Δ9-tetrahydracannabinol) and/or PEA and selected antibacterial agent and possesses antimicrobial synergy potential. THX-160 is a novel pharmaceutical CB2 receptor agonist for the treatment of pain.

We were incorporated under the laws of the State of Israel on August 23, 2004. 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." From December 26, 2005 to August 9, 2018, our Ordinary Shares were traded on the Tel Aviv Stock Exchange.

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 derived from our financial statements or otherwise indicated, U.S. dollar translations of NIS amounts presented in this Annual Report are translated using a rate of NIS 3.748 to USD 1.00, the last exchange rate published by the Bank of Israel by December 31, 2018.

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 Profit and Loss" for the years ended December 31, 2018 and 2017 and the selected data under the caption "Consolidated Statements of Financial Position" as of December 31, 2018 and 2017 from the audited consolidated financial statements included elsewhere in this annual report, which have been prepared in accordance with IFRS. The selected data under the caption "Consolidated Statements of Profit and Loss" for the years ended December 31, 2016 and 2015 and the selected data under the caption "Consolidated Statements of Financial Position" as of December 31, 2016 and 2015 have been derived from audited financial statements not included in this annual report. 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. All figures presented are in U.S. dollars. On December 31, 2017, we changed the financial statements presentation currency from NIS and convenient translation to U.S. dollars to presentation currency of U.S. dollars. As a result, the December 31, 2015, 2016 and 2017 Consolidated Statements of Financial Position and the 2015, 2016 and 2017 Consolidated Statements of Profit and Loss were represented in U.S. dollars. We omitted the presentation of selected financial data for our 2014 fiscal year because such financial data cannot be presented in U.S. dollars without unreasonable effort or expense. Effective October 1, 2018, we changed our functional currency from NIS to U.S. dollars. The change in functional currency is accounted from that date.

	December 31,			
	2018(*)	**2017(*)**	**2016(*)**	**2015(*)**
Consolidated Statements of Profit and Loss	**(in thousands of U.S. dollars)**			
Research and development expenses, net	2,710	1,943	740	240
General and administrative expenses	6.579	3,810	1,268	1,363
Other expense (income), net	425	1	(8)	961
Operating loss	9,714	5,754	2,000	2,564
Finance expenses (income), net	(705)	490	7	4
Tax benefit	(60)	-	-	-
Net loss	8,949	6,244	2,007	2,617
Basic and diluted net loss per Ordinary Share attributable to equity holders of the Company	0.06	0.05	0.05	0.11
Number of Ordinary Shares used in computing loss per Ordinary Share- thousands	140,252,374	139,885,524	37,457,538	23,853,196

(*) Presented according to the change in our functional currency from NIS to U.S. dollars, effective October 1, 2018. The change in functional currency is accounted for that date. Accordingly, comparative profit or loss figures have been translated into U.S. dollars using average exchange rates for the reporting periods.

	December 31,			
	2018(*)	**2017(*)**	**2016(*)**	**2015(*)**
Consolidated Statements of Financial Position	**(in thousands of U.S. dollars)**			
Cash and cash equivalents	1,485	9,195	676	1,573
Total assets	4,560	9,566	1,245	1,666
Total liabilities	4,483	672	1,177	511
Accumulated loss	46,912	38,389	32,145	30,152
Total equity	77	8,389	573	1,155

(*) Presented according to the change in our functional currency from NIS to U.S. dollars, effective October 1, 2018. The change in functional currency is accounted from that date. Accordingly, comparative profit or loss figures and financial position have been translated into U.S. dollars using average exchange rates for the reporting periods.

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 developing a portfolio of approved drugs based on cannabinoid molecules since August 2015.

We have historically incurred substantial net losses; including net losses of approximately $8.9 million for the year ended December 31, 2018 and net losses of approximately $6.2 million in 2017. As of December 31, 2018 and December 31, 2017, we had an accumulated deficit of approximately $46.9 million and approximately $38.4 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 have invested a significant amount in Therapix Healthcare Resources Inc., or THR, in which we hold approximately 80% of the issued and outstanding share capital, during 2018 and 2019, which has commenced liquidation of its assets, and which could adversely impact our reputation or divert management's attention in the event of any material litigation or issues that prolong the liquidation and dissolution process.

In addition, we have invested an aggregate of approximately $2.31 million in THR during 2018 and 2019, through convertible loans. Due in part to significant losses incurred by THR, as well as its failure to maintain required licenses to operate its facilities, THR has commenced liquidation of its assets. The liquidation of THR's remaining assets, or potential claims that may arise from the liquidation and dissolution of THR may adversely affect our reputation or divert management's attention in the event of any material litigation or in the event that the liquidation process is prolonged. At this time, neither we nor THR are able to estimate reliably the timing and results of the proposed liquidation or of any consequences that may occur as a result thereof.

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, 2018, our cash and cash equivalents were approximately $1.48 million, a negative working capital of approximately $1.97 million and an accumulated deficit of approximately $46.85 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 October 31, 2019. 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.

The report of our independent registered public accounting firm contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

The report of our independent registered public accounting firm on our audited consolidated financial statements for the period ended December 31, 2018, contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments to the carrying amounts and classifications of assets and liabilities that might result from the outcome of the uncertainty regarding our ability to continue as a going concern. This going concern opinion could materially limit our ability to raise additional funds through the issuance of equity or debt securities or otherwise. Further reports on our consolidated financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through debt or equity financing. 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 products. This may raise substantial doubts about our ability to continue as a going concern.

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 New Drug Application, or 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 in 2011-2012, we estimate that approximately 138,000 children suffer from Tourette syndrome 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 Federal Food, Drug, and Cosmetic Act of 1938, as amended, or 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). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our potential future NDAs for up to 30 months depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway for our product candidates, there is no guarantee this would ultimately lead to faster product development or earlier approval. Moreover, even if these product candidates are approved under the Section 505(b)(2) pathway, as the case may be, the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products. 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-110 for the treatment of Tourette syndrome. In a letter dated September 29, 2016, the FDA informed us that our request could not be granted at such time, and is being held in abeyance until and subject to us providing additional information pertaining to the overall prevalence of Tourette syndrome in both children and adults, and further clinical data to support our scientific rationale for our request for orphan drug designation within 12 months. In September 2017, we responded to such FDA letter within the designated time frame, and provided the FDA with our articulated and reasoned responses including documentation and clinical data that supports it. On December 26, 2017, we received the FDA's response to our response. The FDA accepted that there is adequate scientific rationale for the treatment of Tourette syndrome with THX-110 mainly through the preliminary results of ongoing clinical trials, suggesting that THX-110 may provide benefit in treating Tourette syndrome. However, the FDA stated that it was unable to grant our request and indicated that we did not provide adequate prevalence estimates, and any evidence to support our statement that only moderate to severe Tourette's patients would require pharmacological treatment. We further responded in January 2018 by providing the requested information. We are currently waiting for the FDA's response. There is no assurance that we will successfully obtain orphan drug designation for Tourette syndrome, 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. (Target Health, Inc., FGK Clinical Research GmbH, or FGK, and others). 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, and 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, or GW, 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. In addition, GW develops a cannabidivarin, or CBDV, based therapy for autism spectrum disorders and therapy for neonatal hypoxic-ischemic encephalopathy, glioblastoma and schizophrenia. 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 and Prader-Willi syndrome. Zynerba Pharmaceuticals, Inc., or Zynerba, is developing a transdermal formulation of cannabidiol for Fragile X and certain refractory epilepsies. In addition, Zynerba is currently developing a transdermal formulation of pro-drug, which is a medication or compound that, after administration, is metabolized (i.e., converted within the body) into a pharmacologically active drug, of THC for neuropsychiatric disorders including Tourette syndrome. Nemus Bioscience, Inc., or Nemus, is focused on the discovery, development and commercialization of cannabis therapeutics. Corbus Pharmaceuticals Holdings is seeking FDA approval for their synthetic cannabinoid for systemic sclerosis, cystic fibrosis, dermatomyositis and systemic lupus erythematosus.

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. Both Congress and the U.S. President have already taken some actions that are intended to limit significantly the Affordable Care Act, and other proposals have been made and are being considered to further modify or even repeal the Affordable Care Act. While some of these actions already appear to be limiting the scope of the Affordable Care Act, it is not clear at this point whether the new proposals will be adopted (either in their current form or a modified form) in the future. 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 being assigned we have a portfolio of two provisional patent applications with the U.S. Patent and Trademark Office, or USPTO, and one patent application filed under the Patent Cooperation Treaty of the World Intellectual Property Organization, or PCT . We also have three patent applications in National Phase Stage in various national entities. 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 exclusively licensed: (i) one U.S. patent from Dekel Pharmaceuticals Ltd., or Dekel, and (ii) one U.S. patent family from Yissum Research Development Company of the Hebrew University of Jerusalem Ltd., or Yissum. We cannot assure you that we will ever enter into definitive license agreements with any 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, 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 Dr. Ascher Shmulewitz, our interim Chief Executive Officer and 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 and interim Chief Executive Officer, 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, and we do not have proprietary rights to Dr. Shmulewitz' inventions that are not included under the consulting and services agreement we entered into with him (pertaining solely to the field of immunomodulators including cannabinoids to treat chronic pain and inflammation).

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 and interim Chief Executive Officer. 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, board of directors' approvals and under the relevant circumstances that applied then, also 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 nine full-time employees and three dedicated consultants that work for us on a part-time basis. 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.

The market price of the ADSs is volatile. The ADS price are and will continue to 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.

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 Jumpstart Our Business Startups Act of 2012, or 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 Securities and Exchange Commission, or 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 of 1933, as amended, or 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 to and 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 Securities Exchange Act of 1934, as amended, or 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 the Companies Law requires us to disclose the annual compensation of our five most highly compensated senior officers on an individual basis, this disclosure is not 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 2019. 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.

ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable results to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our Ordinary Shares provides that owners and holders of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement or the ADSs, including claims under federal securities laws, against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court. However, we believe that a jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the deposit agreement, by a court of the State of New York or a federal court, which have non-exclusive jurisdiction over matters arising under the deposit agreement, applying such law. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement and the ADSs. In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one which is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute), none of which we believe are applicable in the case of the deposit agreement or the ADSs. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or owner of ADSs or by us or the depositary of compliance with any provision of the federal securities laws. If you or any other holder or owner of ADSs brings a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, you or such other holder or owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and / or the depositary. If a lawsuit is brought against us and / or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different results than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

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 U.S. dollars. U.S. dollars is our functional currency and 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 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. Under the Israeli law, a potential bidder for the company's shares, who would as a result of a purchase of shares hold either 25% of the voting rights in the company when no other party holds 25% or more, or 45% of the voting rights in the company where no other shareholders holds 45% of the voting rights, would be required to make a special purchase offer as set out in the provisions of the Israeli law. The Israeli law requires a special purchase offer to be submitted to shareholders for a pre-approval vote. A majority vote is required to accept the offer. An offeror who is regarded as a 'controlling shareholder' under Israeli law cannot vote on the resolution and the procedure includes a secondary vote of the non-voting shareholders and the shareholders who rejected the offer at pre-approval level. A special purchase offer may not be accepted unless shares that carry 5% of the voting rights in the target company are acquired. 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 "Description of Share Capital—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, corporate headquarters and principal research and development facilities are located in Israel. In addition, the vast majority 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. 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 our regular operation, product development and delivery of 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 and 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. 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 invest in Israel or in Israeli companies, or 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, 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 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.

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 and product development.

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. Similarly, Israeli corporations are limited in conducting business with entities from several countries.

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 and 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 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. 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 in part was returned and re-assigned to Hadasit Medical Research Services & Development Ltd., or Hadassit, and in part is still 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, 2018, 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). 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 and certain internally developed assets and technology relating thereto).

However, since certain intellectual property related to the Anti-CD3 technology was developed with financing, in part, from the IIA, we have not been able to assign it to Orimmune, as we have not been able to obtain the consent of the IIA, see Item 4.B. "Business Overview—Intellectual Property—Sales of intellectual property assets" for additional information.

If we are not able to obtain the consent of the IIA, then we may be required to assume the sale activity or abandon it, subject to certain payments and liabilities.

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. Our ADSs representing our Ordinary Shares currently trade in the United States on the Nasdaq Capital Market under the symbol "TRPX." From December 26, 2005 to August 9, 2018, our Ordinary Shares were traded on the Tel Aviv Stock Exchange.

Our registered office and principal place of business is located at 4 Ariel Sharon Street, HaShahar Tower, 16th Floor, Givatayim 5320047, 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. The SEC also maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Our filings with the SEC will also be available to the public through the SEC's website at www.sec.gov.

We are an emerging growth company, as defined in Section 2(a) of the Securities Act, as implemented under 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 including but not limited to not being required to comply with the auditor attestation requirements of the SEC rules under Section 404 of the Sarbanes-Oxley Act. We could 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 common 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 30th, 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 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 2018, 2017 and 2016 amounted to $17,000, $44,000 and $4,000, 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 cannabinoids pharmaceuticals. We are focusing on a drug development program that we call *Joint Pharma*, which targets the treatment of the central nervous system and related indications with our product candidate THX-110. As part of our Joint Pharma program, we are also developing THX-150 and THX-160, which target multi drug resistant bacteria and pain, respectively.

THX-110 is a combination drug candidate based on two components: (1) dronabinol, the active ingredient in an FDA approved synthetic analog of THC, which is the major cannabinoid molecule in the cannabis plant, and (2) PEA, which is an endogenous fatty acid amide that belongs to the class of nuclear factor agonists, which are molecules that regulate the expression of genes. We believe that the combination of THC and PEA may induce a reaction known as the "entourage effect," which has strong potential to treat Tourette syndrome, obstructive sleep apnea and pain.

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 their target ligand, which is an ion or molecule that binds to a central metal atom to form a complex (alternatively known as a coordination entity), such as endocannabinoid anandamide or phytocannabinoid THC 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 developed a proprietary formulation of PEA which we call CannAmide^{TM}.

THX-150 is a drug candidate intended for the treatment of infectious diseases. It consists of dronabinol (synthetic Δ9-tetrahydracannabinol) and/or PEA and selected antibacterial agent and possesses antimicrobial synergy potential.

THX-160 is a novel pharmaceutical CB2 receptor agonist for the treatment of pain. Modulating CB2 receptor activity by selective CB2 receptor agonists holds unique therapeutic potential for addressing pain conditions.

For the development of THX-110 and THX-150, we intend to seek FDA approval for the commercialization of our drug candidates through the Section 505(b)(2) regulatory pathway under the FDC Act. The FDA's 505(b)(2) regulatory pathway permits the filing of a 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 preclinical and clinical data that we would need to generate in order to obtain FDA approval. In addition, with respect to Tourette syndrome, we are pursuing orphan drug designation in the United States. In June 2016, we initially submitted a request for orphan drug designation to the FDA for THX-110 for the treatment of Tourette syndrome. The request is still pending and we are in communication with FDA. The last communication was in December 2018 when we received a letter from the FDA questioning if the sub-group of Tourette syndrome that we are pursuing has a prevalence of fewer than 200,000 individuals and thus eligible for orphan drug designation. There is no assurance that we will successfully obtain orphan drug designation for Tourette syndrome, although we believe that we can provide adequate data to address recent issues raised by the FDA.

The Medical Cannabis Industry

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. A report included in the Marijuana Business Factbook 2017 suggests that by 2021, annual retail marijuana sales in the United States could top $17 billion, which would represent a 300% increase from 2016.

Our Drug Development Programs

THX-110 – Tourette Syndrome, Obstructive Sleep Apnea and Pain

We believe that our product candidate, THX-110, offers a safe and potentially effective solution for a variety of medical concerns. Despite being in its early phases of clinical testing, the application of THX-110 has extended into several treatments, including Tourette syndrome, obstructive sleep apnea, or OSA, and both acute and chronic pain.

Tourette Syndrome

Tourette syndrome is a neuropsychiatric disorder, characterized by physical (motor) tics and vocal (phonic) tics. Motor tics generally precede the development of phonic tics in Tourette syndrome, and the onset of simple tics usually predates that of complex tics. Tourette syndrome ranges from mild symptoms to loud noises and forceful movements that can result in self-injury (e.g. punching oneself in the face, repeating other people's words or involuntary swearing). Many with Tourette syndrome experience additional neurobehavioral problems and comorbidities including inattention, hyperactivity and impulsivity, anger control problems, sleep difficulties, and obsessive-compulsive symptoms. 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 decreases during adolescence and early adulthood, and sometimes disappears entirely; therefore, there are a limited number of adults with Tourette syndrome and it is usually manifested mainly through moderate to severe symptoms.

Market Size

The exact number of people with Tourette syndrome is unknown. The prevalence of Tourette syndrome and Tourette syndrome symptoms is greater in children than in adults. CDC scientists used data from the 2011-2012 National Survey on Children's Health to estimate that one out of every 360 children between the ages of six through 17 have been diagnosed with Tourette syndrome in the United States. This accounts for an estimated 138,000 children. According to 2015 meta-analysis, the Tourette syndrome population prevalence estimate was 0.52% (Scharf JM et al, 2015).

Current Treatment

Pharmacological intervention is considered the first line of therapy for Tourette syndrome, but is reserved for more severe symptoms that interfere with the individual's ability to function. Today, a full class of drugs that interact with dopamine and non-dopamine systems in the brain are used in the treatment of Tourette syndrome symptoms. Many of the drugs used to treat Tourette syndrome are limited to the treatment of a narrow range of Tourette syndrome symptoms (mainly tics), and are associated with severe side effects, both of which limit their utility. 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 Tourette syndrome can be divided into the following groups:

- Antipsychotic medications: belong to a class of drugs primarily used to manage psychosis (including haloperidol, pimozide and fluphenazine), all of which are associated with severe side effects (including weight gain, sedation, akathisia (a state of agitation, distress, and restlessness), nausea and tardive dyskinesia (involuntary movements of the face and jaw), among others).

- Alpha2 Adrenergic Agonists: belong to a class of drugs primarily used to manage hypertension and migraine headaches prevention (including clonidine and guanfacine), which have limited utility despite common application to children with Attention Deficit Hyperactivity Disorder, or ADHD. Similar to antipsychotic medications, these also are associated with several 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 Tourette syndrome patients, which also has associated 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 Tourette syndrome.

Our THX-110 Solution for Tourette syndrome

Our THX-110 platform is a drug candidate for the treatment of Tourette syndrome.

On April 4, 2018, we announced topline results of our Phase IIa investigator-initiated study at Yale University of THX-110 for the treatment of Tourette syndrome. The study was a single-arm, open-label trial, in which each subject both received one daily treatment of THX-110 via oral administration and was followed-up for a period of 12 weeks. 16 subjects participated in the study and received THX-110 at the Yale University Child Study Center at Yale University. The primary endpoint of the study was to assess the performance of THX-110 in the treatment of adult patients suffering from symptoms of Tourette syndrome, as measured by the Yale Global Tic Severity Scale Total Tic Score, or YGTSS-TTS, the customary index for assessing symptom severity. Treatment was given in a dose titration regimen with a maximum dose of THX-110 consisting of 10mg dronabinol and 800mg PEA.

The topline results of the study showed that each of these 16 subjects with medication-refractory Tourette syndrome sustained a significant reduction of tic symptoms (paired t-test: YGTSS-TTS mean difference (mean +/- SD) =7.9+/-8.4, t= 3.7, df=15, p=0.002) from baseline (YGTSS-TTS: 38.4 +/- 8.3) to endpoint YGTSS-TTS: 30.5 +/- 10.9). This resulted in an average tic reduction of 21% across the entire sample of 16 Tourette syndrome subjects. Six of the 16 medication-refractory Tourette syndrome subjects experienced a response to treatment as defined by a reduction in YGTSS-TTS of greater than 25%. Improvement over time with treatment was also observed when generalized linear models were used to analyze repeated measures data on the YGTSS-TTS. In the study, THX-110 demonstrated no significant effects on comorbid ADHD, anxiety, depression or obsessive-compulsive disorder, or OCD, symptoms. The medication was generally well-tolerated by the subjects with only two subjects stopping treatment early (one due to sedation and another due to lack of improvement in tic symptoms). 12 of the 16 subjects elected to proceed with a 24-week extension phase of the trial, which was also completed.

Following the Phase IIa study, we initiated in August 2018 a randomized, double-blind, placebo controlled study to evaluate the safety, tolerability and efficacy of daily oral THX-110 in treating adults with Tourette syndrome, with Hannover Medical School, Germany. The study includes approximately 60 patients. Study patients are randomized to either oral THX-110 or placebo at a 1:1 ratio. The overall estimated study duration is 24 months. We plan to also conduct further preclinical studies in parallel to our clinical plans as part of registration process with the FDA and EMA. Following these studies, if successful, 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-110 in treating Tourette syndrome.

In June 2016, we submitted a request for orphan drug designation to the FDA for THX-110 for the treatment of Tourette syndrome. The request is still pending and we are in communication with FDA. Our last communication was in December 2018 when we received a letter from FDA questioning the prevalence calculation. There is no assurance that we will successfully obtain orphan drug designation for Tourette syndrome, although we believe that we can provide adequate data to address all issues raised by the FDA.

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. In a pre-IND meeting we had with FDA in February 2018, the FDA did not oppose our plans to submit an NDA via the 505(b)(2) pathway relying, in part, on clinical and nonclinical information from literature related to dronabinol and the FDA's previous finding of safety and efficacy for the reference listed drug (Marinol).

Obstructive Sleep Apnea

OSA is characterized by episodic sleep state–dependent collapse of the upper airway, resulting in periodic reductions or cessations in ventilation, with consequent hypoxia, hypercapnia, or arousals from sleep. OSA severity is typically assessed with the apnea–hypopnea index, or AHI, which is the number of apneas and hypopneas per hour of sleep.

Market Size and Current Treatment

At ≥15 AHI (moderate and severe), the prevalence in the general adult population ranges from 6% to 17%, being as high as 49% in the advanced ages. OSA prevalence was also greater in obese men and women (Senaratna CV et al, 2017). A majority of today's OSA treatments are in the form of medical devices known as C-PAPs. The global sleep apnea devices market size was valued at $5.10 billion in 2016 and is expected to grow at a compound annual growth rate, or CAGR, of 7.7% over the forecast period. According to a market research report published by P&S Intelligence, the global sleep apnea devices market is expected to generate $6.8 billion of revenue by 2023. The increasing geriatric population due to increasing life expectancy is expected to increase the prevalence of OSA. Sleep disorders increase with the increase in the age. Furthermore, the prevalence of apnea is high in geriatric population because comorbidities associated with apnea are high in the elderly population. Another factor is the increase in the arousal frequency. The rise in presence of OSA is attributed to the reduction in the size of upper airway lumen due to increasing age factor (Sleep Apnea Devices Market Size, Share & Trends Analysis Report by Product (Single Channel Screening Devices, Actigraphy Systems, PSG Devices, Respiratory Polygraph) By Region, And Segment Forecasts, 2012 – 2022 (https://www.grandviewresearch.com/industry-analysis/sleep-apnea-devices-market). Additionally, and only if other therapies haven't been effective, surgery can be considered.

Our THX-110 Solution for OSA

In October 2017, we signed an agreement with Assuta Medical Center, or Assuta, to conduct a Phase IIa, sponsor-initiated trial for the treatment of OSA THX-110. The study commenced in April 2018.

Within the THX-110 platform, we initiated a proof of concept phase IIa for OSA in 2018, and we expect to complete enrollment by the third quarter of 2019. The OSA trial, titled "Examining the Efficacy of a Therapeutic Combination of Dronabinol (synthetic Δ9-tetrahydracannabinol) and Palmitoylethanolamide for Obstructive Sleep Apnea," is conducted under the leadership of Prof. Yaron Dagan, head of the Sleep Medicine Institute at Assuta. Thirty patients with a confirmed OSA diagnosis are evaluated for one month with the primary efficacy endpoint evaluating a significant change in the AHI, which assesses the quality of sleep before and after treatment, as well as safety of the treatment. Secondary efficacy measurements include a change in blood oxidation index before and after the treatment, improvement in quality assessment index, improvement in fatigue and sleepiness based on the Epworth Sleepiness Scale index.

Chronic and Acute Pain (THX-110)

In March 2018, the FDA cleared the Investigator-Initiated Investigational New Drug application, or the iIND, for THX-110 in the treatment of chronic low back pain. As of the date hereof, we have not initiated a clinical trial under the iIND for THX-110. As such, we are examining alternatives for conducting this program.

Anti-Bacterial

Antibiotics revolutionized medicine in the 20th century, and have together with vaccinations led to the near eradication of diseases such as tuberculosis in the developed world. However, this has led to widespread problems with antimicrobial and antibiotic resistance, so much so that the World Health Organization has classified antimicrobial resistance as a "serious threat." Each year in the United States, at least 2 million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die each year as a direct result of these infections. There are currently considerable challenges with the treatment of infections caused by strains of clinically relevant bacteria that show multi-drug-resistance. New anti-bacterial agents are therefore urgently needed, but only one new class of antibacterial has been introduced in the last 30 years. In addition, some antibiotics have been associated with a range of adverse side effects. Side effects range from mild to very serious depending on the antibiotics used, the microbial organisms targeted, and the individual patient. Pharmaceutical combinations of antimicrobial agents with other molecules capable of increasing the potency of the antimicrobial agents could decrease the minimal therapeutic dosages of antimicrobial agents required, thus minimizing the development of drug resistance, reducing antibiotics-associated side effects, preventing biofilm formation and/or treating the established biofilms. We aim to elucidate the mechanism of action of cannabinoids and cannabinoid-mimetics as potentiator for currently used antibiotics, as well as to provide an alternative remedy for the issue posed by antibiotic resistance. The proposed application consists of the pharmaceutical combinations of current antimicrobial agents with our proprietary formulation of a cannabinioid, THC, and a cannabinoid-like compound, PEA, in the hope to elucidate a new mechanism of action for the development of antibiotic treatment, in particular for bacterial strains showing multi-drug-resistance.

Market Size

Transparency Market Research (TMR) has published a new report titled, “Gram-Positive Bacterial Infections Market - Global Industry Analysis, Size, Share, Growth, Trends, and Forecast, 2018–2026.” Gram-positive bacterial are bacteria that give a positive result in the Gram stain test, which is traditionally used to quickly classify bacteria into two broad categories according to their cell wall. According to the report the global gram-positive bacterial infections market was valued at $58.7 billion in 2017. It is projected to expand at a CAGR of 1.5% for the forecast period of 2018 to 2026. The gram-positive bacterial infections market is projected to expand during the forecast period owing to an increase in the number of cases of gram-positive bacterial infections and rapid rise in antibacterial resistance. Moreover, factors such as increased government initiatives and funding for R&D activities and newer bacterial infection treatment and infection control in healthcare settings drive the global gram-positive bacterial infections market. North America dominated the global gram-positive bacterial infections market and is expected to maintain its position owing to a rise in the prevalence of bacterial infections, better diagnosis, and treatment rate in the region.

Current Treatment

Gram-positive bacterial infections drugs act against gram-positive bacterial infections such as Methycillin-resistant Staphylococcus aureus, or MRSA, infections, sinusitis, cellulitis, and pneumonia. Antibiotics are widely used as the first line of treatment for these infections. Antibacterial resistance is considered to be a serious threat in this century for the treatment of bacterial infections. The market for gram-positive bacterial infections is expanding significantly due to a rise in the number of cases of bacterial infections and rapid increase in antibacterial resistance. Furthermore, infection control in healthcare settings and increasing government initiatives and funding for R&D activities have fueled the gram-positive bacterial infections market.

Our THX-150 Anti-Bacterial Solution

In January 2017, we initiated a program in the antimicrobial therapies area. Our objective is to use our entourage technology in association with cannabinoids 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. Cannabinoids such as THC have been shown to have a wide range of important biological activities, including potential antibacterial activity. We are in the midst of our pre-clinical research stage for our proprietary drug candidate THX-150. We have successfully performed an array of in-vitro studies intended to evaluate the synergistic effects of THX-150 components in various strains of multi drug resistant bacteria. In addition we are assessing the efficacy of THX-150 in an animal model of thigh infection.

Pain (THX-160)

Pain is the most common reason for physician consultation in most developed countries. It is a major symptom in many medical conditions, and can interfere with a person's quality of life and general functioning. Opioid medications can provide short, intermediate or long acting analgesia depending upon the specific properties of the medication and whether it is formulated as an extended release drug. Opioids are efficacious analgesics in chronic malignant pain and modestly effective in nonmalignant pain management. However, there are associated adverse effects, especially during the commencement or change in dose. Prolonged opioid use may cause drug tolerance, chemical dependency, diversion and addiction. The potency and availability of these substances, despite their high risk of addiction and overdose, have made them popular both as formal medical treatments and as recreational drugs. Due to their sedative effects on the medulla oblongata, opioids in high doses present the potential for respiratory depression, and may cause respiratory failure and death. In a 2013 review study published in Fundamental & Clinical Pharmacology, various studies were cited demonstrating that cannabinoids exhibit comparable effectiveness to opioids in models of acute pain and even greater effectiveness in models of chronic pain. Cannabis produces several compounds with known analgesic activities known together as cannabinoids, such as THC and cannabidiol (CBD). All cannabinoids bind and act through one of the two characterized cannabinoid receptors: CB1 and CB2. However, activation of the CB1 receptor (as for example in the case of THC) leads to unwanted psychoactive "high" and other adverse events, whereas activation of CB2 does not lead to any psychoactivity. In addition and unrelated to the above sentence, the affinity of the cannabis derived cannabinoids to these receptors is limited and partial. Newly synthetic cannabinoid HU-433, a specific CB2 agonist with full CB2 receptor affinity, was synthesized by Prof. Raphael Mechoulam from Hebrew University of Jerusalem, and is our proprietary new chemical entity.

More than 100 million Americans are suffering from pain. The annual economic burden of prescription opioids misuse in 2016 sums in $78.5 million, while the total incremental cost of health care due to pain ranged from $261 to $300 billion.

Our THX-160 Pain Solution

In July 2018, we executed a license agreement with Yissum, the technology transfer company of the Hebrew University of Jerusalem, for THX-160, a synthetic cannabinoid synthesized by Prof. Mechoulam. We completed two preliminary preclinical studies evaluating analgesic and opioid-sparing effects of this compound in a rat model of acute and chronic pain. In the preclinical studies, THX-160 was well tolerated and did not cause any significant adverse clinical effects. In addition, efficacy studies demonstrated the analgesic superiority of THX-160 over control and were comparable to high-dose morphine analgesic effects and in some instances exerted greater potency. The efficacy and safety of THX-160 was shown for both acute and chronic pain.

Other programs

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. We have an additional program that we call *BrainBright Pharma*, with our product candidate THX-130 which is a low dose THC treatment.

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

Therapix Healthcare Resources, Inc.

On July 26, 2018, and as amended in July, August and October 2018, we entered into an agreement for convertible loans, the Convertible Loans Agreement, with THR. On July 31, 2018, THR entered into an asset purchase agreement with a third party for equipment, a laboratory and patient medical records.

On October 3, 2018, we converted an aggregate of approximately $1.63 million of convertible loans issued under the Convertible Loans Agreement and, as a result of such conversion and other non-cash startup expenses previously provided to THR, we obtained an equity ownership interest of 82.36% in THR. We currently have approximately $688,000 in convertible loans outstanding to THR.

THR was engaged in operating pain treatment clinics to treat an assortment of different pains, including acute pain, spine pain, chronic headaches, cancer pain, oral/maxillofacial pain, neuropathic pain and rheumatologic/myofascial pain.

Due in part to significant losses incurred by THR, as well as its failure to maintain required licenses to operate its facilities, THR has commenced liquidation of its assets. The liquidation of THR's remaining assets, or potential claims that may arise from the liquidation and dissolution of THR may adversely affect our reputation or divert management's attention in the event of any material litigation or in the event that the liquidation process is prolonged. At this time, neither we nor THR are able to estimate reliably the timing and results of the proposed liquidation or of any consequences that may occur as a result thereof.

Intellectual Property

Our intellectual property portfolio comprises three granted U.S. patents and seven pending patent applications, of which four applications have either the PCT, pending status or have entered national stage and are under examination by national authorities. Of this portfolio, we have exclusively licensed one granted U.S. patent from Dekel and one patent family from Yissum.

Internally Developed Patent Applications

In April 2015, we filed a provisional application with the USPTO for combinations of cannabinoids, n-acylethanolamines, and inhibitors of n-acylethanolamine degradation, which, in April 2016 was converted into the international PCT stage and in October 2017 into National Phase in the following state entities: U.S., EPO (European Patent Office), Israel, Australia, Canada, China and Japan. 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 Tourette syndrome. 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, in May 2016 entered the PCT stage, and in November 2017 into National Phase in the following state entities: U.S., EPO, Israel, Australia, Canada, China and Japan. 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 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 converted to a non-provisional application PCT application in July 2017 and in January 2019 into National Phase in the following state entities: USA, EPO, and China. Any resulting patent from this application would be expected to expire in July 2037.

In January 2018, we filed a provisional application with the USPTO for the technology which describes methods of treating OSA. This application converted to a non-provisional application PCT application in January 2019. Any resulting patent from this application would be expected to expire in January 2039.

In March 2013, we filed a provisional application with the USPTO for the technology of proprietary sequences of anti-CD3 antibody and the utilization of the latter in various autoimmune diseases, as well as in hepato-pathologies. The provisional application has been converted to a PCT and then entered a National Status in December 2014 in the US, EPO, China, Canada and Japan. In the USA it has received a grant status in June 2018.

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. This upfront payment of shares on account of future royalty payments was originally a pre-condition for the closing of the agreement and was subject to TASE's prior approval. This pre-condition was subsequently forfeited by Dekel under the first amendment of the license agreement, to enable the agreement to enter into effect even prior to TASE approval, which was eventually obtained later on. 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 (which was paid in April 2018); 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.

On July 29, 2018, we entered into an exclusive, worldwide, sublicensable, royalty-bearing license agreement with Yissum for a license to make commercial use of the licensed technology, in order to develop, obtain regulatory approvals, manufacture, market, distribute or sell products, or the Yissum License Agreement. According to the Yissum License Agreement, we shall pay Yissum royalties at the rates of 3% of net sales, subject to the royalty reductions as described in the Yissum License Agreement. All right, title and interest in and to the Yissum License Agreement shall vest solely in Yissum, and we shall hold and make use of the rights granted. All rights in the development results shall be solely owned by us, except to the extent that an employee of the Yissum, including the researcher, is considered an inventor of a patentable invention arising from the development results, in which case such invention and all patent applications and/or patents claiming such invention shall be owned jointly by us and Yissum, as appropriate, and Yissum's share in such joint patents shall be automatically include in the Yissum License Agreements.

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, Canada, 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 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 and certain internally developed assets and technology relating thereto). We have been assisting Karma Link with the activities related to the assignment of the license with all relevant parties and authorities. During May 2017, we entered into the Amendment with Karma Link and Orimmune, pursuant to which the parties acknowledged that our discussions with Hadasit regarding the possibility of assigning the license to Orimmune, as contemplated in the transfer agreement, have yet to mature into an agreement with Hadasit, due to Hadasit's objection to the proposed assignment. We agreed to bear certain fees expenses related to the license incurred prior to the date hereof in the amount of $60,000, which were paid to Orimmune. In addition, during a period of six months commencing as of the date of the amendment, we agreed to bear certain additional fees and expenses related to the license. It was determined that such additional amounts will not exceed $15,000. All such additional fees and expenses shall be coordinated with our approval in advance. In consideration for such participation by us, it was agreed to increase the percentages of the predetermined rate. 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.

The 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 the IIA's claim that such registration is not in compliance with the IIA rules regarding use of its grants. Following further discussions between Hadasit and us held during the second half of 2017, and through the first quarter of 2018, after not succeeding in assigning the license to a buyer, we signed the Termination Agreement. According to the Termination Agreement, Hadasit assigned to us the Therapix Patent, and we re-assigned to Hadasit all of its rights, title and interest in the patents that developed by Hadasit prior to the Hadasit License.

On April 18, 2018, we submitted an application with the IIA to approve the assignment of the Therapix Patent to Orimmune. We are currently in discussions with the IIA in connection with the terms of approval of this request, which will, *inter* alia, address a previous refusal received by the IIA to a request to recognize the registration of a joint patent with Hadasit, under the license agreement, which according to the IIA did not comply with the rules and regulations with respect to use of funds received under the IIA grant.

On July 4, 2018, and according to the Termination Agreement, we paid Hadassit an amount of approximately $104,000 due to, inter alia, accrued costs and expenses relating to the filing, prosecution and maintenance of the patent rights; license maintenance fee due to Hadasit for the years 2016 and 2017 and unpaid related consultancy fees for work performed during 2015.

On December 13, 2018, an additional amendment to the transfer agreement was signed, or the Additional Amendment, between us, Karma Link and Orimmune, under which the parties acknowledged that despite our efforts and assistance in the discussions with Hadasit regarding the possibility of assigning the license to Orimmune, Orimmune chose not to enter into an agreement with Hadasit. In addition and notwithstanding the foregoing, we are willing to assign to Orimmune the entire right, title and interest in specific patents, subject to fulfilment of certain conditions precedent which are in effect as of the date of this annual report.

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, 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 and Prader-Willi syndrome. 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 is developing a transdermal formulation of cannabidiol, and Nemus is focused on the discovery, development and commercialization of cannabis therapeutics.

In addition, GW develops a CBDV based therapy for autism spectrum disorders and therapy for neonatal hypoxic-ischemic encephalopathy, glioblastoma and schizophrenia. Zynerba is developing a transdermal formulation of cannabidiol for Fragile X and certain refractory epilepsies. In addition, Zynerba is currently developing a transdermal formulation of pro-drug of THC for neuropsychiatric disorders including Tourette syndrome. Nemus is focused on the discovery, development and commercialization of cannabis therapeutics. Corbus Pharmaceuticals is seeking FDA approval for their synthetic cannabinoid for systemic sclerosis, cystic fibrosis, dermatomyositis and systemic lupus erythematosus.

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. The use of contracted manufacturing and reliance on collaboration partners is relatively cost-efficient and has may eliminate the need to directly invest in manufacturing facilities and additional staff. Nevertheless, we are looking into entering into transactions with a potential partner that owns or has clinical or commercial scale manufacturing capabilities.

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 regulations may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending New Drug Applications (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 testing, the submission to the FDA of an Investigational New Drug Application (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 drug substance and drug product's 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 original 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 proposed clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational product 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. Clinical protocols 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 and any amendment involving testing on of U.S. patients study subjects within the United States 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 the FDA believes that the clinical trial either is not being conducted in accordance with FDA requirements regulations or presents an unacceptable risk to the clinical trial subjects. The trial protocol and informed consent information for subjects 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.

505(b)(2) Regulatory Approval Process

Section 505(b)(2) of the FDCA, or 505(b)(2), provides an alternate regulatory pathway to FDA approval for new or improved formulations or new uses of previously approved drug products. Specifically, 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 or use from the person by or for whom the investigations were conducted. The applicant may rely upon the FDA's prior findings of safety and efficacy for an approved product that acts as the reference listed drug for purposes of a 505(b)(2) NDA. The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support any changes from the reference listed drug. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Orange Book Listing

Section 505 of the FFDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy, but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical and clinical data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book. These products may be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Any applicant who submits an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV certification. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through a Paragraph IV certification. If the applicant does not challenge the listed patents or does not indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the competitor has provided a Paragraph IV certification to the FDA, the competitor must also send notice of the Paragraph IV certification to the holder of the NDA for the reference listed drug and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner 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 prevents the FDA from approving the application until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the applicant or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a Paragraph IV certification, the NDA holder or patent owner regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation. The applicant may also elect to submit a statement certifying that its proposed 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.

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

The FDA provides periods of regulatory exclusivity, which provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug for a period of three or five years following the FDA's approval of the NDA. Five years of exclusivity are available to NCEs. An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent, or not involving the sharing of electron pairs between atoms, derivatives, such as a complex (i.e., formed by the chemical interaction of two compounds), chelate (i.e., a chemical compound), or clathrate (i.e., a polymer framework that traps molecules), of the molecule, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review or approve an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed.

If a product is not eligible for the NCE exclusivity, it may be eligible for three years of exclusivity. Three-year exclusivity is available to the holder of an NDA, including a 505(b)(2) NDA, for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials, other than bioavailability or bioequivalence trials, was essential to the approval of the application and was conducted or sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the condition of the new drug's approval. As a general matter, three-year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

NDA Submission and Review by the FDA

Assuming successful completion of the required clinical and preclinical testing, among other items, the results of product development, including chemistry, manufacture and controls, nonclinical studies and clinical trials are submitted to the FDA, along with proposed labeling, as part of an NDA. The submission of an NDA requires payment of a substantial user fee to the FDA. These user fees must be paid at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in some circumstances. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have an approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first marketing application.

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 2018 is $2,421,495$.

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. 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 substance and drug product is are manufactured. The FDA will not approve the product candidate product 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 plan 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). An 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 (clinicaltrials.gov) maintained by the U.S. National Institutes of Health. Information related to the product candidate product, 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 drug product 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

Tourette's syndrome 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. 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 product 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.

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 drug product will be subject to certain post-approval requirements. . Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including manufacturing, periodic reporting, product sampling and distribution, advertising, promotion, drug shortage reporting, compliance with any post-approval requirements imposed as a conditional of approval such as Phase 4 clinical trials, REMS and surveillance, recordkeeping and reporting requirements, including adverse experiences. 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 with 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 with a prevalence of 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-110 for the treatment of Tourette syndrome. In a letter dated September 29, 2016, the FDA informed us that our request could not be granted at such time, and is being held in abeyance until and subject to us providing additional information pertaining to the overall prevalence of Tourette syndrome in both children and adults, and further clinical data to support our scientific rationale for our request for orphan drug designation within 12 months. In September 2017, we responded to such FDA letter within the designated time frame, and provided the FDA with our articulated and reasoned responses including documentation and clinical data that supports it. On December 26, 2017, we received the FDA's response to our response. The FDA accepted that there is adequate scientific rationale for the treatment of Tourette syndrome with THX-110 mainly through the preliminary results of ongoing clinical trials, suggesting that THX-110 may provide benefit in treating Tourette syndrome. However, the FDA stated that it was unable to grant our request and indicated that we did not provide adequate prevalence estimates, and any evidence to support our statement that only moderate to severe Tourette's patients would require pharmacological treatment. We further responded in January 2018 by providing the requested information. We are currently waiting for the FDA's response. There is no assurance that we will successfully obtain orphan drug designation for Tourette syndrome, although we believe that we can provide adequate data to address all issues raised by the FDA.

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.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for our products, once approved, and related treatments will be available from third-party payors, such as government health administration authorities, private health insurers and managed care organizations. Third-party payors determine which medications they will cover and separately establish reimbursement levels. Even if we obtain coverage for a given product by a third-party payor, the third-party payor's reimbursement rates may not be adequate to make the product affordable to patients or profitable to us, or the third-party payors may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices as a condition of coverage, are using restrictive formularies and preferred drug lists to leverage greater discounts in competitive classes and are challenging the prices charged for medical products. Further, no uniform policy for determining coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available, or if reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

As a condition of receiving Medicaid coverage for prescription drugs, the Medicaid Drug Rebate Program requires manufacturers to calculate and report to CMS their Average Manufacturer Price, or AMP, which is used to determine rebate payments shared between the states and the federal government and, for some multiple source drugs, Medicaid payment rates for the drug, and for drugs paid under Medicare Part B, to also calculate and report their average sales price, which is used to determine the Medicare Part B payment rate for the drug. In January 2016, CMS issued a final rule regarding the Medicaid Drug Rebate Program, effective April 1, 2016, that, among other things, revises the manner in which the AMP is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the ACA. Drugs that are approved under a biologics license application, or BLA, or an NDA, including a 505(b)(2) NDA, are subject to an additional requirement to calculate and report the manufacturer’s best price for the drug and inflation penalties which can substantially increase rebate payments. For BLA and NDA drugs, the Veterans Health Care Act requires manufacturers to calculate and report to the Department of Veterans Affairs a different price called the Non-Federal AMP, offer the drugs for sale on the Federal Supply Schedule, and charge the government no more than a statutory price referred to as the Federal Ceiling Price, which includes an inflation penalty. A separate law requires manufacturers to pay rebates on these drugs when paid by the Department of Defense under its TRICARE Retail Pharmacy Program. Knowingly submitting false pricing information to the government creates potential federal False Claims Act liability.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted legislation at the federal and state levels designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump Administration’s budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump Administration have both stated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have been increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Additional health reform measures may continue and affect our business in unknown ways.

The Foreign Corrupt Practices Act

The FCPA prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the companies to maintain books and records that accurately and fairly reflect all transactions of the companies, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

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.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for, or purchasing, leasing, ordering, or arranging for the purchase, lease or order of, any good, facility, item or service reimbursable, in whole or in part, by Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value, including unlawful financial inducements paid to prescribers and beneficiaries, as well as impermissible promotional practices. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, amended the intent requirement of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute, or the specific intent to violate it, to have violated the statute. The ACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil and criminal false claims laws, including the federal False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or for approval by, the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government.

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including public and private payors, or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. The ACA amended the federal health care fraud criminal statute implemented under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have violated the statute.

Additionally, the federal Open Payments program pursuant to the Physician Payments Sunshine Act, created under Section 6002 of the ACA and its implementing regulations, require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with specified exceptions) to report annually information related to specified payments or other transfers of value provided to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually specified ownership and investment interests held by physicians and their immediate family members.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on HIPAA covered entities and their business associates, including mandatory contractual terms and the implementation of certain safeguards of such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways, may not have the same effect and may not be preempted by HIPAA, thus complicating compliance efforts.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any payor, including commercial insurers. We may also be subject to 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, and/or state laws that require drug manufacturers to report information related to marketing expenditures or payments and other transfers of value to physicians and other healthcare providers.

Enforcement actions can be brought by federal or state governments or, in some cases, as "qui tam" actions brought by individual whistleblowers in the name of the government. Depending on the circumstances, failure to comply with these laws can result in penalties, including criminal, civil and/or administrative criminal penalties, damages, fines, disgorgement, debarment from government contracts, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion from government programs, refusal to allow us to enter into supply contracts, including government contracts, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our business.

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, 2018, 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. 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

We have one, active, majority controlled subsidiary, THR, and three inactive wholly-owned subsidiaries: Nasvax Inc., Evero Health Ltd. (previously known as Weex Biosciences Ltd.) and Brain bright Ltd.

Therapix Healthcare Resources Inc. is a subsidiary incorporated in Delaware of which we own approximately 82.36% of its share capital. THR was engaged in operating pain treatment clinics to treat an assortment of different pains, including, acute pain, spine pain, chronic headaches, cancer pain, oral/maxillofacial pain, neuropathic pain and rheumatologic/myofascial pain. We converted an aggregate of approximately $1.63 million of convertible loans issued under a convertible loans agreement and, as a result of such conversion and other non-cash startup expenses previously provided to THR, we obtained an equity ownership interest of 82.36% in THR.

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.

D. Property, Plants and Equipment

Our offices are located at 4 Ariel Sharon Street, HaShahar Tower, 16th Floor, Givatayim 5320047, Israel, where we currently occupy approximately 1,800 square feet. We lease our facilities and our lease ends on July 10, 2020. Our current monthly rent payment is NIS 19,500 (approximately $5,500). Our subsidiary, THR, rents headquarters, lab and clinics in different cities in Tennessee. The main lease agreement is for THR's headquarters and lab in Brentwood, Tennessee, which is estimated at $31,000 per month and ends in August 2028. Our current total monthly rent payment for THR's seven operating lease agreements is approximately $80,874. THR is currently in default with regards to the payment of each of its leases, including its headquarters, a lab and clinics in different cities in Tennessee.

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. Our discussion and analysis for the year ended December 31, 2016 can be found in our Annual Report on Form 20-F for the fiscal year ended December 31, 2017, filed with the SEC on March 26, 2018.

The following financial data in this narrative are expressed in thousands, except for share and share data or as otherwise noted.

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 cannabinoids pharmaceuticals. We are focusing on a drug development program that we call *Joint Pharma*, which targets the treatment of the central nervous system and related indications with our product candidate THX-110. As part of our Joint Pharma program, we are also developing THX-150 and THX-160, which target multi drug resistant bacteria and pain, respectively.

THX-110 is a combination drug candidate based on two components: (1) dronabinol, the active ingredient in an FDA approved synthetic analog of THC, which is the major cannabinoid molecule in the cannabis plant, and (2) PEA, which is an endogenous fatty acid amide that belongs to the class of nuclear factor agonists, which are molecules that regulate the expression of genes. We believe that the combination of THC and PEA may induce a reaction known as the "entourage effect," which has strong potential to treat Tourette syndrome, OSA and pain. THX-150 is a drug candidate intended for the treatment of infectious diseases. It consists of dronabinol (synthetic Δ9-tetrahydracannabinol) and/or PEA and selected antibacterial agent and possesses antimicrobial synergy potential. THX-160 is a novel pharmaceutical CB2 receptor agonist for the treatment of pain.

A. Operating Results

We have not generated any revenues since our inception.

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,	
	2018	**2017**
	(in thousands of U.S. dollars)	
Wages and related expenses	667	321
Share-based payments	109	103
Clinical studies	692	511
Research and preclinical studies	593	362
Chemistry and formulations	54	330
Regulatory and other expenses	595	276
	2,710	1,943

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

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,	
	2018	2017
	(in thousands of U.S. dollars)	
Wages and related expenses	1,866	808
Share-based payment	495	759
Professional and directors fees	1,407	1,007
Investor relations and business expenses	368	871
Office maintenance, rent and other expenses	768	211
Regulatory expenses	77	80
Expenses due to litigations & claims	250	-
Business development	1,348	74
Total	6,579	3,810

Comparison of the year ended December 31, 2018 to the year ended December 31, 2017

Results of Operations

	December 31,	
	2018	2017
	(in thousands of U.S. dollars)	
Research and development expenses	2,710	1,943
General and administrative expenses	6,579	3,810
Other expense (income), net	425	1
Operating loss	9,714	5,754
Financial Expense (income), net	(705)	490
Tax benefit	(60)	-
Net loss	8,949	6,244
Net loss attributable to holders of Ordinary Shares	8,523	6,244

Research and Development Expenses

Our research and development expenses for the year ended December 31, 2018 amounted to $2,710, representing an increase of $767, or 39%, compared to $1,943 for the year ended December 31, 2017. The increase was primarily attributable to an increase of $346 in wages and related expenses, an increase of $319 in regulatory and other expenses, an increase of $231 in research and preclinical studies and a decrease of $276 in chemistry and formulations, reflecting the continuance of clinical studies, research and preclinical studies. Research and development expenses for the year ended December 31, 2018 reflect increased research and development operations due to the continuance of the cannabinoid projects.

General and administrative expenses

Our general and administrative expenses totaled $6,579 for the year ended December 31, 2018, representing an increase of $2,769 or 73%, compared to $3,810 for the year ended December 31, 2017. The increase was primarily attributable to hiring new employees, rise in wages and related expenses, business development expenses and professional and directors' fees.

Other expense and income

Our other expense and income for the year ended December 31, 2018 was $425, representing an increase of $424, or 425%, as compared to other expense and income of $1 for the year ended December 31, 2017. The increase was primarily attributable to impairment of goodwill and intangible assets.

Operating loss

Our operating loss for the year ended December 31, 2018 was $9,714, representing an increase of $3,960, or 69%, as compared to an operating loss of $5,754 for the year ended December 31, 2017.

Financial expense and income

Financial expense and income consist of exchange rate differences, bank fees, loans interest and other transactional costs.

We recognized financial income net, for the year ended December 31, 2018, of $705, representing a change of $1,195, as compared to financial expenses, net of $490 for the year ended December 31, 2017. The change was primarily due to changes in the fair value of financial instruments, interest income and exchange rate valuation losses on dollar balances.

Total Comprehensive Loss

Our total comprehensive loss for the year ended December 31, 2018 was $9,234, representing an increase of $3,451, or 60%, as compared to $5,783 for the year ended December 31, 2017.

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, 2018. 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

Our employees and other service providers 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-Merton 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 is based on fluctuations in the price of our ADS prices on the Nasdaq Capital Market.

Risk free interest rate - The risk free interest rate is based on the U.S. Treasury yield curve, in accordance with the option's contractual term.

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 - The share price is determined according to the last known or above closing price of our ADSs at the grant date.

B. Liquidity and Capital Resources

Overview

Since our inception in 2004, and through December 31, 2018, we have funded our operations principally with $4,193 from the issuance of Ordinary Shares (including ADSs) and warrants. As of December 31, 2018, we had $1,485 in cash and cash equivalents, and an additional amount of $10 in short-term bank deposits.

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

	December 31,	
	2018	**2017**
	(in thousands of U.S. dollars)	
Operating activities	(7,132)	(4,579)
Investing activities	(2,094)	(53)
Financing activities	1,536	13,175
Effect of exchange rate changes on cash	(20)	(24)
Net increase (decrease) in cash and cash equivalents	(7,710)	8,519

Operating Activities

Net cash used in operating activities was $7,132 during 2018 in comparison $4,579 during 2017. The increase of $2,553 was primarily attributable to an increase in research and development and general and administrative expenses.

Investing Activities

Net cash used in investing activities of $2,094 during the year ended December 31, 2018 primarily reflected the issuance of convertible loans to Cure Pharmaceutical Holding Corp, or Cure and an investment in THR.

Net cash used in investing activities of $53 during the year ended December 31, 2017 primarily reflected purchasing of equipment.

On April 17, 2018, we lent Cure an amount of $0.5 million, or the Cure Loan, in a convertible loan agreement. According to the convertible loan agreement, we had the option to instruct Cure, prior to the maturity date of the loan, to repay the loan amount together with all interest accrued thereon. On December 31, 2018, we instructed Cure to repay the loan (with the accrued interest) on the maturity date. The Cure Loan was fully repaid, including interest, on April 30, 2019, and the convertible loan agreement was terminated with no further effect.

During 2018 and 2019, we lent THR approximately $2.31 million in THR, through convertible loans. On October 3, 2018, we converted an aggregate of approximately $1.63 million of convertible loans issued and, as a result of the conversion and other non-cash startup expenses previously provided to THR, we obtained an equity ownership interest of 82.36% in THR. We currently have approximately $688 in convertible loans outstanding to THR.

Financing Activities

Net cash provided by financing activities of $1,536 in the year ended December 31, 2018 consisted mainly of $1,481 of net proceeds from the issuance of convertible debentures.

Net cash provided by financing activities of $13,175 in the year ended December 31, 2017 consisted mainly of $13,800 of net proceeds from our U.S. initial public offering, or U.S. IPO, offset by expenses relating to our U.S. IPO and listing on Nasdaq in March 2017, of $2,021.

In March 2017, we issued to an investor 5,357,143 Ordinary Shares in a private placement, at a price per share of NIS 0.70 (approximately $0.19). In addition, the investor was entitled to price protection rights to participate in our future private placements or public offerings upon the same or lesser terms offered to future investors, on a pro-rata basis to his holdings. Since we issued ADSs in the IPO which took place later in March 2017 at a public offering price of $6.00 per ADS, which is less than $7.71 per ADS (approximately $0.19 per Ordinary Share), we issued the investor an additional 1,529,910 Ordinary Shares.

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. IPO and the exercise of the underwriters' option, respectively, at a price of $6.00 per ADS**.**

On November 23, 2018, we entered into a securities purchase agreement and a registration rights agreement with YA II PN Ltd., or YA II PN, a fund managed by Yorkville Advisors Global L.P., for the sale in a private placement of up to $2.5 million in principal amount of unsecured convertible debentures, or the Debentures. Interest on the Debentures will accrue at a rate of 5% per annum and is payable upon the maturity date of the Debentures, being 12 months from the issuance of each Debenture. The first tranche of $1.5 million of the Debentures was issued on November 23, 2018, and YA II PN received 9,171 ADSs as a commitment fee. The outstanding principal, together with accrued and unpaid interest, will be convertible, at the option of the YA II PN, into ADSs at 95% of the lowest daily volume weighted average price during the five consecutive trading days, immediately preceding the conversion date. Provided that the ADSs are trading below $7.00, we have the right to redeem in cash the Debentures at 110% of the principal amount of the Debentures plus accrued interest. To date, the outstanding debt under the Debenture is $1.25 million, after paying YA II PN approximately $0.25 million in exchange of YA II PN participating in the April 2019 fundraising. On March 14, 2019, an amendment to the securities purchase agreement was signed due to the fact that we did not comply with certain abovementioned conditions and accordingly deemed to be in default by YA II PN. According to the amendment, YA II PN agreed to waive the requirements under the securities purchase agreement and as such, we are not in default pursuant to the terms of the securities purchase agreement. In addition, we and YA II PN mutually agreed to waive any and all requirements to hold a second closing or third closing.

On April 1, 2019, we issued 642,853 ADSs in a public offering at a purchase price of $3.50 per ADS, and warrants to purchase 482,139 ADSs with an exercise price of $3.50 per ADS, in a concurrent private placement.

Current Outlook

We have financed our operations to date primarily through proceeds from sales of our Ordinary Shares and ADSs exercises of warrants 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, 2018, our cash and cash equivalents including short-term bank deposits were $10.

We believe that our existing cash resources, including the funds that we raised in our April 2019 offering, will be sufficient to fund our current operations at least until October 31, 2019; 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 April 2019 registered direct offering of ADSs and private placement of warrants and other past fundraisings) 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, 2018:

	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
	(in thousands of U.S. dollars)				
Operating leases:					
License and contractual agreements (1-4)	1,219	223	996		
Facility (5-6)	4,716	825	1,218	937	1,736

(1) As of December 31, 2018, we had contractual obligations with respect to (1) clinical investigation and laboratory services contract with Hannover Medical School to conduct a phase IIb clinical trial, in the amount of $835, (2) our agreement with Assuta to conduct a Phase IIa, sponsor-initiated trial for the treatment of OSA using our proprietary cannabinoid-based technology, THX-110, in the amount of $35, (3) license technology agreement with Yissum in order to develop, obtain regulatory approvals, manufacture, market, distribute or sell products in the amount of $135, (4) our agreement with FGK to perform CRO activities for the Tourette syndrome study, in the amount of $214, (5) our lease agreement with a third party for an area of approximately 2,153 square feet, in the amount of $114, and (6) THR lease agreements with a third party in the aggregate of approximately 53,417 square feet, in the amount of $4.602.

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 May 13, 2019:

Name	Age	Position
Dr. Ascher Shmulewitz	63	Chairman of the Board of Directors and Interim Chief Executive Officer
Oz Adler	32	Chief Financial Officer
Dr. Adi Zuloff-Shani	50	Chief Technologies Officer
Amit Berger (1) (2) (3)	53	Director
Dr. Yafit Stark (1) (2) (3)	65	Director
Zohar Heiblum (1) (2) (3)	63	Director
Stephen M. Simes (3)	67	Director
Eric So (3)	43	Director

(1) Member of the Compensation Committee
(2) Member of the Audit Committee
(3) 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 and was appointed our interim Chief Executive Officer on November 1, 2017. 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.

Mr. Oz Adler, CPA, has served as our Chief Financial Officer since April 24, 2018 and as our VP Finance from March 1, 2018 until April 24, 2018. He previously served as our Controller commencing in September 2017. Mr. Adler has experience in a wide variety of managerial, financial, tax and accounting. Since 2012, Mr. Adler was employed as a certified public accountant at Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global. Mr. Adler holds a B.A. degree in Accounting and Business management from The College of Management, 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 a research and development 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. 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 25 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. Dr. Stark has served as Vice President Global Clinical Research at Teva Pharmaceutical Industries Ltd. Dr. Stark has established and managed 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 31 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. 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 and led the company to an IPO on Tel Aviv Stock Exchange in 1994. Since then, Mr. Heiblum has been involved in various companies as an investor, consultant, board member and active Chairman. Since 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 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 Ltd. (in receivership) and as chairman of Z. Roth Industries Ltd., which is a leading metal designer and producer of products designed to be situated in 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 research and development, which acts as the executive agency of the Israel Innovation Authority. 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. Mr. Simes currently serves as an advisor and consultant to biopharma companies. Mr. Simes is a member of the Ops Team of SmartHealth Activator. Mr. Simes serves on the advisory board for NeuroLucent a biotech company working on novel approaches for the treatment of Alzheimer's disease, in addition to several other startup biopharma companies in oncology and 3D bioprinting. 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 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. Eric So has served on our Board of Directors since June 2017. Mr. So has over 15 years' experience advising both private and public companies. He has been the Managing Director, Co-founder and chief strategy officer for Globalive Technology Partners Inc. since December 2017 and has been chairman of HyperBlock Technologies Corp. since October 2017. Mr. So has served as chief legal and corporate development officer, a private internet marketing company, since 2012. Mr. So served as a director of Riot Blockchain, Inc. from October 2017 until February 2018. An alumnus of Torys LLP, Eric holds a Bachelor of Science from McGill University and a law degree from the University of Windsor.

Scientific Advisory Board

We have a Scientific Advisory Board of seven researchers in the field(s) of: psychiatry, Tourette syndrome, 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 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.

Dr. Yossi Tam received his B.Med.Sc., M.Sc., Ph.D. and D.M.D. from the Hebrew University of Jerusalem. Dr. Tam did his postdoctoral training at the National Institutes of Health (NIH), and in 2011, became a staff scientist at the NIH. In June 2014, Dr. Tam moved to the Hebrew University of Jerusalem, where he heads the Obesity and Metabolism Laboratory at the Institute for Drug Research, and focuses on targeting the endocannabinoid (eCB) system for Obesity, Diabetes and the metabolic syndrome. Dr. Tam also serves as the Director of the Hebrew University's Multidisciplinary Center on Cannabinoid Research and a Scientific Advisory Board Member of several biotech companies, which develop a portfolio of non-psychoactive cannabinoid and cannabinoidmodulating medicines for unmet market needs. Dr. Tam won major national and international grants, and authored over 40 peer-reviewed papers in leading journals, and two book chapters. Having a clinical background with basic science training, Dr. Tam has always been interested in how science can directly improve people's everyday lives. Thus, he has strived unceasingly to integrate his clinical curiosity and experimental knowledge, in order to deepen the understanding of clinically relevant research questions.

Prof. Elon Eisenberg, is the Dean of the Faculty of Medicine at the Technion - Israel Institute of Technology. Prof. Eisenberg is a Professor of Neurology and Pain Medicine at the Faculty of Medicine and holds the Otto Barth Family Academic Chair in Biomedical Science. Prof. Eisenberg graduated from Sackler School of Medicine, Tel-Aviv University in Israel. Prof. Eisenberg completed a residency in Neurology, at Rambam Medical Center, Haifa, Israel, and Neurology - Pain Fellowship at Massachusetts General Hospital, Harvard Medical School in Boston, USA. Prof. Eisenberg has been the director of the Institute of Pain Medicine at Rambam Health Care Campus, Haifa, Israel, and the President of the Israeli Pain Association. Prof. Eisenberg is currently the director of the Pain Research Unit at the Institute of Pain Medicine, Rambam Health Care Campus. H Prof. Eisenberg's main areas of research include mechanisms and treatment of pain with special emphasis on neuropathic pain, CRPS, cancer pain, opioids and cannabinoids. Prof. Eisenberg has published about two-hundred articles, book chapters and other manuscripts in various areas of pain.

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 Tourette syndrome 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 Tourette syndrome. Over the past eighteen years, Dr. Müller-Vahl has investigated more than 12000 patients with Tourette syndrome, both children and adults, and has served as the head of the Tourette syndrome 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 Tourette syndrome, 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, five 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 Tourette syndrome, 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, 2018. 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, 2018.

	Salary/ Fee and Related Benefits	Pension, Retirement and Other Similar Benefits	Share Based Compensation
All directors and senior management as a group, consisting of 9 persons (*)	$ 986	59	$ 517

(*) Includes Doron Ben Ami, our former Chief Strategy Officer. Mr. Ben Ami resigned in May 2018.

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, 2018.

Annual Compensation (in thousands of U.S. dollars)

Executive Officer	Salary/ Fee and Related Benefits	Pension, Retirement and Other Similar Benefits	Share Based Compensation (1)	Total
Dr. Ascher Shmulewitz, Interim Chief Executive Officer and Chairman	$ 401	$ -	$ 273	$ 674
Dr. Adi Zuloff-Shani, Chief Technologies Officer	$ 224	$ 34	$ 51	$ 309
Oz Adler, Chief Financial Officer	$ 184	$ 25	$ 21	$ 230
Stephen Simes, Director	$ 33	$ -	$ 53	$ 86
Other directors on an individual basis (2)	$ 33	$ -	$ 33	$ 63

(1) Share based compensation includes the cost of our non-cash share-based compensation in 2018.

(2) Unless otherwise detailed in this table, all of our non-executive directors received the same amount of compensation for the year ended December 31, 2018.

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 Chairman and each of our executive officers. 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, subject to a pre-determined target-based bonus plan, which is usually set during the first quarter of each calendar year following the recommendation of our compensation committee and the approval of our Board of Directors. The annual 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 interim Chief Executive Officer and Chairman.

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 six members. We believe that Mr. Berger, Mr. Heiblum, Dr. Stark, Mr. Simes and Mr. So are all "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. The terms of our interim Chief Executive Officer and Chairman are currently subject to the services agreement that we have entered into with him (in his capacity as an active Chairman), which terms were approved with the prior review and approval of our compensation committee, the Board of Directors and the general meeting of our shareholders (see below regarding appointment of our Chairman as our interim Chief Executive Officer for a term of three years). All other executive officers are appointed by the Board of Directors or by our interim 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 in case the terms are not compatible with the provisions of the compensation policy, to our shareholders' approval as well), 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-year 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 allow 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, our Chairman is also acting as our interim Chief Executive Officer, which was approved by our shareholders at our 2017 annual general meeting, for no additional compensation, for a term of no more than three years (until November 1, 2020).

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 of Directors, 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 research and development and clinical trials committee are described below. See "—Committees of the Board of Directors" 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, or the External Directors Relief Resolution. As of the date hereof, the required conditions precedent of said External Directors Relief Resolution are still satisfied.

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 foregoing 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.

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: two of which (the audit committee and the compensation committee) are mandatory (and to date comprised of the same members and combined into one functional 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, reviewing regulatory authorities' findings, receiving reports regarding irregularities and legal compliance, acting according to "whistleblower policy" and recommending to our Board of Directors if so required, and overseeing our policies and procedures regarding compliance with 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 and our shareholders approved an amended compensation policy at our 2017 annual general meeting of shareholders on November 1, 2017.

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 during and for as long as our ADSs are listed on the Nasdaq Capital Market.

Internal Auditor

Under the Companies Law, the board of directors of an Israeli public company 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 an 84 months run-off insurance under reasonable customary terms. In addition, we have a similar insurance framework included and in effect under our compensation policy.

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 we 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 a 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, 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 initial public offering in the United States and any other subsequent public offerings, 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 initial public offering in the United States and any other subsequent public offerings.

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 December 31, 2018, we had three members of senior management (including our Chairman), all of whom are full-time employees. In addition, we had eight 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 May 13, 2019, 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	7,851,988(3)	3.93%
Oz Adler	216,668(4)	*
Dr. Adi Zuloff-Shani	1,025,000(5)	*
Stephen M. Simes	995,833(6)	*
Amit Berger	437,500(7)	*
Dr. Yafit Stark	437,500(7)	*
Zohar Heiblum	437,500(7)	*
Eric So	437,500(7)	*
All directors and executive officers as a group (8 persons)	11,839,490(8)	5.93%

* 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 199,561,352 Ordinary Shares issued and outstanding as of May 13, 2019 plus Ordinary Shares relating to options and warrants 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) 669,680 Ordinary Shares, options to purchase 423,037 Ordinary Shares at an exercise price of NIS 0.79 (approximately $0.21) per share and options to purchase 250,000 Ordinary Shares at an exercise price of NIS 0.50 (approximately $0.14) per share, held directly by Dr. Shmulewitz, (ii) 2,338,440 Ordinary Shares, held by Dekel, which is an Israel company controlled by Dr. Shmulewitz; and (iii) options to purchase 1,983,331 Ordinary Shares at an exercise price of NIS 0.50 (approximately $0.14) per share, and options to purchase 2,187,500 Ordinary Shares at an exercise price of NIS 0.72 (approximately $0.19) per share held by Medgenesis Partners Ltd., which, to the best of our knowledge, is an Israeli company controlled by Dr. Shmulewitz.

(4) Includes options to purchase 216,668 Ordinary Shares at an exercise price of NIS 0.50 (approximately $0.14) per share.

(5) Includes options to purchase 500,000 Ordinary Shares at an exercise price of NIS 1.06 (approximately $0.28) per share and options to purchase 525,000 Ordinary Shares at an exercise price of NIS 0.50 (approximately $0.14) per share.

(6) Includes options to purchase 558,333 Ordinary Shares at an exercise price of NIS 0.86 (approximately $0.23) per share and options to purchase 437,500 Ordinary Shares at an exercise price of NIS 0.50 (approximately $0.14) per share.

(7) Consists of options to purchase 437,500 Ordinary Shares at an exercise price of NIS 0.50 (approximately $0.14) per share.

(8) Includes options to purchase 8,831,370 Ordinary Shares.

Equity Incentive Plans

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

In July 2005, we adopted the Israeli Share Option Plan (2005), or 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 May 13, 2019, 31,000,000 Ordinary Shares were reserved for issuance under the plans, of which options to purchase 17,390,000 Ordinary Shares were issued and outstanding thereunder. Of such outstanding options, options to purchase 10,438,024 Ordinary Shares were vested as of May 13, 2019, with a weighted average exercise price of NIS 0.59 (approximately $0.17) 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 three 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 and such option agreements may contain acceleration provisions upon certain merger, acquisition, or change of control transactions. 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 of Directors, 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 of Directors, 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

As of May 13, 2019, none of the holders of our Ordinary Shares had beneficial ownership of 5% or more of our outstanding Ordinary Shares.

Changes in Percentage Ownership by Major Shareholders

During the last three years, there were no significant changes in percentage ownership by major shareholders (i.e., of or more than 5% of our issued and outstanding share capital) except as detailed below:

- Dr. Haim Amir invested approximately $1,000,000 in March 2017, in consideration of an aggregate of 5,357,143 Ordinary Shares, constituting approximately 11.6% of our issued share capital after the investment, which reduced the beneficial ownership percentages of our other major shareholders. Dr. Amir's holdings were later reduced in our public offering in April 2017, as mentioned below.

- We issued 2,300,000 ADSs in a public offering in March and April 2017, constituting approximately 65.8% (in the aggregate) of our issued share capital after the offering, which reduced the beneficial ownership percentages of our major shareholders.

Record Holders

As of May 13, 2019, there were six holders of record of our Ordinary Shares, one of which has a registered address in the United States. Based upon a review of the information provided to us by The Bank of New York Mellon, the depository of the ADSs, as of May 13, 2019, there were 69 holders of record of the ADSs on record with the Depository Trust Company.

These numbers are not representative of the number of beneficial holders of our shares nor is it representative of where such beneficial holders reside, since many of these shares were held of record by brokers or other nominees.

We are not controlled by another corporation, by any foreign government or by any natural or legal persons except as set forth herein, and there are no arrangements known to us which would result in a change in control 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 employees, officers, service providers 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 and our interim Chief Executive Officer, 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 former major shareholders, which 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, pursuant to which we paid Dekel the first milestone payment of $25,000 in cash in March 2017. On April 24, 2018, we paid to Dekel the second milestone under the license agreement in the amount of $75,000 upon the successful completion of our Phase IIa trial.

Except as mentioned above, no other milestone was achieved during 2018 and to the date hereof.

In addition, we are required to pay a third milestone payment of $75,000 upon the earlier of: (i) generating net revenues of at least $200,000 from the commercialization of the technology, or (ii) the approval of the FDA / the EMA of a drug based on the licensed assets. Subject to our discretion, the milestone payment is 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.

Yissum License Agreement

On July 29, 2018, we entered into the Yissum License Agreement. According to the Yissum License Agreement, we shall pay Yissum royalties at the rates of 3% of net sales, subject to the royalty reductions as described in the Yissum License Agreement. All of the reductions in the royalties combined, in aggregate, shall be capped at, and not exceed, 50% of the respective royalty rate. We are also obligated to pay sublicense fees, which will be paid at a rate of 20% of the sublicense consideration.

All right, title and interest in and to the Yissum License Agreement shall vest solely in Yissum, and we shall hold and make use of the rights granted. All rights in the development results shall be solely owned by us, except to the extent that an employee of the Yissum, including the researcher, is considered an inventor of a patentable invention arising from the development results, in which case such invention and all patent applications and/or patents claiming such invention shall be owned jointly by us and Yissum, as appropriate, and Yissum's share in such joint patents shall be automatically included in the Yissum License Agreement.

On October 4, 2018, we paid Yissum a total amount of $50,000 due under the Yissum License Agreement. We estimate that the expenses due to the research program of the Yissum License Agreement and additional reimbursement for historical patent costs will be approximately $135,000.

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 former 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 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 were 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 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 or 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 was entitled to price protection 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 U.S. IPO on Nasdaq at a public offering price of $6.00 per ADS, which is less than $7.71 per ADS, we issued 1,529,910 Ordinary Shares to Dr. Haim Amir according to the price protection provision mentioned above.

Investment in Therapix Healthcare Resources Inc.

On July 26, 2018, and as amended in July, August and October 2018, we entered into an agreement for convertible loans, or the Convertible Loans Agreement, with THR, a Delaware corporation, which was engaged in operating pain treatment clinics to treat an assortment of different pains, including, acute pain, spine pain, chronic headaches, cancer pain, oral/maxillofacial pain, neuropathic pain and rheumatologic/myofascial pain. On July 31, 2018, THR entered into an asset purchase agreement with a third party for equipment, a laboratory and patient medical records.

On October 3, 2018, we converted an aggregate of approximately $1.65 million of convertible loans issued under the Convertible Loans Agreement and, as a result of such conversion and other non-cash startup expenses previously provided to THR, we obtained an equity ownership interest of 82.36% in THR. We currently have approximately $688,000 in convertible loans outstanding to THR.

Dr. Ascher Shmulewitz, our Chairman and interim Chief Executive Officer, serves as the chairman of THR. Dr. Shmulewitz has not and currently does not receive compensation in his capacity as chairman of THR.

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

Liquidation of Therapix Healthcare Resources, Inc.

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On October 3, 2018, we converted an aggregate of approximately $1.63 million of convertible loans issued under the Convertible Loans Agreement and, as a result of such conversion and other non-cash startup expenses previously provided to THR, we obtained an equity ownership interest of 82.36% in THR. We currently have approximately $688,000 in convertible loans outstanding to THR.

Due in part to significant losses incurred by THR, as well as its failure to maintain required licenses to operate its facilities, THR has commenced liquidation of its assets. The liquidation of THR's remaining assets, or potential claims that may arise from the liquidation and dissolution of THR may adversely affect our reputation or divert our management's attention in the event of any material litigation or in the event that the liquidation process is prolonged. At this time, neither we nor THR is able to estimate reliably the timing and results of the proposed liquidation or of any consequences that may occur as a result thereof.

In addition, as of December 31, 2018, several claims were filed against THR by different suppliers, due to the fact that THR, due to its economic situation, was, and is not able to comply with the terms of the contracts signed with each specific supplier. The claims are in an amount aggregating to approximately $789,000. THR is looking to settle all claims and as of December 31, 2018, has recorded a provision of $250,000.

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 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." From December 26, 2005 to August 9, 2018, our Ordinary Shares were traded on the TASE.

B. Plan of Distribution

Not applicable.

C. Markets

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 51-358165-2.

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 our issued and outstanding share capital and at least 1% of our voting rights, or one or more shareholder, which holds at least 5% of our 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 were traded on the TASE, the Securities Law did 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 has 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 our 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 23% of a company's taxable income. 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.

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 research and development 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 six times the value of the grants received plus interest, with a possibility to reduce such payment to up to three times the value of the grants received plus interest if the research and development 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.

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 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 24%. 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 (23% in 2018, and in 2019).

Individual and corporate shareholder dealing in securities are taxed at the tax rates applicable to business income– 23% for corporations in 2018 and a marginal tax rate of up to 50% in 2018 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, 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.

Excess Tax

Individuals who are subject to tax in Israel are also subject to an additional tax at a rate of 3% as of 2018 on annual income exceeding a certain threshold (NIS 641,880 for 2018 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 and 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, (including with respect to the TCJA, as defined below), 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 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 partnerships (or other pass-through entities) or persons who hold Ordinary Shares or ADSs through a partnership or other pass-through entity are not addressed.

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 and the discussion of "qualified dividend income" below, a U.S. Holder, other than certain U.S. Holder's that are U.S. corporations, 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, unless such corporate holders hold at least 10% of our shares and are eligible for a dividend received deduction, as described below. We do not expect to maintain calculations of our earnings and profits under U.S. federal income tax principles and, therefore, U.S. Holders should expect that the entire amount of any distribution generally will be reported as dividend income.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, or the TCJA. The TCJA provides a 100% deduction for the foreign-source portion of dividends received from "specified 10-percent owned foreign corporations" by U.S. corporate holders, subject to a one-year holding period. No foreign tax credit, including Israeli withholding tax (or deduction for foreign taxes paid with respect to qualifying dividends) would be permitted for foreign taxes paid or accrued with respect to a qualifying dividend. This deduction would be unavailable for "hybrid dividends." The dividend received deduction enacted under the TCJA may not apply to dividends from a passive foreign investment company, as discussed below.

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 and the TCJA, 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. Individuals who recognize long-term capital gains may be taxed on such gains at reduced rates of tax. The deduction of capital losses is subject to various limitations.

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. An additional 3.8% net investment income tax (described below) may apply to gains recognized upon the sale, exchange or other taxable disposition of our Ordinary Shares or ADS by certain U.S. Holders who meet certain income thresholds.

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 have been a PFIC during 2018 although we have not determined whether we will be a PFIC in 2019, 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 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; or (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 24% 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 recently enacted legislation, 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, or FBAR, 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.

Tax Cuts and Jobs Act

On December 22, 2017, President Trump signed into law the TCJA. Although this is the most extensive overhaul of the United States tax regime in over thirty years, other than for certain U.S. corporate holders, none of the provisions of the TCJA are expected to materially impact U.S. Holder's with respect to such holder's ownership of our Ordinary Shares or the ADSs.

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. The SEC 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.

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 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 mainly in NIS/U.S. dollar currency exchange rates. As of December 31, 2018, approximately three-quarters of our liquid assets are held in U.S. dollars, and the majority of our expenses is denominated in U.S. dollars. Changes of 5% and 10% in the U.S. Dollar/NIS exchange rate would decrease/increase our loss for 2018 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. Beginning October 1, 2018, our functional currency is the U.S. dollar.

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

***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 (including rights) that 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 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 (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

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

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

See Item 8.A “Consolidated Statements and Other Financial Information—Legal Proceedings—Liquidation of Therapix Healthcare Resources, Inc.” for additional information.

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

None.

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, 2018, 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

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with International Financial Reporting Standards, or IFRS. We have a program for the review of our internal control over financial reporting to ensure compliance with the requirements of the Exchange Act and Section 404 of the Sarbanes-Oxley Act. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with IFRS;
- provide reasonable assurance that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

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

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In conducting its assessment of internal control over financial reporting, management based its evaluation on the Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission as at December 31, 2018. Based on its evaluation, our management has concluded that our internal control over financial reporting was effective as at December 31, 2018.

(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, 2018, 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, 2017 and 2018. Kost Forer Gabbay & Kasierer (a member of EY Global) has served as our principal independent registered public accounting firm since 2009 [(1)].

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, 2017 and 2018:

	Year Ended December 31,	
	2017	**2018**
Audit fees	$ 160,000	$ 210,000
Audit-related fees [(2)]	-	80,000
Tax fees [(3)]	$ 11,700	$ 15,000
All other fees [(4)]	-	6,000
Total	$ 171,700	$ 311,000

(1) In our Notice of Meeting and Proxy Statement for our Annual General Meeting of Shareholders held Thursday, March 7, 2019, we mistakenly stated that EY Global has audited our financial statements during the last 14 years.
(2) 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.
(3) Includes ongoing tax consultation.
(4) Includes consulting for financing purposes.

Pre-Approval of Auditors' Compensation

We previously approved an audit committee's charter, under which, among others, our audit committee is responsible for, among others: (1) pre-approving audit and non-audit services provided to us by the independent registered public accounting firm; (2) review and approve disclosures relating to fees and non-audit services required to be included in the SEC reports; (3) Subject to the 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 (4) to establish pre-approval policies and procedures for the engagement of independent accountants to render us services.

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, we are 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 have elected 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 in consistency 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, or (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; 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 a specified minimum price. 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.

- *Annual Shareholders Meeting.* As opposed to the Nasdaq Stock Market Rule 5620(a), which mandates that a listed company hold its annual shareholders meeting within one year of the company's fiscal year-end, we are required, under the Companies Law, to hold an annual shareholders meeting each calendar year and within 15 months of the last annual shareholders meeting.

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).
2.4	Form of Warrant to purchase Ordinary Shares Represented by American Depositary Shares, dated March 2019 (filed as Exhibit 4.1 to Form 6-K (File No. 001-38041) filed on March 28, 2019, and incorporated herein by reference).
2.(d)	Description of Securities (filed herewith).
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	License Agreement dated July 29, 2018, by and between the Company and Yissum Research Development Company of the Hebrew University of Jerusalem Ltd. (filed herewith).**
4.3	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).
4.4	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).
4.5	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).
4.6	Form of Indemnification Agreement (filed as Exhibit 4.12 to our Annual Report on Form 20-F as filed with the Securities and Exchange Commission on May 1, 2017, and incorporated herein by reference).
4.7	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).
4.8	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).
4.9	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).
4.10	Second Amendment to License Agreement dated as of September 17, 2017, by and between the Company and Dekel Pharmaceuticals Ltd. (filed as Exhibit 4.16 to our Annual Report on Form 20-F as filed with the Securities and Exchange Commission on April 30, 2018, and is incorporated herein by reference).
4.11	Amended Compensation Policy approved by the Company's shareholders on October 25, 2017 (filed as Annex B to Exhibit 1 to our Form 6-K filed on September 19, 2017, and incorporated herein by reference).
4.12	Form of Securities Purchase Agreement, dated March 28, 2019 (filed as Exhibit 10.1 to Form 6-K (File No. 001-38041) filed on March 28, 2019, 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).
15.1	Consent of Kost, Forer, Gabbay & Kasierer, a member of EY Global (filed herewith).
101	The following financial statements from the Company's 20-F for the fiscal year ended December 31, 2018 formatted in XBRL: (i) Consolidated Statements of Profit or and Loss, (ii) Consolidated Statements of Comprehensive Income, (iii) Consolidated Statements of Financial Position, (iv) Consolidated Statements of Changes in Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to the Consolidated Financial Statements.

* Confidential treatment was granted with respect to certain portions of this exhibit pursuant to 17.C.F.R. §240.24b-2. Omitted portions were filed separately with the SEC.

** Certain identified information in the exhibit has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to Therapix if publicly disclosed.

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/ Ascher Shmulewitz
Ascher Shmulewitz, M.D., Ph. D
Chief Executive Officer

Date: May 15, 2019

THERAPIX BIOSCIENCES LTD.

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2018

U.S. DOLLARS IN THOUSANDS

INDEX

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the Shareholders and the Board of Directors of
THERAPIX BIOSCIENCES LTD

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Therapix Biosciences Ltd. and its subsidiaries (the "Company") as of December 31, 2018 and 2017, 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, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2018 and 2017, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1c to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1c. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KOST FORER GABBAY & KASIERER
KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

Haifa, Israel
May 15, 2019

We have served as the Company's auditor since 2009.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31, 2018	December 31, 2017
		USD in thousands	
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	6	$ 1,485	$ 9,195
Restricted deposits		10	24
Other accounts receivable	7	404	278
Convertible loan	8	531	-
		2,430	9,497
NON-CURRENT ASSETS:			
Restricted deposit	16k	23	-
Prepaid public offering costs		-	19
Property and equipment, net	10	2,107	50
		2,130	69
		$ 4,560	$ 9,566

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

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31, 2018	December 31, 2017
		USD in thousands	
LIABILITIES AND EQUITY			
CURRENT LIABILITIES:			
Credit from others	13b	$ 91	$ -
Trade payables	11	1,618	1,017
Other accounts payable	12	844	160
Related parties	22	874	-
Convertible debenture	13c	779	-
Conversion component of convertible debenture	13c	277	-
		4,483	1,177
EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:	17		
Share capital		3,822	3,812
Share premium		38,108	36,612
Reserve from share-based payment transactions	18	4,409	5,311
Foreign currency translation reserve	2d	497	782
Transactions with non-controlling interests		261	261
Accumulated deficit		(46,912)	(38,389)
Total equity attributable to Therapix Biosciences Ltd. shareholders		185	8,389
Non-controlling interests		(108)	-
Total equity		77	8,389
Total liabilities and equity		$ 4,560	$ 9,566

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

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

	Note	Year ended December 31, 2018	2017	2016
		USD in thousands		
Research and development expenses	19a	$ 2,710	$ 1,943	$ 740
General and administrative expenses	19b	6,579	3,810	1,268
Other (income) expenses, net	19c	425	1	(8)
Operating loss		9,714	5,754	2,000
Finance income	19d	(828)	(1)	(1)
Finance expenses	19e	123	491	8
Loss before taxes		9,009	6,244	2,007
Tax benefit		(60)	-	-
Net loss		8,949	6,244	2,007
Attributable to:				
Equity holders of the Company		8,523	6,244	1,993
Non-controlling interests		426	-	14
		8,949	6,244	2,007
Basic and diluted net loss per share attributable to equity holders of the Company	20	0.06	0.05	0.05
Basic and diluted loss per ADS attributable to equity holders of the Company	20	$ 2.44	$ 2.14	$ 2.14

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

CONSOLIDATED STATEMENTS COMPREHENSIVE INCOME

	Note	Year ended December 31, 2018	2017	2016
		USD in thousands		
Net loss		$ 8,949	$ 6,244	$ 2,007
Amounts that will not be reclassified subsequently to profit or loss:				
Adjustments arising from translating financial statements from functional currency to presentation currency	2d	285	(461)	(190)
Total components that will not be reclassified subsequently to profit or loss		285	(461)	(190)
Amounts that will be or that have been reclassified to profit or loss when specific conditions are met:				
Amounts transferred to the statement of profit or loss for sale of foreign operation		-	-	6
Total components that will be or that have been reclassified to profit or loss		-	-	6
Total other comprehensive income (loss)		285	(461)	(184)
Total comprehensive loss		9,234	5,783	1,823
Attributable to:				
Equity holders of the Company		8,808	5,783	1,979
Non-controlling interests		426	-	(156)
		$ 9,234	$ 5,783	$ 1,823

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

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Attributable to equity holders of the Company									
	Share capital	Share premium	Reserve from share-based payment transactions	Foreign currency translation reserve from associate	Transactions with non-controlling interests	Accumulated deficit	Foreign currency translation reserve	Total	Non-controlling interests	Total equity
	USD in thousands									
Balance at January 1, 2016	$ 941	$ 25,132	$ 4,822	$ 6	$ 261	$ (30,152)	$ 301	$ 1,311	$ (156)	$ 1,155
Loss	-	-	-	-	-	(1,993)	-	(1,993)	(14)	(2,007)
Total other comprehensive income (loss)	-	-	-	(6)	-	-	20	14	170	184
Total comprehensive loss	-	-	-	(6)	-	(1,993)	20	(1,979)	156	(1,823)
Deconsolidation of a subsidiary (see Note 9b)	-	-	-	-	-	-	-	-	-	-
Exercise of share options	141	1,151	(378)	-	-	-	-	914	-	914
Expiration of share options	-	296	(296)	-	-	-	-	-	-	-
Cost of share-based payment	5	21	301	-	-	-	-	327	-	327
Balance at December 31, 2016	1,087	26,600	4,449	-	261	(32,145)	321	573	-	573
Loss	-	-	-	-	-	(6,244)	-	(6,244)	-	(6,244)
Total other comprehensive income (loss)	-	-	-	-	-	-	461	461	-	461
Total comprehensive loss	-	-	-	-	-	(6,244)	461	(5,783)	-	(5,783)
Issue of share capital (net of issue expenses) (1)	189	769	-	-	-	-	-	958	-	958
Issue of share capital (net of issue expenses) (2)	2,207	7,928	-	-	-	-	-	10,135	-	10,135
Issue of share capital (net of issue expenses) (3)	329	1,315	-	-	-	-	-	1,644	-	1,644
Cost of share-based payment	-	-	862	-	-	-	-	862	-	862
Balance at December 31, 2017	3,812	36,612	5,311	-	261	(38,389)	782	8,389	-	8,389
Loss	-	-	-	-	-	(8,523)	-	(8,523)	(426)	(8,949)
Total other comprehensive income (loss)	-	-	-	-	-	-	(285)	(285)	-	(285)

Total comprehensive loss	-	-	-	-	-	(8,523)	(285)	(8,808)	(426)	(9,234)
Non-controlling interests arising from initially consolidated company (see Note 5)	-	-	-	-	-	-	-	-	318	318
Issue of share capital (net of issue expenses) (see Note 13c)	10	(10)	-	-	-	-	-	-	-	-
Expiration of share options	-	1,506	(1,506)	-	-	-	-	-	-	-
Cost of share-based payment	-	-	604	-	-	-	-	604	-	604
Balance at December 31, 2018	$ 3,822	$ 38,108	$ 4,409	$ -	$ 261	$ (46,912)	$ 497	$ 185	$ (108)	$ 77

(1) Net of issuance expenses of $61 thousand.
(2) Net of issuance expenses of $1,865 thousand.
(3) Net of issuance expenses of $156 thousand.

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2018	2017	2016
	USD in thousands		
Cash flows from operating activities:			
Net loss	$ (8,949)	$ (6,244)	$ (2,007)
Adjustments to reconcile net loss to net cash used in operating activities:			
Adjustments to the profit or loss items:			
Depreciation and amortization	147	5	4
Loss (gain) from sale of equipment	(7)	1	-
Cost of share-based payment	604	862	327
Finance expenses (income), net	(748)	525	2
Impairment loss of intangible assets	273	-	-
Impairment loss of goodwill	160	-	-
Aborted public offering costs	53	-	-
Tax benefit	(60)	-	-
Gain from sale of investments in investees	-	-	(34)
	422	1,393	299
Working capital adjustments:			
Increase in other accounts receivable	(99)	(143)	(110)
Increase in trade payables	177	349	233
Increase in other accounts payable	649	66	111
Increase in related parties	668	-	-
	1,395	272	234
Net cash used in operating activities	$ (7,132)	$ (4,579)	$ (1,474)

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2018	2017	2016
	USD in thousands		
Cash flows from investing activities:			
Investment in restricted bank deposits	$ (10)	$ (11)	$ -
Purchase of property and equipment	(17)	(44)	(4)
Proceeds from sale of property and equipment	44	2	-
Proceeds from sale of an investment in previously consolidated subsidiary (a)	-	-	(1)
Grant of convertible loans	(2,125)	-	-
Acquisition of initially consolidated subsidiary (b)	14	-	-
Net cash used in investing activities	(2,094)	(53)	(5)
Cash flows from financing activities:			
Proceeds from issue of share capital (net of issuance expenses)	-	13,193	-
Proceeds from exercise of share options	-	-	914
Issue of convertible debentures (net of issuance expenses)	1,481	-	-
Prepaid public offering costs	(36)	(18)	(349)
Receipt of short-term credit from others	91	-	-
Net cash provided by financing activities	1,536	13,175	565
Exchange rate differences on cash and cash equivalents and restricted deposits in foreign currency	301	(527)	(8)
Exchange rate differences on translation differences on cash and cash equivalents	(321)	503	25
	(20)	(24)	17
Increase (decrease) in cash and cash equivalents	(7,710)	8,519	(897)
Cash and cash equivalents at the beginning of the period	9,195	676	1,573
Cash and cash equivalents at the end of the period	$ 1,485	$ 9,195	$ 676

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2018	2017	2016
	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	$ -	$ -	$ (205)
Non-controlling interests	-	-	171
Gain from sale of subsidiary	-	-	33
	-	-	(1)
(b) Acquisition of initially consolidated subsidiary:			
The subsidiaries' assets and liabilities at date of acquisition:			
Working capital (excluding cash)	648	-	-
Property and equipment	(2,192)	-	-
Customer relationships	(307)	-	-
Deferred taxes liability	60	-	-
Goodwill	(160)	-	-
Non-controlling interests	318	-	-
	(1,633)	-	-
Conversion of convertible loans	1,647	-	-
	14	-	-
(c) Significant non-cash transactions:			
Issue of share capital	10	-	-
Unpaid issue expenses	$ 30	$ -	$ 87

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" or the "Company"), a pharmaceutical company, was incorporated in Israel and commenced its operations on August 23, 2004. Until March 2014, Therapix and its subsidiaries at the time (the "Group") 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 a portfolio of approved drugs based on cannabinoid molecules. The Company's main focus will be on developing an entourage technology based cannabinoid drug for the Central Nervous System indications, including, but not limited, to Tourette syndrome, Pain, Obstructive Sleep Apnea ("OSA") and a cannabinoid based drug for Mild Cognitive Impairment using the low dose technology.

The Company was a dual-listed company, which had its shares traded on the Tel-Aviv Stock Exchange ("TASE") since December 26, 2005, and on the Nasdaq Stock Market ("Nasdaq") since March 27, 2017. On August 7, 2018, the Company delisted its shares from the TASE. The Company completed an initial public offering ("IPO") in the United States on March 27, 2017, and raised approximately $13.7 million. Since the IPO, the Company has had its American Depository Shares ("ADSs") registered with the U.S. Securities and Exchange Commission ("SEC") and has been listed on the Nasdaq.

The headquarters of Therapix are located in the Tel Aviv district (Givataaim), Israel.

As of December 31, 2018, Therapix has four subsidiaries (the "Subsidiaries"):

- NasVax Inc., a Delaware corporation - fully owned (100%);
- Brain Bright Ltd., an Israeli company - fully owned (100%);
- Evero Health Ltd. (previously Weex Biosciences Ltd.), an Israeli company - fully owned (100%);
- Therapix Healthcare Resources Inc. ("THR"), a Delaware corporation, in which control was achieved on October 3, 2018 - Therapix holds 82.36% of THR's equity. THR was established on July 31, 2018 (see Note 5).

All the Subsidiaries are private companies, and as of the date of these financial statements, except for THR, all other subsidiaries are inactive companies with no assets or liabilities. Therefore, only THR's financial statements are consolidated within the Group. Therapix also owns approximately 27% of Lara Pharm Ltd.'s ("Lara") share capital; however, the Company does not have significant influence on Lara since it has no representation in Lara's board of directors. The Company wrote-off the entire investment in Lara in 2015 (see Note 9a).

All information in the financial statements regarding the ADSs is a presumption that all of the Company's shares have been converted into ADS (Each ADS represents forty (40) ordinary shares).

The consolidated financial statements of the Group for the year ended December 31, 2018, were approved for issue on May 13, 2019 (the "Approval Date").

NOTE 1:- GENERAL (CONT.)

b. Functional currency and presentation currency:

The functional currency of the Company, which is the currency that best reflects the economic environment in which the Company operates and conducts its transactions, was the New Israeli Shekel ("NIS") until October 1, 2018, when the Company change the functional currency to the U.S. Dollars ("USD" or "$") after concluding that according to in IAS 21, "The Effects of Changes in Foreign Exchange Rates" ("IAS 21"), the USD is the primary currency of the economic environment in which the Company operates (see Note 2d).

The consolidated financial statements are presented in USD since the Company believes that preparing the consolidated financial statements in USD provides more relevant information to the investors.

c. The Group incurred a net loss of approximately $9 million and had negative cash flows from operating activities of approximately $7 million for the year ended December 31, 2018. As of December 31, 2018, the Group had an accumulated deficit of approximately $47 million as a result of recurring operating losses. As discussed in Note 1a above, the Group's business strategy is to focus on developing an entourage technology based cannabinoid drug.

As of the Approval Date of the consolidated financial statements, the Group has not yet started recognizing revenues from sales and its operation is dependent on its ability to raise additional funds from existing and/or new investors in order to finance its activity. This dependency will continue until the Group will be able to completely finance its operations by selling its products. In addition, as of the Approval Date of the consolidated financial statements, the Group has not raised the necessary funding in order to continue its activity in the foreseeable future.

These abovementioned factors raise substantial doubt about the Group's ability to continue as a going concern. The financial statements do not include any adjustments to the carrying amounts and classifications of assets and liabilities that might result should the Group be unable to continue as a going concern.

d. Definitions:

The Company	-	Therapix Biosciences Ltd.
The Group	-	Therapix Biosciences Ltd. and its investees, as detailed in Note 1a.
Subsidiaries	-	Companies that are controlled by the Company, as defined IFRS 10, "Consolidated Financial Statements" ("IFRS 10"), and whose accounts are consolidated with those of the Company (if active).
Related parties	-	As defined in International Accounting Standard ("IAS") 24, "Related Party Disclosures" ("IAS 24").

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 IFRS, as issued by the International Accounting Standards Board ("IASB").

The Group's financial statements have been prepared on a cost basis, unless otherwise indicated.

The Group has elected to present the profit or loss items using the function of expense method.

The financial statements are presented in USD and all values are rounded to the nearest thousand ('000), except when otherwise indicated.

b. The operating cycle:

The operating cycle of the Group is one year.

c. Consolidated financial statements:

The consolidated financial statements comprise 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. Potential voting rights are considered when assessing whether an entity has control. 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 the Company and of the Subsidiaries are prepared as of the same dates and periods. The consolidated financial statements are prepared using uniform accounting policies by all companies in the Group. 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. Profit or loss and components of other comprehensive income are attributed to the Company and to non-controlling interests. 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:

Effective on October 1, 2018, due to changes in certain economic facts and circumstances that indicate that the functional currency has changed from NIS to USD, the Company changed its functional currency from NIS to the USD. The Company accounted for the change in functional currency prospectively.

The Company's management believes that since October 1, 2018, the USD is the primary currency of the economic environment in which the Company operates. Thus, the functional and reporting currency of the Company is the USD. In determining the appropriate functional currency that should be used, the Company followed the guidance in IAS 21.

As of October 1, 2018, all the Company's assets and liabilities were translated using the current rate method, using the USD exchange rate as of September 30, 2018, and equity was translated using the historical exchange rate at the relevant transaction date.

Until October 1, 2018, the financial statements were translated as follows:

a) Assets and liabilities at the end of each reporting period (including comparative data) are translated at the closing rate at the end of the reporting period;

b) Income and expenses for each period included in profit or loss (including comparative data) is translated at average exchange rates for the relevant periods; however, if exchange rates fluctuate significantly, income and expenses are translated at the exchange rates at the date of the transactions;

c) Share capital, capital reserves and other changes in capital are translated at the exchange rate prevailing at the date of incurrence or at average exchange rates for the relevant periods;

d) Retained earnings are translated based on the opening balance translated at the exchange rate at that date; and

e) All resulting translation differences are recognized as a separate component of other comprehensive income (loss) in equity "foreign currency translation reserve."

Transactions denominated in foreign currency (other than the functional currency) are recorded on 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. Non-monetary assets and liabilities denominated in foreign currency and measured at fair value are retranslated into the functional currency using the exchange rate prevailing at the date when the fair value was determined. Non-monetary assets and liabilities measured at cost are translated at the exchange rate at the date of the transaction.

The functional currency of THR is the USD as well.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

e. Business combinations and goodwill:

Business combinations are accounted for by applying the acquisition method. The cost of the acquisition is measured at the fair value of the consideration transferred on the acquisition date with the addition of non-controlling interests in the acquiree. In each business combination, the Company chooses whether to measure the non-controlling interests in the acquiree based on their fair value on the acquisition date or at their proportionate share in the fair value of the acquiree's net identifiable assets.

Direct acquisition costs are carried to the statement of profit or loss as incurred.

Goodwill is initially measured at cost which represents the excess of the acquisition consideration and the amount of non-controlling interests over the net identifiable assets acquired and liabilities assumed. If the resulting amount is negative, the acquirer recognizes the resulting gain on the acquisition date.

f. Cash equivalents:

Cash equivalents are considered as highly liquid investments, including unrestricted short-term bank deposits with an original maturity of three months or less from the date of investment or with a maturity of more than three months, but which are redeemable on demand without penalty and which form part of the Group's cash management.

g. Restricted deposit:

Restricted deposit is cash invested in a short-term deposit (between three months and one year) or in a long-term deposit (with a maturity of more than one year from the date of investment).

Restricted deposits are designated to secure the Company's office facilities lease agreements and its credit cards.

h. 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 Israel's Innovation Authority (formerly: the Office of the Chief Scientist, the "IIA") are recognized upon receipt as a liability if future economic benefits are expected from the research project that will result in royalty-bearing sales.

A liability for the loan is first measured at fair value using a discount rate that reflects a market rate of interest. The difference between the amount of the 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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

h. Government grants: (Cont.)

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" ("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 a corresponding reduction in research and development expenses.

Amounts paid as royalties are recognized as settlement of the liability.

i. Fair value measurement:

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurement is based on the assumption that the transaction will take place in the asset's or the liability's principal market, or in the absence of a principal market, in the most advantageous market.

The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

Fair value measurement of a non-financial asset takes into account a market participant's ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities measured at fair value or for which fair value is disclosed are categorized into levels within the fair value hierarchy based on the lowest level input that is significant to the entire fair value measurement:

Level 1	-	Quoted prices (unadjusted) in active markets for identical assets or liabilities.
Level 2	-	Inputs other than quoted prices included within Level 1 that are observable directly or indirectly.
Level 3	-	Inputs that are not based on observable market data (valuation techniques which use inputs that are not based on observable market data).

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

j. 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:

A 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.

2. Deferred taxes:

Deferred taxes are computed in respect of temporary differences between the carrying amounts in the financial statements and the amounts attributed for tax purposes.

Deferred taxes are measured at the tax rate that is expected to apply when the asset is realized or the liability is settled, based on tax laws that have been enacted or substantively enacted by the reporting date.

Deferred tax assets are reviewed at each reporting date and reduced to the extent that it is not probable that they will be utilized. Deductible carryforward losses and temporary differences for which deferred tax assets had not been recognized are reviewed at each reporting date and a respective deferred tax asset is recognized to the extent that their utilization is probable.

Taxes that would apply in the event of the disposal of investments in investees have not been taken into account in computing deferred taxes, as long as the disposal of the investments in investees is not probable in the foreseeable future. Also, deferred taxes that would apply in the event of distribution of earnings by investees as dividends have not been taken into account in computing deferred taxes, since the distribution of dividends does not involve an additional tax liability or since it is the Company's policy not to initiate distribution of dividends from a subsidiary that would trigger an additional tax liability.

Taxes on income that relate to distributions of an equity instrument and to transaction costs of an equity transaction are accounted for pursuant to IAS 12, "Income Taxes" ("IAS 12").

Deferred taxes are offset if there is a legally enforceable right to offset a current tax asset against a current tax liability and the deferred taxes relate to the same taxpayer and the same taxation authority.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

k. 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, "Leases" ("IAS 17").

The Group as lessee:

Leases in which substantially all the risks and rewards of ownership of the leased asset are not transferred to the Group 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.

l. Property and equipment, net:

Property is measured at cost, including directly attributable 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:

	%	Mainly %
Lab equipment	6-50	33%
Computers	33-50	33%
Office furniture and equipment	20-33	25%
Vehicles	55	-
Leasehold improvements	see below	-

Leasehold improvements are depreciated on a straight-line basis over the shorter of the lease term (including the extension option held by a 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. 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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

m. Intangible assets:

Separately acquired intangible assets are measured on initial recognition at cost including directly attributable costs. Intangible assets acquired in a business combination are measured at fair value at the acquisition date. Expenditures relating to internally generated intangible assets, excluding capitalized development costs, are recognized in profit or loss when incurred.

Intangible assets with a finite useful life are amortized over their useful life and reviewed for impairment whenever there is an indication that the asset may be impaired. The amortization period and the amortization method for an intangible asset are reviewed at least at each year end.

n. Impairment of non-financial assets:

The Company evaluates the need to record an impairment of non-financial assets 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. In measuring value in use, the expected future cash flows are discounted using a pre-tax discount rate that reflects the risks specific to the asset. The recoverable amount of an asset that does not generate independent cash flows is determined for the cash-generating unit to which the asset belongs. Impairment losses are recognized in profit or loss.

o. 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” (“IAS 39”). IFRS 9 mainly focuses on the classification and measurement of financial assets and it applies to all assets within the scope of IAS 39.

IFRS 9 has been applied for the first time on January 1, 2018, using the modified retrospective approach with certain reliefs and without restatement of comparative figures. After having evaluated the effects of the application of IFRS 9, the Group believes that the adoption has no material effect on the Group’s financial statements.

The accounting policy for financial instruments applied until December 31, 2017, is as follows:

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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

o. Financial instruments: (Cont.)

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:

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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

o. Financial instruments: (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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

o. Financial instruments: (Cont.)

The accounting policy, according to IFRS 9, for financial instruments applied commencing from January 1, 2018, is as follows:

1. Financial assets:

Financial assets are measured upon initial recognition at fair value plus transaction costs that are directly attributable to the acquisition of the financial assets, except for financial assets measured at fair value through profit or loss in respect of which transaction costs are recorded in profit or loss.

The Group classifies and measures debt instruments in the financial statements based on the following criteria:

- The Group's business model for managing financial assets; and
- The contractual cash flow terms of the financial asset.

a) Debt instruments are measured at amortized cost when:

The Group's business model is to hold the financial assets in order to collect their contractual cash flows, and the contractual terms of the financial assets give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding. After initial recognition, the instruments in this category are measured according to their terms at amortized cost using the effective interest rate method, less any provision for impairment.

On the date of initial recognition, the Group may irrevocably designate a debt instrument as measured at fair value through profit or loss if doing so eliminates or significantly reduces a measurement or recognition inconsistency, such as when a related financial liability is also measured at fair value through profit or loss.

b) Debt instruments are measured at fair value through profit or loss when:

A financial asset which is a debt instrument does not meet the criteria for measurement at amortized cost or at fair value through other comprehensive income. After initial recognition, the financial asset is measured at fair value and gains or losses from fair value adjustments are recognized in profit or loss.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

o. Financial instruments: (Cont.)

1. Financial assets: (Cont.)

c) Equity instruments and other financial assets held for trading:

Investments in equity instruments do not meet the above criteria and accordingly are measured at fair value through profit or loss.

Other financial assets held for trading such as derivatives, including embedded derivatives separated from the host contract, are measured at fair value through profit or loss unless they are designated as effective hedging instruments.

Dividends from investments in equity instruments are recognized in profit or loss when the right to receive the dividends is established.

2. Derecognition of financial assets:

A financial asset is derecognized only when:

- The contractual rights to the cash flows from the financial asset has expired;
- The Group has transferred substantially all the risks and rewards deriving from the contractual rights to receive cash flows from the financial asset or has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset; or
- The Group has retained its contractual rights to receive cash flows from the financial asset but has assumed a contractual obligation to pay the cash flows in full without material delay to a third party.

A transaction involving factoring of accounts receivable and credit card vouchers is derecognized when the abovementioned conditions are met.

3. Financial liabilities:

a) Financial liabilities measured at amortized cost:

Financial liabilities are initially recognized at fair value less transaction costs that are directly attributable to the issue of the financial liability.

After initial recognition, the Group measures all financial liabilities at amortized cost using the effective interest rate method, except for Financial liabilities at fair value through profit or loss such as derivatives;

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

o. Financial instruments: (Cont.)

3. Financial liabilities: (Cont.)

b) Financial liabilities measured at fair value through profit or loss:

At initial recognition, the Group measures financial liabilities that are not measured at amortized cost at fair value. Transaction costs are recognized in profit or loss.

After initial recognition, changes in fair value are recognized in profit or loss.

4. Derecognition of financial liabilities:

A financial liability is derecognized only when it is extinguished, that is when the obligation specified in the contract is discharged or cancelled or expires. A financial liability is extinguished when the debtor discharges the liability by paying in cash, other financial assets, goods or services, or is legally released from the liability.

5. Offsetting financial instruments:

Financial assets and financial liabilities are offset and the net amount is presented in the statement of financial position if there is a legally enforceable right to set off 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 set-off 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 set-off 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.

6. Compound financial instruments:

Convertible debentures which contain both an equity/derivative component and a liability component are separated into two components. This separation is performed by first determining the liability component based on the fair value of an equivalent non-convertible liability. The value of the conversion component is determined to be the residual amount. Directly attributable transaction costs are apportioned between the equity component and the liability component based on the allocation of proceeds to the equity and liability components.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

o. Financial instruments: (Cont.)

7. Issue of a unit of securities:

The issue of a unit of securities involves the allocation of the proceeds received (before issue 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. Issue costs are allocated to each component pro rata to the amounts determined for each component in the unit.

p. 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.

q. Revenue recognition:

The Group has not yet generated any revenues from the sale of goods or from rendering services related to the sold products.

r. 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.

s. Earnings (loss) per share/ADS:

Earnings (loss) per share or per ADS are calculated by dividing the net income (loss) attributable to equity holders of the Company by the weighted number of ordinary shares or ADSs outstanding during the period.

Basic loss per share or ADS includes only shares or ADSs that were outstanding during the period.

Potential ordinary shares or ADSs are included in the computation of diluted loss per share or per ADS when their conversion increases loss per share or ADS from continuing operations.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

t. Share/ADS-based payment transactions:

The Company's employees and other service providers may receive remuneration in the form of share/ADS-based payments ("Equity-settled transactions").

Equity-settled transactions:

The Group's employees/other service providers may receive remuneration in the form of equity-settled share-based payment transactions.

Equity-settled transactions:

The cost of equity-settled transactions with employees is measured at the fair value of the equity instruments granted at grant date. The fair value is determined using an acceptable option pricing model ("OPM").

As for other service providers, the cost of the transactions is measured at the fair value of the goods or services received as consideration for 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 and/or service conditions are to be satisfied ending on the date on which the relevant employees become 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 Group's best estimate of the number of equity instruments that will ultimately vest.

No expense is recognized for awards that do not ultimately vest, except for awards where vesting is conditional upon a market condition, which are treated as vesting irrespective of whether the market condition is satisfied, provided that all other vesting conditions (service and/or performance) are satisfied.

u. 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 wholly before twelve months after the end of the annual 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 Group 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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

u. Employee benefit liabilities: (Cont.)

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 Group has defined contribution plans to its employees according to the specific laws per country.

v. Provisions:

A provision in accordance with IAS 37 is recognized when the Group has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. When the Group expects part or all of the expense to be reimbursed, for example under an insurance contract, the reimbursement is recognized as a separate asset but only when the reimbursement is virtually certain. The expense is recognized in the statement of profit or loss net of any reimbursement.

Following are the types of provisions included in the financial statements:

Legal claims:

A provision for claims is recognized when the Group has a present legal or constructive obligation as a result of a past event, it is more likely than not that an outflow of resources embodying economic benefits will be required by the Group to settle the obligation and a reliable estimate can be made of the amount of the obligation.

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 Group 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 Group evaluates whether the lease transfers substantially all the risks and rewards incidental to ownership of the asset. In this respect, the Group 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.

- Effective control:

  The Company assesses whether it controls a company in which it holds less than the majority of the voting rights, among others, by reference to the size of its holding of voting rights relative to the size and dispersion of holdings of the other vote holders including voting patterns at previous shareholders' meetings.

- 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 OPM. The inputs to the model include share price, exercise price and assumptions regarding expected volatility, expected life of share option and expected dividend yield.

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 Group 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 IIA:

  Government grants received from the IIA at the Ministry of Industry, Trade and Labor 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 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.

- Fair value of financial instruments:

  When the fair values of financial assets and financial liabilities recorded in the statement of financial position cannot be derived from active markets, their fair value is determined using a variety of valuation techniques that include the use of valuation models. The inputs to these models are taken from observable markets where possible, but where this is not feasible, estimation is required in establishing fair values. The models are tested for validity by calibrating to prices from any observable current market transactions in the same instrument when available.

NOTE 4:- DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION

a. IFRS 16, "Leases":

In January 2016, the IASB issued IFRS 16, "Leases" ("IFRS 16"). According to IFRS 16, 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.

The effects of the adoption of the IFRS 16 are as follows:

- 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, see below) 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 expense separately.

- Variable lease payments that are not dependent on changes in the Consumer Price Index ("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 re-measure the lease liability and the effect of the re-measurement is an adjustment to the carrying amount of the right-of-use asset.

- The accounting treatment by lessors remains substantially unchanged, namely classification of a lease as a finance lease or an operating lease.

IFRS 16 is effective for annual periods beginning on or after January 1, 2019. Early adoption is permitted. At this stage, the Group does not intend to early adopt IFRS 16.

IFRS 16 permits lessees to use one of the following approaches:

1. Full retrospective approach - according to this approach, the effect of the adoption of IFRS 16 at the beginning of the earliest period presented will be carried to equity. Also, the Group will restate the comparative figures in its financial statements. The balance of the liability as of the date of initial adoption of IFRS 16 as per this approach will be calculated using the interest rate implicit in the lease, unless this rate cannot be easily determined in which case the lessee's incremental borrowing rate of interest will be used.

2. Modified retrospective approach - this approach does not require restatement of comparative data. The balance of the liability as of the date of initial adoption of IFRS 16 will be calculated using the lessee's incremental borrowing rate of interest on the date of initial adoption of IFRS 16. As for the outstanding right-of-use asset, the Group may apply one of the two following alternatives to account for each lease separately:

NOTE 4:- DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION (CONT.)

a. IFRS 16, "Leases": (Cont.)

2. Modified retrospective approach: (Cont.)

- Recognizing an asset in the amount of the recognized liability, with certain adjustments; or

- Recognizing an asset as if the asset had always been measured according to the provisions of IFRS 16.

Any difference arising on the date of first-time adoption of IFRS 16 as a result of the modified retrospective approach will be carried to equity.

The Group expects to use the modified retrospective approach for the first-time adoption of IFRS 16 by measuring the right-of-use asset equally to the obligation to make lease payments as presented on the date of initiation.

The Group has extensive lease contracts consisting of buildings. In the context of examining the potential impact of IFRS 16 on the financial statements, the Group is reviewing the following issues:

- The existence of lease extension options - according to IFRS 16, non-cancellable lease terms also include periods that are covered by the lease extension options if it is likely that the lessee will exercise the option. The Group is examining the existence of such options in its lease agreements and whether or not it is likely that they will be exercised by it.

  In the context of such examination, the Group studies all the relevant facts and circumstances that are likely to create an economic incentive for exercising the option, among others, significant leasehold improvements that have been or are expected to be performed, the significance of the leasehold to the Group's activity and past experience in connection with the exercise of such extension options. IFRS 16 incorporates two exceptions, whereby lessees are entitled to account for leases according to the current accounting treatment of operating leases, in the event of leases of assets of a low financial value or in the event of leases for a period of up to one year.

- Separation of contract components - according to IFRS 16, all lease components of a contract should be separated from non-lese components when the lessee is allowed the relief of choosing not to distinguish between such components according to categories of base assets but rather jointly account for them as a single lease component. The Group is reviewing the existence of non-lease components in its current lease contracts such as for the provision of management and maintenance services and whether the above relief should be applied to each category of base assets.

NOTE 4:- DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION (CONT.)

a. IFRS 16, "Leases": (Cont.)

- Discount interest rate - the Group is examining how to determine the discount rate for measuring a right-of-use asset on the date of initial adoption of IFRS 16, based on the initial adoption approach chosen by it. In this context, the Group is also examining its ability to estimate the fair value of the leasehold and the lessor's initial costs if it should choose the retrospective approach, or alternatively estimate the lessee's incremental borrowing rate of interest assuming that the interest rate implicit in the lease cannot be determined using the full retrospective approach or if it should choose the modified retrospective approach in view of the lease period and the nature of the leasehold.

The Group is also evaluating the need for adjustments to its systems, internal control, policies and procedures that will be necessary in order to apply the provisions of IFRS 16.

The Group estimates that the effect of the initial adoption of IFRS 16 as of January 1, 2019, will result in an increase of approximately $2.703 million in the Group's total assets and liabilities. The above quantitative disclosures rely on the effects as they are currently known to the Group based on existing data and parameters. The adoption of IFRS 16 may require certain adjustments in the Group's future financial statements for 2018, after specific policies have been finalized with respect to the application issues currently under review.

In addition, as a result of the initial adoption of IFRS 16, the Group estimates that in the year ending on December 31, 2019, there will be a decrease of rental expenses of $684 thousand, an increase in depreciation and amortization of $405 thousand and an increase in financing expenses of $454 thousand. Overall, the adoption of IFRS 16 is expected to result in a decrease in the Group's operating expenses of $279 and in an increase in the Group's loss before taxes of $175 thousand. Also, as a result of the IFRS 16 adoption, an increase in cash flow from operating activities of $230 thousand is expected.

NOTE 5:- BUSINESS COMBINATIONS:

Acquisition of Therapix Healthcare Resources Inc.:

On July 31, 2018, the Company entered into an agreement for convertible equity (the "Convertible Equity Agreement") with THR, which is a company that was incorporated in Delaware, on July 26, 2018, and an unaffiliated third party. Since July 31, 2018, THR was engaged in operating pain treatment clinics, mainly in Tennessee, to treat an assortment of different pains, including, acute pain, spine pain, chronic headaches, cancer pain, oral/maxillofacial pain, neuropathic pain and rheumatologic/myofascial pain. Under the Convertible Equity Agreement, the Company loaned an aggregate amount of $1.625 million (the "THR Loan") to THR. The maturity date of the loan, which accrues interest at a rate of 9% per annum, will occur upon demand of the Company and under certain conditions detailed in the Convertible Equity Agreement as follows:

- The Company shall have the right to instruct THR in writing, no later than October 3, 2018 (the "Execution Date") to repay the THR Loan, together with all interest accrued in cash at the Execution Date.

- The Company will have the right to convert the THR Loan, together with all interest accrued, into that number of shares of the most senior class of shares of THR, existing at the time of such conversion, at a price per share equal to the fair market value of such shares as shall be determined by THR's board of directors. Notwithstanding anything to the contrary, the Company shall not exercise any conversion rights under the Convertible Equity Agreement together with all interest accrued unless and until, at least, one of the following conditions is met: (1) Three THR clinics become fully operational; or (2) the directors of THR authorize the formal issuance of shares of THR at their initial meeting or in a resolution of lieu of an initial meeting.

In the event the terms mentioned above are not fulfilled within twelve months after the Execution Date, then the THR Loan will be converted automatically. In addition, if the THR Loan will be converted by the Company, the Company shall have the right to appoint 50% of the members of THR's board of directors, including the chairman of the board of directors. According to THR's certificate of incorporation, the chairman of the board of directors shall cast the decisive vote in the event that voting of the board of directors is tied.

On October 3, 2018 (the "Acquisition Date"), following the fact that the above mentioned conditions were met, the Company converted the entire THR Loan and as a result holds 82.36% of THR's equity, and accordingly achieved control over THR. Until December 31, 2018, no further changes were made to THR's equity. In addition, since the Acquisition Date and until December 31, 2018, the Company loaned to THR an additional amount of $487 thousand by four additional loans, which accrued interest at a rate of 9% per annum. Also, since January 1, 2019, and until the date of Approval Date, the Company loaned to THR an additional amount of $202 thousand by four additional loans under the same terms as the abovementioned loans.

NOTE 5:- BUSINESS COMBINATIONS: (CONT.)

Acquisition of Therapix Healthcare Resources Inc.: (Cont.)

Up and until the Acquisition Date and the beginning of consolidation, the THR Loan was treated as a convertible loan (as a financial asset), presented at its fair value through profit or loss pursuant to IFRS 9, plus accrued interest in the total amount of $22 thousand. Accordingly, on the Acquisition Date, no adjustments were required to the value of the investment which represents the purchase consideration of $1.647 million.

The Group has elected to measure the non-controlling interests in THR at the proportionate share of the non-controlling interests of the fair value of THR's net identifiable assets.

The Company recognized the fair value of the assets acquired and liabilities assumed in the business combination according to a provisional measurement. The purchase consideration and the fair value of the acquired assets and liabilities may be adjusted within twelve months from the Acquisition Date.

The fair value of the identifiable assets and liabilities of THR on the Acquisition Date:

	Fair value USD in thousands
Cash	$ 14
Other accounts receivable	45
Property and equipment, net	2,192
Customer relationships, net	307
	2,558
Trade payables	(445)
Other accounts payable	(42)
Related Parties	(206)
Deferred taxes liability, net	(60)
	(753)
Net identifiable assets	1,805
Non-controlling interests	(318)
Goodwill arising on acquisition	160
Total purchase cost	$ 1,647

The goodwill arising from the acquisition is attributed to the expected benefits from the synergies of the combination of the activities of the Company and THR.

NOTE 5:- BUSINESS COMBINATIONS: (CONT.)

Acquisition of Therapix Healthcare Resources Inc.: (Cont.)

Cash outflow/inflow on the Acquisition Date:

	USD in thousands
Cash paid	$ 1,647
Cash acquired with THR at the Acquisition Date	(14)
Net cash	$ 1,633

Since the Acquisition Date until December 31, 2018, THR contributed a total loss in the amount of $2.335 million to the Group's total loss for the year ended on December 31, 2018 (the loss attributed to the non-controlling interests is $412 thousand).

On December 31, 2018, the Group reviewed the goodwill for impairment and due to significant losses incurred by THR, as well as its failure to maintain required licenses to operate its facilities, the Group decided to fully impair the goodwill which have arisen from THR's acquisition. Accordingly, on December 31, 2018, the intangible asset due to THR's customer relationships was fully impaired as well.

On March 26, 2019, due in part to significant losses incurred by THR, as well as its failure to maintain required licenses to operate its facilities, the Group's management anticipates that THR will commence a liquidation process of its assets in the near future. The liquidation of THR's remaining assets, or potential claims that may arise from the liquidation and dissolution of THR may adversely affect the Group's reputation or divert management's attention in the event of any material litigation. As of the date of approval of the financial statements, the Group is not able to estimate reliably the timing and results of the proposed liquidation or of any consequences that may occur as a result thereof, except for what is disclosed in these financial statements.

NOTE 6:- CASH AND CASH EQUIVALENTS

	December 31,	
	2018	2017
	USD in thousands	
Cash for immediate withdrawal - in NIS	$ 247	$ 93
Cash for immediate withdrawal - in USD	1,238	9,102
	$ 1,485	$ 9,195

NOTE 7:- OTHER ACCOUNTS RECEIVABLE

	December 31,	
	2018	2017
	USD in thousands	
Prepaid expenses	$ 250	$ 224
Government authorities	66	54
Other receivables	88	-
	$ 404	$ 278

NOTE 8:- CONVERTIBLE LOAN

On April 17, 2018, the Company entered into a convertible loan agreement with Cure Pharmaceutical Holding Corp. ("Cure" and the "Convertible Loan Agreement," respectively), a U.S.-based company. Under the Convertible Loan Agreement, the Company lent Cure an amount of $500 thousand (the "Cure Loan"). The maturity date of the Cure Loan, together with an interest at a rate of 9% per annum, was set as April 30, 2019 (the "Maturity Date"). In addition, according to the Convertible Loan Agreement, the Company had the option to instruct Cure, prior to the Maturity Date, to repay the Cure Loan amount together with all interest accrued thereon, in lieu of the conversion (described below), in which case Cure will effect such repayment on the Maturity Date. Conversion of the Cure Loan could have been upon one out of several options mentioned in the Convertible Loan Agreement.

On December 31, 2018, the Company instructed Cure to repay the Cure Loan (with the accrued interest) on the Maturity Date. Therefore, the Cure Loan balance as of December 31, 2018, was presented on a cost basis, with the accrued interest of 9% per annum. The Cure Loan was fully repaid, including interest, on April 30, 2019, and the Convertible Loan Agreement was terminated with no further effect.

NOTE 9:- INVESTMENT IN ASSOCIATE AND INVESTMENTS IN INVESTEES

a. Investment in Lara:

On June 15, 2014, a definitive investment agreement was signed between the Company and Lara, an Israeli company that operates in the field of medical cannabis, which determined, among others, that the Company will invest in Lara up to a total of $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 $800 thousand against shares that will represent about 48% of Lara's issued and outstanding share capital (approximately 27% on a fully diluted basis). In May 2016, following various claims that the parties held against each other, 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, and that it will be released from making the remaining payments under the Investment Agreement and all other terms of the Investment Agreement will have no further binding effect.

NOTE 9:- INVESTMENT IN ASSOCIATE AND INVESTMENTS IN INVESTEES (CONT.)

a. Investment in Lara: (Cont.)

Pursuant to the Settlement Agreement, the Company's representative on Lara's board of directors resigned. Also, the Company doesn't have the right to appoint a director. Accordingly, the Company no longer has significant influence over Lara. As of December 31, 2018, the balance of the investment in Lara is $0.

b. Sale of Orimmune Bio Ltd. and the Termination of the Hadasit License Agreement:

On June 22, 2016, the Company entered into a share transfer agreement (the "Transfer Agreement") with its then wholly owned subsidiary, Orimmune Bio Ltd. ("Orimmune") and Karma Link Ltd. (the "Buyer"), whereby the Company will sell its interests in Orimmune to the Buyer and use its best efforts transfer to Orimmune and assign its rights in the Anti-CD3 technology (which was in-licensed by the Company from Hadasit Medical Research Services & Development Ltd., ("Hadasit") and certain internally developed assets and technology relating thereto) (the "License"), assist in obtaining all the necessary approvals for such technology transfer, in return to a predetermined rate (which is a low double-digit number) of all receipts which the Buyer will receive from Orimmune or from third parties in connection with the shares and/or assets of Orimmune, up to an aggregate of approximately $10 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). During the interim period until the completion of the License assignment process, among others, 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).

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, Orimmune's future sale to a third party. As a result of the loss of control, the Company recorded a capital gain in the amount of $34 thousand.

During May 2017, an amendment to the Transfer Agreement was signed (the "Orimmune Amendment") between the Company, the Buyer and Orimmune, in which the parties acknowledged that the Company's discussions with Hadasit regarding the possibility of assigning the License to Orimmune, as contemplated in the Transfer Agreement, have yet to mature into an agreement with Hadasit, due to Hadasit's objection to the proposed assignment. As a gesture of good faith, the Company agreed to bear certain fees expenses related to the License incurred prior to the date hereof in the amount of $60 thousand, which were paid to Orimmune. In addition, during a period of 6 months commencing as of the date of the Orimmune Amendment, the Company agreed to bear certain additional fees and expenses related to the License. It was determined that such additional amounts will not exceed $15 thousand. All such additional fees and expenses shall be coordinated and approved by Company in advance.

NOTE 9:- INVESTMENT IN ASSOCIATE AND INVESTMENTS IN INVESTEES (CONT.)

b. Sale of Orimmune Bio Ltd. and the Termination of the Hadasit License Agreement: (Cont.)

The Orimmune Amendment further emphasized that in the event that the parties were unable to successfully assign the License within such 6-month period, the Company would be deemed to have satisfied its obligation to use reasonable commercial efforts according to the Transfer Agreement. In consideration of the foregoing, it was agreed to increase the percentages of the predetermined rate of all receipts which the Buyer will receive from the Orimmune or from third parties in connection with the shares and/or assets of the Orimmune.

Following further discussions between the Company and Hadasit held during 2017, and through the first quarter of 2018, after not succeeding in assigning the License to the Buyer, on March 29, 2018, the Company and Hadasit signed a mutual termination agreement (the "Termination Agreement") of the License. According to the Termination Agreement, among others, the License (and its related historic consulting agreements associated with the License) shall be terminated as of that date, and will not have any further force and effect, except for certain matters as prescribed under the Termination Agreement. In addition, payment to Hadasit of outstanding amount was set, and with respect to the transfer of IP rights, Hadasit will assign to the Company all of its rights in the Hadasit/Therapix patent rights. Thereafter, the Company will re-assign to Hadasit all of its rights, title and interest in and to the Hadasit/Therapix patent rights ("Assignment of IP"). The consummation of the Assignment of IP abovementioned shall be subject to receipt of the necessary approval of the IIA.

On April 18, 2018, the Company submitted an application with the IIA to approve the Assignment of IP (the "Application"). The Company had discussions with the IIA in connection with the terms of approval of the Application, which will, inter alia, address a previous refusal received by the IIA to a request to recognize the registration of a joint patent with Hadasit, under the License, which according to the IIA did not comply with the rules and regulations with respect to use of funds received under the IIA grant. Following the above-mentioned discussions, the IIA has approved an arrangement for the joint patent registration.

On July 4, 2018, and according to the Termination Agreement, the Company paid Hadasit approximately $104 thousand due to, inter alia, accrued costs and expenses relating to the filing, prosecution and maintenance of the patent rights, license maintenance fee due to Hadasit for the years 2016 and 2017, and unpaid related consultancy fees for work performed during 2015.

On December 13, 2018, an additional amendment to the Transfer Agreement was signed (the "Additional Amendment") between the Company, the Buyer and Orimmune, under which the parties acknowledged that despite the Company's efforts and assistance in the discussions with Hadasit regarding the possibility of assigning the License to Orimmune, Orimmune chose not to enter into an agreement with Hadasit. In addition and notwithstanding the foregoing, the Company is willing to assign to Orimmune the entire right, title and interest in specific patents, subject to fulfilment of certain conditions precedent which are still in effect as of the date of this financial statement.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10:- PROPERTY AND EQUIPMENT, NET

	Computers	Lab equipment	Office furniture and equipment	Leasehold improvements	Vehicles	Total
	USD in thousands					
Cost:						
Balance at January 1, 2018	$ 36	$ 13	$ 23	$ 23	$ -	$ 95
Initially consolidated company	42	2,031	111	-	8	2,192
Additions during the year	8	-	1	7	-	16
Disposals during the year	(20)	(39)	-	-	-	(59)
Adjustments arising from translating financial statements from functional currency to presentation currency	-	(1)	(1)	(1)	-	(3)
Balance at December 31, 2018	66	2,004	134	29	8	2,241
Accumulated depreciation:						
Balance at January 1, 2018	26	10	8	1	-	45
Additions during the year	12	88	8	4	1	113
Disposals during the year	-	(3)	-	-	-	(3)
Adjustments arising from translating financial statements from functional currency to presentation currency	(22)	2	-	(1)	-	(21)
Balance at December 31, 2018	16	97	16	4	1	134
Depreciated cost at December 31, 2018	**50**	**1,907**	**118**	**25**	**7**	**2,107**
Depreciated cost at December 31, 2017	**$ 10**	**$ 3**	**$ 15**	**$ 22**	**$ -**	**$ 50**

NOTE 11:- TRADE PAYABLES

	December 31,	
	2018	2017
	USD in thousands	
Open debts	$ 978	$ 399
Accrued expenses	640	618
	$ 1,618	$ 1,017

NOTE 12:- OTHER ACCOUNTS PAYABLE

	December 31,	
	2017	2016
	USD in thousands	
Employees and payroll accruals	$ 484	$ 130
Provisions due to litigations and claims (*)	250	-
Accrued vacation	52	30
Other payables	58	-
	$ 844	$ 160

(*) Refer to Note 16j for more information in this matter.

NOTE 13:- FINANCIAL INSTRUMENTS

a. Classification of financial assets and financial liabilities:

The financial assets and financial liabilities in the consolidated statements of financial position are classified by groups of financial instruments pursuant to IFRS 9:

	December 31,	
	2018	2017
	USD in thousands	
Financial assets:		
Cash and restricted deposits	$ 1,518	$ 9,219
Convertible loan (see Note 8)	531	-
	2,049	9,219
Financial liabilities:		
Current financial liabilities carried at amortized cost	3,336	1,177
Credit from others (see Note 13b)	91	-
Convertible debenture (see Note 13c)	779	-
Conversion component of convertible debenture (see Note 13c)	277	-
	$ 4,483	$ 1,177

b. Credit from others:

On August 30, 2018, GLPS Staffing Solutions Professional LLC ("GLPS"), a related party of THR (see Note 22d.5), signed a Billing Services Agreement (the "Billing Services Agreement") with Anesthesia Business Consultants LLC. ("ABC"). According to the Billing Services Agreement, ABC shall provide a credit line to THR or GLPS which shall not exceed $250 thousand (the "Credit Line"). The Credit Line shall be repaid at the rate of $50 thousand for each twelve month period during the term of the Billing Services Agreement.

NOTE 13:- FINANCIAL INSTRUMENTS (CONT.)

b. Credit from others: (Cont.)

The Credit Line will bear an annual interest of 6.5% (the interest will change according to different terms under the Billing Services Agreement).

As of December 31, 2018, the withdrawn balance of the Credit Line was $91 thousand (including interest, in which the withdrawal was made on November 13, 2018), all classified under current liabilities due to the expected liquidation of THR (See Note 5).

c. Convertible Debentures:

On November 23, 2018 (the "Issuance Date"), the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") and a registration rights agreement with YA II PN Ltd. ("Yorkville"), a fund managed by Yorkville Advisors Global L.P., for the sale in a private placement of up to $2.5 million in principal amount of unsecured convertible debentures (the "Convertible Debentures"). Interest on the Convertible Debentures will accrue at a rate of 5% per annum and can be repaid in cash with an addition of an 10% redemption premium upon the maturity date of the Convertible Debentures, being 12 months from the issuance of each Convertible Debenture.

The first tranche of $1.5 million of the Convertible Debentures was issued on November 26, 2018. In addition, $78 thousand were deducted due to issue expenses, and Yorkville received 9,171 ADSs of the Company in return to additional commitment fees (valued at $75 thousand) (see Note 17e.3). Also, an additional fee of $10 thousand was deducted from the $1.5 million due to payments to Yorkville's legal counsels. Two other tranches of $500 thousand each of the Convertible Debentures shall be purchased by Yorkville conditional on the passage of time and/or certain triggering events as disclosed in the Securities Purchase Agreement. If the Company will not comply with the triggering events mentioned, the Company will be deemed to be in default pursuant to the terms, and inter alia, the interest on the Convertible Debentures will accrue up to a rate of 15% per annum. The Company shall pay Yorkville additional commitment fees upon issuance of each such tranche, to be paid at the Company's option in cash or ADSs of the Company. From and after the date of issuance of the Convertible Debentures, the outstanding principal, together with accrued and unpaid interest, will be convertible, at the option of Yorkville, into the Company's ADSs at the lower of $7.00 or 95% of the lowest daily volume-weighted average price ("VWAP") during the five consecutive trading days immediately preceding the conversion date.

As of December 31, 2018, the Convertible Debentures had not been converted.

On March 14, 2019, an amendment to the Securities Purchase Agreement was signed due to the fact that the Company did not comply with certain abovementioned conditions and accordingly deemed to be in default by Yorkville. According to the amendment, Yorkville agreed to waive the requirements under the Securities Purchase Agreement and as such, the Company shall not be deemed to be in default pursuant to the terms of the Securities Purchase Agreement. In addition, the Company and Yorkville mutually agreed to waive any and all requirements to hold a second closing or third closing ($500 thousand each).

NOTE 13:- FINANCIAL INSTRUMENTS (CONT.)

c. Convertible Debentures: (Cont.)

Valuation process and techniques:

The Company's management considers the appropriateness of the valuation methods and inputs, and may request that alternative valuation methods are applied to support the valuation arising from the method chosen.

The valuation of the Convertible Debentures was set in accordance with IFRS 9 and IAS 32, "Financial Instruments: Presentation" ("IAS 32"). IFRS 9 and IAS 32 determine the accepted method in allocating the consideration received from a bundle of securities. According to the guidelines of IFRS 9 and IAS 32, the allocation is based on the method of the remainder of consideration, when there is a hierarchy regarding the financial instruments measured at fair value and the financial instruments recognized as the remainder of consideration.

According to IFRS 9 and IAS 32, the allocation is based on the following hierarchy:

- Derivative and other financial instrument, measured at fair value through its contractual life.

- Financial liabilities and other complex instruments which are not recognized at fair value.

- Equity instruments.

IFRS 9 and IAS 32 also determine that a derivative which may be settled other than by the exchange of a fixed amount of cash or another financial asset for a fixed number of the entity's own equity instruments, will be defined as a financial liability, measured and presented at fair value each period. Accordingly, and as mentioned in the Securities Purchase Agreement, in the event of conversion, the amount of shares to be issued is unknown (not fixed). Therefore, according to the definition mentioned above, the conversion component is classified as a financial liability that will be measured at fair value, through profit or loss, as of the Issuance Date and on any following financial reporting date (accordingly, issue expenses related to the derivative will be recorded through profit or loss). The remainder of the consideration will be attributed to the debt component and no consideration will be left to attribute to the equity instrument (issuance of 9,171 ADSs mentioned above).

The valuation of the conversion component of Convertible Debentures was set at fair value, as required in IFRS 9, and in accordance with IFRS 13, "Fair value measurement," and was categorized as Level 3 by the Company.

General Overview of Valuation Approaches used in the Valuation:

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

NOTE 13:- FINANCIAL INSTRUMENTS (CONT.)

c. Convertible Debentures: (Cont.)

Economic methodology:

The convertible component was calculated using the Monte Carlo Simulation Model, an OPM which takes into account six parameters as disclosed below for each period valuated:

	November 23, 2018	December 31, 2018
The price of the ADS as of the valuation date	$ 7.46	$ 3.25
The exercise price of the option (*)	$ 7	$ 7
The option contractual term	1 year	1 year
The expected volatility of the price of the ADS	91.3%	99.33%
The risk-free interest rate for the option contractual term	2.67%	2.62%
The expected dividends over the option's expected term	0%	0%

(*) The lower of $7.00 or 95% of the lowest daily VWAP during the five consecutive trading days immediately preceding the conversion date.

Hereinafter is the attribution of the consideration of the Convertible Debentures:

	USD in thousands
Conversion component of Convertible Debentures - measured at fair value	$ 745
Convertible Debentures, net of issue expenses - measured at amortized cost	706
ADS issued	-
(*)	$ 1,451

(*) Net of issue expenses in the amount of $39 thousand due to the conversion component of Convertible Debentures which were recognized in profit or loss.

Reconciliation of the fair value measurements that are categorized within Level 3 of the fair value hierarchy in financial instruments:

	USD in thousands
Balance at November 23, 2018	$ 745
Finance income	(468)
Balance at December 31, 2018	$ 277

NOTE 13:- FINANCIAL INSTRUMENTS (CONT.)

d. Financial risk factors:

The Group's activities expose it to various financial risks such as market risks (foreign currency risk and interest risk), credit risk and liquidity risk. The Group's comprehensive risk management plan focuses on activities that reduce to a minimum any possible adverse effects on the Group'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 Group is exposed to exchange rate risk resulting from the exposure to different currencies, mainly the USD until October 1, 2018, and since then mainly the NIS (see Note 2d). 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 related to the Company are held in two banks in Israel which are considered financially solid. In regards to THR, all cash and cash equivalents are also are held in two banks in the U.S., which are considered financially solid as well.

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. As of December 31, 2018, The Company expects to settle all of its financial liabilities in less than one year. However, as mentioned in Note 5, THR will commence a liquidation process of its assets in the near future.

The carrying amounts of cash and cash equivalents, and all other financial assets and liabilities approximate their fair value.

Refer to Note 1c for more information.

NOTE 14:- 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 of 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 of 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,		
	2018	2017	2016
	USD in thousands		
Expenses in respect of defined contribution plans	$ 65	$ 52	$ 31

NOTE 15:- TAXES ON INCOME

a. Tax rates applicable to the Group:

Therapix incorporated in Israel:

Presented hereunder are the tax rates relevant to the Company in the years 2016 - 2018:

The Israeli statutory corporate tax rate and real capital gains were 23% in 2018, 24% in 2017 and 25% in 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), 2017, 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.

THR incorporated in the U.S.

On December 22, 2017, the U.S. Tax Cuts and Jobs Act (the "TCJA") was signed into law, permanently lowering the corporate federal income tax rate from 35% to 21%, effective January 1, 2018. THR is subject to U.S. Federal tax and State income tax where THR operates (mainly in the state of Tennessee). The weighted tax rate in 2018 was 27.5%.

The change in the tax rate had no effect on the financial statements in 2018.

b. Tax assessments:

The assessments of the Company are deemed final through the 2013 tax year. However, as of December 31, 2018, THR has no final tax assessments.

c. Carryforward tax losses and other temporary differences:

Therapix and THR both have accumulated tax losses since their inceptions.

As of December 31, 2018, Therapix's net carryforward tax losses are expected to grow to approximately $34 million ($30 million as of December 31, 2017). In addition, as of December 31, 2018, THR's net carryforward tax losses are expected to be approximately $2.5 million.

Therapix and THR are not expected to be profitable for tax purposes for tax year 2018.

NOTE 16:- CONTINGENT LIABILITIES, COMMITMENTS, CLAIMS AND LIENS

a. The Israel Securities Authority Administrative Letter of Claims against the Company:

From 2014 until 2017, the Company was subject to an administrative inquiry relating to the Company's reports (quality and scope of disclosure) to the Israel Securities Authority ("ISA") and the TASE with respect to the termination of a license agreement the Company had with Ramot at Tel-Aviv University Ltd. ("Ramot") for certain technology covering the Company's Alzheimer's technology and program, which was terminated in the beginning of 2014. 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 $43 thousand as an administrative penalty (the "Administrative Monetary Sum") (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 was subject to a one year probationary condition, whereby if he was found to commit a similar violation, he will be prevented from serving as an officer or director of a public company. As of December 31, 2018, the entire Administrative Monetary Sum was paid by the Company.

In connection with the Administrative Monetary Sum, and because of a previous undertaking by the Company under a previous investment agreement as of 2016 between the Company and Jesselson Investments Ltd. ("Jesselson"), whereby if monetary sanction by the ISA is higher than $20 thousand, it will be imposed on the Company as a result of the abovementioned proceedings, the Company will be required to compensate Jesselson on the entire amount by way of cash payment or by equity payment (i.e., issuing Jesselson additional shares in an amount equal to the amount of the monetary sanctions divided by NIS 0.5 per share), at the discretion of Jesselson. As of December 31, 2018, the Company's debt to Jesselson is still outstanding, therefore a provision in the amount of $43 thousand was recorded.

In addition, under a different settlement agreement, the Company's Chairman also agreed under such proceedings, among others, to pay the same amount as an administrative penalty only (and to be subject to a one year probationary condition, whereby if he is found to have made similar alleged breaches, (which he was not), he would have been prevented from serving as an officer or director of a public company.

b. New License Agreement with Ramot at Tel Aviv University Ltd.:

In February 2016, the Company entered into an exclusive, irrevocable, worldwide research and license agreement with 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 $62 thousand. 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 ("FDA"), 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.

NOTE 16:- CONTINGENT LIABILITIES, COMMITMENTS, CLAIMS AND LIENS (CONT.)

b. New License Agreement with Ramot at Tel Aviv University Ltd.: (Cont.)

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.

On March 13, 2019, further to discussions between the Company and Ramot, the Company notified Ramot of its intent to terminate such agreement. As of the date hereof, the Company does not believe that terminating the agreement will have a material effect on the Company's operations and business.

c. License Agreement with 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 and interim Chief Executive Officer, Dr. Ascher 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. As of December 31, 2017, 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 thousand 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 thousand upon the successful completion of a Phase I/IIa trial; and (iii) $75 thousand upon the earlier of generating net revenues of at least $200 thousand from the commercialization of the technology or the approval of the FDA or the European Medicines Agency, 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 16:- CONTINGENT LIABILITIES, COMMITMENTS, CLAIMS AND LIENS (CONT.)

c. License Agreement with Dekel Pharmaceuticals Ltd.: (Cont.)

On April 24, 2018, the Company paid the second milestone to the license agreement with Dekel in the amount of $75 thousand upon the successful completion of a Phase IIa trial. No other milestones were achieved during 2018 (see Note 22d.1).

d. Term sheet Agreement with Belvit Pharma LLC.:

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 tetrahydrocannabinol ("THC") with enhanced bioavailability. The Company initially intends to exploit this technology with respect to Mild Cognitive Impairments. 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's expense, a pharmacokinetics ("PK")/bioavailability study. 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 a PK/bioavailability study. The patent expiration date of any patent maturing from this application would likely be 2037. On August 25, 2017, the Company has received Chesapeake IRB (an Association for the Accreditation of Human Research Protection Programs-accredited company) approval for the protocol and ICF for the above mention PK study. Accordingly, the Company paid approximately $89 thousand for the PK study.

On April 30, 2018, the Company notified Belvit of its intent to terminate the binding term sheet dated June 7, 2016, between the Company and Belvit. Accordingly, the Company is discontinuing the development of its ultra-low dose THC via sublingual administration. As of December 31, 2018, the Company has no other commitments regarding this study.

e. On November 22, 2016, the Company entered into an investigator initiated study contract with Yale University ("Yale") to conduct a phase IIa clinical trial. In December 2016, the first patient was enrolled. The proposed trial will evaluate the safety, tolerability and efficacy of THX-110 in treating approximately 18 Tourette syndrome subjects aged 18 to 60. The total agreement is estimating in the amount of approximately $230 thousand.

On December 4, 2017, the enrolment was completed. During 2018, the Company paid Yale $120 thousand and recorded a provision in the amount of $11 thousand.

NOTE 16:- CONTINGENT LIABILITIES, COMMITMENTS, CLAIMS AND LIENS (CONT.)

f. On November 16, 2017, the Company entered into an agreement with FGK Clinical Research GmbH ("FGK") to perform CRO activities for the Tourette syndrome study that was performed in Germany during 2018. FGK will provide, inter alia, regulatory writing and submissions, CRF services, supervision of the study conduct, data management and statistical analysis. During the year ended on December 31, 2018, the Company paid FGK $394 thousand due to the agreement. As of December 31, 2018, the agreement was on hold. Additional payments in the aggregate amount of $214 thousand are expected in the future.

g. License Agreement with Yissum Research Development Company of the Hebrew University of Jerusalem Ltd:

In March 2017, the Company entered into an exclusive, worldwide, sublicensable, royalty-bearing license (the "Yissum License Agreement") 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, 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.

On March 18, 2018, the Company agreed to terminate the Yissum License Agreement, effective as of June 18, 2018, except for provisions which are expressly intended to survive termination. The Company did not make any regulatory filings and there were no development results generated under the Yissum License Agreement. In connection with such termination, the parties agreed to a mutual release. The Company estimates that the termination of the Yissum License Agreement shall have no material effect on its on-going projects and activities. In addition, the main reasons for said termination rest in the Company's intentions on focusing on more advanced drug delivery projects that are already under development.

On July 29, 2018, the Company entered into exclusive, worldwide, sublicensable, royalty-bearing license with Yissum for license to make commercial use of the licensed technology, in order to develop, obtain regulatory approvals, manufacture, market, distribute or sell products, all within the field and the territory only, as determined in the agreement (the "New License Agreement"). According to the New License Agreement, the Company shall pay Yissum royalties at the rates of future net sales, subject to the royalty reductions as described in the New License Agreement. The Company is also obligated to pay sublicense fees, out of the sublicense consideration. All right, title and interest in and to the New License Agreement shall vest solely in Yissum, and the Company shall hold and make use of the rights granted. All rights in the development results shall be solely owned by the Company, except to the extent that an employee of the Yissum, including the researcher, is considered an inventor of a patentable invention arising from the development results, in which case such invention and all patent applications and/or patents claiming such invention shall be owned jointly by the Company and Yissum, as appropriate, and Yissum's share in such joint patents shall be automatically included in the New License Agreements.

NOTE 16:- CONTINGENT LIABILITIES, COMMITMENTS, CLAIMS AND LIENS (CONT.)

g. License Agreement with Yissum Research Development Company of the Hebrew University of Jerusalem Ltd: (Cont.)

On October 4, 2018, the Company paid Yissum a total amount of $50 thousand due to the New License Agreement. The Company estimates that the expenses due to the research program of the New License Agreement and additional reimbursement for historical patent costs will be approximately $135 thousand.

h. On April 11, 2017, the Company entered into an investigator initiated study contract with Hannover Medical School ("MHH") to conduct during 2018 a phase IIb clinical trial titled "A Randomized, Double-Blind, Placebo controlled study to Evaluate the Safety, Tolerability and Efficacy of Up to Twice Daily Oral THX-110 in Treating Adults with Tourette Syndrome" in treating approximately 20 Tourette syndrome subjects aged 18 to 65. Upon the execution of the agreement the Company paid the first installment in the amount of $122 thousand out of a total estimated amount of approximately $776 thousand. Due to regulatory and strategic reasons, the Company decided to change the study design from investigator initiated to an industry sponsored trial. During October 2017, a discussion was carried out between the Company and MHH and the latter was informed about this change and a termination letter stating the above was sent to MHH on November 19, 2017. MHH acknowledges it will have to pay back parts of the first instalment that were paid by the Company in accordions with the initial contract.

On August 13, 2018, the Company entered into an agreement with MHH to conduct a clinical investigation and laboratory services for a randomized, double-blind, placebo-controlled proof of concept study to evaluate the safety, tolerability and efficacy of daily oral THX-110 in treating adults with Tourette syndrome in an estimated amount of $835 thousand.

i. On October 3, 2017, the Company entered into an agreement with Assuta Medical Center ("Assuta") to conduct a Phase IIa, sponsor-initiated trial for the treatment of OSA using the Company's proprietary cannabinoid-based technology, THX-110. The study was commenced in the second quarter of 2018. The expenses that were paid to Assuta during 2018 amounted to $20 thousand. The Company estimates that future expenses due to the agreement will aggregate to approximately $35 thousand.

j. As of December 31, 2018, several claims were filed against THR by different suppliers, due to the fact that THR, due to its economic situation (as discussed in Note 5), was, and as of the Approval Date of the consolidated financial statements, is not able to comply with the terms of the contracts signed with each specific supplier. The claims are in an amount aggregating to approximately $789 thousand. THR is looking to settle all claims and as of December 31, 2018, has recorded a provision of $250 thousand.

NOTE 16:- CONTINGENT LIABILITIES, COMMITMENTS, CLAIMS AND LIENS (CONT.)

k. Operating lease commitments:

- *Therapix Operating Lease Agreements:*

On July 10, 2017, a three-year (effective on August 1, 2017), lease agreement was signed with a third party (the "Lease Agreement") for an area of approximately 167 square meters in order to relocated the Company's offices from the Azrieli Center in Tel-Aviv to Hashahar tower in Givataaim. The monthly lease fee according to the Lease Agreement was set at approximately $6 thousand, linked to the NIS and Israeli CPI. The total rent expenses for the year ended on December 31, 2018, were approximately $72 thousand. As of December 31, 2018, the minimum lease payments for the following 19 months under the Lease Agreement are expected to be in the total amount of approximately $114 thousand.

According to the Lease Agreement, and in order to secure the Company's obligation for the lease of the offices above mentioned, the Company provided a bank guarantee of approximately $23 thousand in favor of the lessor. To secure the bank guarantee, the Company pledged such amount in a bank account.

- *THR Operating Lease Agreements:*

As of December 31, 2018, THR had seven operating lease agreements for its headquarters, lab and clinics in different states and cities in the U.S., in which the main lease agreement is for THR's headquarters and lab in Brentwood, Tennessee, which is estimated at $31 thousand per month, and is the longest agreement signed, which secured THR's usage of the buildings until August 2028. THR's total rent and related expenses since the Acquisition Date up until December 31, 2018, were approximately $253 thousand.

The future minimum lease fees payable as of December 31, 2018, are as follows:

	USD in thousands
For the year ended on December 31, 2019	$ 753
For the year ended on December 31, 2020	588
For the year ended on December 31, 2021 and onwards until 2028	3,261
	$ 4,602

THR was not requested to provide any bank guarantees due to the lease agreements.

NOTE 17:- EQUITY

a. Composition of share capital:

	December 31, 2018		December 31, 2017	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
	Number of shares			
Ordinary shares of NIS 0.1 par value each	300,000,000	140,252,374	300,000,000	139,885,534

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 were 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.

Description of American Depositary Shares ("ADSs"):

The Bank of New York Mellon, as depositary, will register and deliver ADSs. Each ADS represents forty (40) ordinary shares [or the right to receive forty (40) ordinary share] deposited with the principal Tel Aviv office of Bank HaPoalim, as custodian for the depositary. Each ADS will also represent any other securities, cash or other property which may be held by the depositary.

b. Changes in share capital:

Issued and outstanding share capital:

	Number of ordinary shares	NIS par value
Balance at January 1, 2018	139,885,534	13,988,553
Issuance of share capital	366,840	36,684
Balance at December 31, 2018	140,252,374	14,025,237

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 17:- 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:

1. 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 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 the Company's 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 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 shares), the Company issued the Investor an additional 1,529,910 ordinary shares. These issuances had no impact on the Company's Profit or Loss for the year ended on December 31, 2017.

2. On March 27, 2017, the Company announced the closing of its IPO 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 were 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.

3. Further to the matter discussed in Note 13c, on November 23, 2018, the Company issued to Yorkville 9,171 ADSs (equivalent to 366,840 ordinary shares).

NOTE 17:- EQUITY (CONT.)

f. Share options:

1. Further to the matter discussed in Note 16c, on May 16, 2016, after obtaining the TASE approval and as part of the conditions of the license agreement with Dekel, which became effective on August 19, 2016, 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.

2. Further to the description in Note 16c, 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, 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. The remaining share options held by Dekel expired on August 20, 2016, according to their original terms.

NOTE 18:- 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,		
	2018	2017	2016
	USD in thousands		
Expense arising from equity-settled share-based payment transactions	$ 604	$ 862	$ 301

1. The share-based payment transactions that the Company granted to its employees and consultants are described below.

During 2005, the Company's Board adopted the 2005 Employees Share Option Plan (the "2005 ESOP"). Ten years later, during 2015, the Company's Board adopted a new plan, the 2015 Employees Share Option Plan (the "2015 ESOP"). Under both the 2005 ESOP and 2015 ESOP, the Company may grant its employees and other service providers options to purchase the Company's ordinary shares ("Share Options"). As of December 31, 2017, no Share Options under the 2005 ESOP were available for grant. On August 29, 2017, the Board reserved an additional amount of 26,000,000 ordinary shares for the purposes of the 2015 ESOP (in addition to the originally 5,000,000 ordinary shares which were reserved under the plan), out of which a total of 8,280,475 were still available for grant as of December 31, 2018. No Share Options were granted during the year ended December 31, 2018.

NOTE 18:- SHARE-BASED PAYMENT TRANSACTIONS (CONT.)

a. The expense recognized in the financial statements: (Cont.)

2. Further to the description in Note 22d.2, and following the completion of the Company's IPO (see Note 17e.2), the unvested Share Options granted to the Company's former Chief Executive Officer ("CEO") on February 16, 2016, were fully vested. The total expenses recognized in respect of these Share Options were approximately $41 thousand, $80 thousand and $13 thousand during the year 2017, 2016 and 2015, respectively. In addition, as per the Company's former CEO employment terms, all installments of his Share Options (not including the Share Options above mentioned) that have not vested yet, continued to vest until the end of his notice, by October 4, 2017. The total expenses recognized in respect to these Share Options were approximately $4 thousand during the year ended on December 31, 2017, and $46 thousand for the period stated on the dates of commencement of the CEO's other grants up until December 31, 2016. All expenses, in the amount of approximately $10 thousand, which were recognized in respect to the Share Options installments that have not vested until October 4, 2017, were forfeited.

   On January 4, 2018, after not exercising any of the vested Share Options for the ninety days period granted according to the 2015 ESOP, the entire reserve from share-based payment transactions due to grants to the former CEO in the total amount of approximately $174 thousand, expired.

3. On August 29, 2017, the Company granted 413,750 ADS options (equal to 16,550,000 Share Options) under the 2015 ESOP to directors (and former directors), officers, employees and consultants, some of which were approved at the November 1, 2018, general meeting of the Company's shareholders. In addition, On December 11, 2017, the Company granted 49,000 ADS options (equal to 1,960,000 Share Options) under the 2015 ESOP to employees and consultants.

   The fair values of the ADS options, which were approved in August and November 2017, were $4.01 and $3.46 per ADS option, respectively. One grantee's grant was valued at $3.24 per ADS option, due to a higher exercise price of $7.10 instead of $5.60 like all other grantees. The fair value of the ADS options, which were approved on December 2017, was $3.81 per ADS option. One grantee's grant (a consultant of the Company) was valued at $3.45 per ADS option, due to a different expiration date. The exercised price is $5.60.

   The fair value for ADS options granted during 2017 was estimated using the Black-Scholes option pricing model with the following assumptions:

	2017		
	August	**November**	**December**
Dividend yield (%)	0%	0%	0%
Expected volatility (%)	76.52	77.01	73.12-76.16
Risk-free interest rate (%)	1.83	2.1%	2.16-2.23
Expected life of share options	6 years	6 years	6 years

NOTE 18:- SHARE-BASED PAYMENT TRANSACTIONS (CONT.)

b. Movement during the year:

1. The following table lists the number of Share Options or ADS options (see Note 17a), the weighted average exercise prices of Share Options or ADS options and changes in directors (and former directors), officers, employees and consultants Share Options or ADS options during the current and previous year:

	Number of share options	Weighted average exercise price USD	Number of ADS options	Weighted average exercise price USD
2018:				
Share/ADS options outstanding at the beginning of the year	22,719,525	$ 0.17	567,988	$ 6.72
Share/ADS options forfeited during the year	(750,000)	0.14	(18,750)	5.60
Share/ADS options expired during the year	(4,156,488)	0.16	(103,912)	6.53
Share/ADS options outstanding at the end of the year	17,813,037	0.15	445,326	6.18
Share/ADS options exercisable at the end of the year	9,138,863	0.16	228,472	6.58
2017:				
Share/ADS options outstanding at the beginning of the year	4,365,279	0.22	109,132	8. 84
Share/ADS options granted during the year	18,510,000	0.17	462,750	6.73
Share/ADS options forfeited during the year	(155,754)	0.26	(3,894)	10.33
Share/ADS options outstanding at the end of the year	22,719,525	0.17	567,988	6.72
Share/ADS options exercisable at the end of the year	7,602,026	$ 0.19	190,051	$ 7.46

2. No share/ADS options were granted during 2018. The weighted average fair value of the Options and ADS options granted in 2017 was $0.09 and $3.51, respectively.

3. The weighted average remaining contractual life of the share/ADS options outstanding was 4.99 years and 5.28 years as of December 31, 2018 and 2017, respectively.

4. The range of exercise prices of Share Options outstanding at the end of the year was $0.13 - $0.28 as of December 31, 2018, and $0.03 - $3.46 as of December 31, 2017. The range of exercise prices of ADS options outstanding at the end of the year was $5.20 - $11.20 as of December 31, 2018, and $1.20 - $138.40 as of December 31, 2017.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 19:- ADDITIONAL INFORMATION TO THE ITEMS OF PROFIT OR LOSS

		Year ended December 31,		
		2018	2017	2016
		USD in thousands		
a.	*Research and development expenses:*			
	Wages and related expenses	$ 667	$ 321	$ 195
	Share-based payment	109	103	100
	clinical studies	692	511	-
	Regulatory and other expenses	595	316	40
	Research and preclinical studies	593	362	387
	Chemistry and formulations	54	330	18
		2,710	1,943	740
b.	*General and administrative expenses:*			
	Wages and related expenses	1,866	808	399
	Share-based payment	495	759	201
	Professional and directors fees	1,407	1,007	495
	Business development expenses	1,348	74	87
	Office maintenance, rent and other expenses	768	211	58
	Investor relations and business expenses	368	871	-
	Expenses due to litigations and claims	250	-	-
	Regulatory expenses	77	80	28
		6,579	3,810	1,268
c.	*Other (income) expenses:*			
	Impairment of goodwill	160	-	-
	Impairment of intangible assets	273	-	-
	Capital gain from sale of property and equipment	(8)	-	-
	Share-based payment	-	-	26
	Capital gain from sale of subsidiary	-	-	(34)
	Capital loss from sale of property and equipment	-	1	-
		425	1	(8)
d.	*Finance income:*			
	Finance income due to the Convertible Debentures	(468)	-	-
	Exchange rate differences	(303)	-	-
	Finance income from the convertible loan	(35)	-	-
	Intercompany finance income	(22)	-	-
	Interest income on bank deposits	-	(1)	(1)
		(828)	(1)	(1)
e.	*Finance expenses:*			
	Finance expenses due to the Convertible Debentures	112	-	-
	Finance expenses from interest and commissions	11	5	1
	Exchange rate differences	-	486	7
		$ 123	$ 491	$ 8

NOTE 20:- LOSS PER SHARE OR ADS

a. Details of the number of shares and loss used in the computation of loss per share:

	Year ended December 31,					
	2018		2017		2016	
Amounts used in the computation of basic and diluted loss	Weighted number of shares (*) In thousands	Loss USD in thousands	Weighted number of shares (*) In thousands	Loss USD in thousands	Weighted number of shares (*) In thousands	Loss USD in thousands
Basic loss per share	139,924	$ (8,523)	116,743	$ (6,244)	37,458	$ (1,993)
Effect of potential dilutive Ordinary shares (**)	19,433	(395)	-	-	-	-
Diluted loss per share	159,357	$ (8,918)	116,743	$ (6,244)	37,458	$ (1,993)

(*) In order to calculate the weighted number of ADSs, the weighted number of shares was divided by 40 (refer to Note 17a).

(**) Due to the effect of the Convertible Debentures.

b. The computation of diluted loss per share or ADS did not include the following convertible securities since their inclusion would decrease the loss per share (anti-dilutive effect):

1. Share or ADS options to employees, officers, directors and consultants.

2. Non-marketable warrants to investor.

NOTE 21:- OPERATING SEGMENTS

The Group applies the principles of IFRS 8, "Operating Segments" ("IFRS 8"), regarding operating segments. The segment reporting is based on internal management reports of the Group's management, which are regularly reviewed by the chief operating decision maker to make decisions about resources to be allocated and assess performance. According to the principles of IFRS 8, the Group's management determined that since October 3, 2018, following the acquisition of THR (see Note 5), the Group has two reportable segments:

1. Development of drugs based on cannabinoid molecules to be approved by an official regulatory authority (the Company's operation); and

2. Pain clinic services, including lab services (THR's operation).

Due to the fact that both segments do not generate any revenues, and the economic situation of THR (as described in Note 5), the Group decided that a detailed note regarding operating segments will not add any material information to the financial statements, which was not already disclosed in Note 5.

NOTE 22:- TRANSACTIONS AND BALANCES WITH RELATED PARTIES

a. Balances with related parties:

	December 31, 2018		December 31, 2017	
	Key management personnel	Other related parties	Key management personnel	Other related parties
	USD in thousands		USD in thousands	
Current Liabilities	$ 511	$ 629	$ 54	$ 92

b. Transactions with related parties (not including amounts described in Note 22c):

	Year ended December 31,		
	2018	2017	2016
	USD in thousands		
Research and development expenses (Note 22d.1)	$ 75	$ -	$ -
General and administrative expenses (Note 22d.5)	$ 769	$ 1	$ 51
Other expenses	$ -	$ -	$ 26

c. Benefits to key management personnel (including directors):

	Year ended December 31,		
	2018	2017	2016
	USD in thousands		
Short-term benefits	$ 1,379	$ 1,043	$ 592
Share-based payment (Note 18)	$ 520	$ 312	$ 232

d. Material agreements signed with related parties:

1. Refer to Note 16c for information regarding the license agreement with Dekel, a private company controlled by the Company's chairman and interim CEO, Dr. Ascher Shmulewitz.

2. On May 24, 2017, the Company announced that following a mutual decision of the Board and the Company's former Chief Executive Officer, Dr. Elran Haber, Dr. Haber would step down from his position as the Company's Chief Executive Officer. As per his employment terms, all installments of his Options, which were granted on May 4, 2014, and May 20, 2015, continued to vest until the end of his notice, by October 4, 2017. See Note 18a.2 for further description in this matter.

NOTE 22:- TRANSACTIONS AND BALANCES WITH RELATED PARTIES (CONT.)

d. Material agreements signed with related parties: (Cont.)

3. On November 1, 2017, the general meeting of the Company's shareholders appointed the Chairman of the Board, Dr. Ascher Shmulewitz, as the Company's Interim CEO, to be in this office for an initial period no longer than three years.

4. In May 2017, the Company entered into an employment agreement with a Chief Financial Officer (the "Former CFO") for a three months trial period. On December 19, 2017, the Company entered into a separation agreement with the Former CFO as further detailed below. In addition, the Company's former VP Finance, Mr. Guy Goldin, has ceased providing on going services, and as of January 1, 2018, renders his financial services on an hourly basis (as a consultant to the Company). Since December 2017, Mr. Oz Adler, served as the Company's VP Finance, and during 2018 was appointed as the Company's and the Group's CFO.

   With respect to the departure of the Former CFO, the Company entered into a mutually-amicable separation agreement (the "Separation Agreement") on December 19, 2017 (the "Effective Date"). Under the terms of the Separation Agreement (which are similar in essence to his original termination terms under his employment agreement), the Former CFO received severance in the amount of (i) three months' salary through the end of the notice period following the Effective Date and (ii) a bonus equal to two months of salary. In addition, all of the Former CFO's outstanding options to purchase 47,500 ADSs of the Company deemed fully vested as of the Effective Date and were exercisable until June 19, 2018. On June 19, 2018, all share options, in respect of which expenses in the amount of approximately $160 thousand were recorded, expired.

5. THR works jointly with GLPS based on a signed Service Agreement (the "GLPS Service Agreement"). According to the GLPS Service Agreement, GLPS is the employer of the physicians and nurse practitioners operating THR's pain management clinics. The pain management clinics operate under the name of Therapix Medical Solutions. THR provides the corporate oversight and management services (i.e. operational and financial: accounting, payroll, human resources etc.) to the clinics. THR only employees the non-medical staff working at the clinics, as well as the corporate staff.

   GLPS is a related party of the Group due to the fact that GLPS in owned by the CEO and the Chief Medical Officer ("CMO") of THR, which are also Directors of THR.

   As of December 31, 2018, the balance due to GLPS for the services under the GLPS Service Agreement is in the amount of approximately $629 thousand.

NOTE 23:- EVENTS AFTER THE REPORTING DATE

On March 28, 2019, the Company entered into a definitive securities purchase agreement (the "Purchase Agreement") with institutional investors to purchase (i) 642,853 of the Company's ADSs, representing 25,714,120 ordinary shares, at a purchase price of $3.50 per ADS, in a registered direct offering (the "Registered Direct Offering"); and (ii) warrants to purchase up to 482,139 ADSs, representing 19,285,560 ordinary shares, with an initial exercise price of $3.50 per ADS (the "Warrants"), in a concurrent private placement (the "Private Placement" and, together with the Registered Direct Offering, the "Offerings").

The total gross proceeds to the Company from the Offerings were approximately $2.25 million. The closing of the sale of the ADSs and Warrants occurred on April 1, 2019.

The ADSs to be issued under the Registered Direct Offering were issued pursuant to a prospectus supplement dated as of March 28, 2019, which was filed with the SEC, in connection with a takedown from the Company's shelf registration statement on Form F-3, which became effective on July 20, 2018.

The Warrants which were issued in the Private Placement, along with the ADSs issuable upon their exercise, were offered pursuant to Section 4(a)(2) under the Securities Act of 1933, as amended, and Regulation D promulgated thereunder and may not be offered or sold in the United States absent registration with the SEC or an applicable exemption from such registration requirements.

The Warrants will be exercisable beginning immediately as of their issuance date and have a term of three years.

In addition, following a payment of approximately $250 thousand to Yorkville as part of their participation in the Purchase Agreement, the outstanding debt under the Securities Purchase Agreement mentioned in Note 13c, has decreased to $1.25 million.

Exhibit 2.(d)

Description of Rights of Each Class of Securities

Type and Class of Securities

Therapix Biosciences Ltd.'s (the "Company") authorized share capital consisted of 300,000,000 ordinary shares, NIS 0.1 par value per share ("Ordinary Shares"), of which 165,966,494 shares were issued and outstanding as of such date. All of the Company's outstanding Ordinary Shares have been validly issued, are fully paid and non-assessable.

Preemptive Rights

The Company's Ordinary Shares are not redeemable and are not subject to any preemptive right.

Limitations or Qualifications

Not applicable.

Other Rights

Not applicable.

Rights of the Shares

The Company's Ordinary Shares shall confer upon the holders thereof:

- equal right to attend and to vote at all of the Company's 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 the Company's dissolution, in the distribution of the Company's assets legally available for distribution, on a per share pro rata basis.

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

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.

Limitations on the Rights to Own Ordinary Shares

The Company's fully paid Ordinary Shares are issued in registered form and may be freely transferred under the Company's 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 the Company's Ordinary Shares by non-residents of Israel is not restricted in any way by the Company's 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.

Provisions Restricting Change in Control of the Company's Company and Ownership Threshold - Acquisitions under Israeli Law

Merger

The Israeli Companies Law (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.

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 the Company's securities were traded on the Tel Aviv Stock Exchange, the Israeli Securities Law did not allow the Company to create and issue shares having rights different from those attached to the Company's 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 the Company's articles of association, which requires the prior approval of the holders of a majority of the voting power attaching to the Company's 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.

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.

Differences between law of different jurisdictions

Not applicable.

Changes in the Company's Capital

The Company's articles of association enable the Company to increase or reduce the Company's share capital. Any such changes are subject to the provisions of the Companies Law and must be approved by a resolution duly passed by the Company's 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 the Company's Board of Directors and an Israeli court.

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

- increase the Company's 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 has not been taken or agreed to be taken by any person;
- consolidate and divide all or any of the Company's share capital into shares of larger nominal value than the Company's existing shares;
- subdivide the Company's existing shares or any of them, the Company's share capital or any of it, into shares of smaller nominal value than is fixed;
- reduce the Company's 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.

Debt Securities

Not applicable.

Warrants and Rights

Not applicable.

Other Securities

Not applicable.

Name of the Depositary

The Bank of New York Mellon, as depositary, will register and deliver American Depositary Shares ("ADSs"). Each ADS will represent forty (40) shares (or a right to receive forty (40) shares) deposited with the principal Tel Aviv office of Bank HaPoalim, as custodian for the depositary. Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The depositary's office at which the ADSs will be administered is located at 101 Barclay Street, New York, New York 10286. The Bank of New York Mellon's principal executive office is located at 225 Liberty Street, New York, New York 10286.

American Depositary Shares

A holder of the Company's ADSs (the "Holder") may hold ADSs either (A) directly (i) by having an ADR, which is a certificate evidencing a specific number of ADSs, registered in the Holder's name, or (ii) by having ADSs registered in the Holder's name in the Direct Registration System, or (B) indirectly by holding a security entitlement in ADSs through the ADS Holder's broker or other financial institution. If the Holder hold ADSs directly, the Holder is a registered ADS holder, also referred to as an ADS holder. This description assumes the Holder is an ADS holder. If the Holder holds the ADSs indirectly, the Holder must rely on the procedures of the Holder's broker or other financial institution to assert the rights of ADS holders described in this section. The Holder should consult with his broker or financial institution to find out what those procedures are.

The Direct Registration System, also referred to as DRS, is a system administered by The Depository Trust Company, also referred to DTC, under which the depositary may register the ownership of uncertificated ADSs, which ownership is confirmed by statements sent by the depositary to the registered holders of uncertificated ADSs.

As an ADS holder, the Company will not treat the Holder as one of the Company's shareholders and the Holder will not have shareholder rights. Israeli law governs shareholder rights. The depositary will be the holder of the shares underlying the Holder's ADSs. As a registered holder of ADSs, the Holder will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The Company's articles of association contain a provision that gives the authority to the Company's Board of Directors (instead of the Company's officers or shareholders at a general meeting, for example) to refer an action to arbitration. However, such arbitration provision is not mandatory and it does not prevent ADS holders or ordinary shareholders from pursuing claims under the United States federal securities laws.

The following is a summary of the material provisions of the deposit agreement. For more complete information, the Holder should read the entire deposit agreement and the form of ADR.

Dividends and Other Distributions

How will the Holder receive dividends and other distributions on the shares?

The depositary has agreed to pay to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. The Holder will receive these distributions in proportion to the number of shares the Holder's ADSs represent.

Cash.

The depositary will convert any cash dividend or other cash distribution the Company pays on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. It will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, the Holder may lose some or all of the value of the distribution.*

Shares.

The depositary may distribute additional ADSs representing any shares the Company distributes as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares sufficient to pay its fees and expenses in connection with that distribution (or ADSs representing those shares).

Rights to purchase additional shares.

If the Company offers holders of the Company's securities any rights to subscribe for additional shares or any other rights, the depositary may make these rights available to ADS holders. If the depositary decides it is not legal and practical to make the rights available but that it is practical to sell the rights, the depositary will use reasonable efforts to sell the rights and distribute the proceeds in the same way as it does with cash. The depositary will allow rights that are not distributed or sold to lapse. *In that case, the Holder will receive no value for them.*

If the depositary makes rights available to ADS holders, it will exercise the rights and purchase the shares on the Holder's behalf. The depositary will then deposit the shares and deliver ADSs to the persons entitled to them. It will only exercise rights if the Holder pays it the exercise price and any other charges the rights require the Holder to pay.

U.S. securities laws may restrict transfers and cancellation of the ADSs represented by shares purchased upon exercise of rights. For example, you may not be able to trade these ADSs freely in the United States. In this case, the depositary may deliver restricted depositary shares that have the same terms as the ADSs described in this section except for changes needed to put the necessary restrictions in place.

Other Distributions.

The depositary will send to ADS holders anything else the Company distributes on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what the Company distributed and distributes the net proceeds, in the same way as it does with cash. Or, it may decide to hold what the Company distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from the Company that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. The Company has no obligation to register ADSs, shares, rights or other securities under the Securities Act. The Company also has no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. *This means that the Holder may not receive the distributions the Company makes on the Company's shares or any value for them if it is illegal or impractical for the Company to make them available to the Holder*.

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if the Holder or the Holder's broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names the Holder requests and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

The Holder may surrender his ADSs at the depositary's office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at the Holder's request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

The Holder may surrender his ADR to the depositary for the purpose of exchanging the Holder's ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Alternatively, upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do the Holder vote?

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. *Otherwise, the Holder won't be able to exercise the Holder's right to vote unless the Holder withdraw the shares. However, the Holder may not know about the meeting enough in advance to withdraw the shares.*

The depositary will notify ADS holders of shareholders' meetings and arrange to deliver the Company's voting materials to them if the Company asks it to. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they much reach the depositary by a date set by the depositary.

The depositary will try, as far as practical, subject to the laws of Israel and of the Company's articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. The depositary will only vote or attempt to vote as instructed or as described in the following sentence. If the Company asked the depositary to solicit the Holder's instructions at least 30 days before the meeting date but the depositary does not receive voting instructions from the Holder by the specified date, it will consider the Holder to have authorized and directed it to give a discretionary proxy to a person designated by the Company to vote the number of deposited securities represented by the Holder's ADSs. The depositary will give a discretionary proxy in those circumstances to vote on all questions at to be voted upon unless the Company notifies the depositary that:

- the Company does not wish to receive a discretionary proxy;
- there is substantial shareholder opposition to the particular question; or
- the particular question would have an adverse impact on Company's shareholders.

The Company is required to notify the depositary if one of the conditions specified above exists.

The Company cannot assure the Holder that the Holder will receive the voting materials in time to ensure that the Holder can instruct the depositary to vote the Holder's shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that the Holder may not be able to exercise the Holder's right to vote and there may be nothing the Holder can do if the Holder's shares are not voted as the Holder requested.*

In order to give the Holder a reasonable opportunity to instruct the Depositary as to the exercise of voting rights relating to Deposited Securities, if the Company requests the Depositary to act, the Company agrees to give the Depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

Exhibit 4.2

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THERAPIX BIOSCIENCES LTD. IF PUBLICLY DISCLOSED. OMISSIONS ARE DENOTED IN BRACKETS THROUGHOUT THIS EXHIBIT.

RESEARCH AND LICENSE AGREEMENT

This Research and License Agreement ("**Agreement**") is made in Jerusalem this 29 day of June, 2018 (the "**Effective Date**"), by and between:

YISSUM RESEARCH DEVELOPMENT COMPANY OF THE HEBREW UNIVERSITY OF JERUSALEM, LTD., of Hi Tech Park, Edmond J. Safra Campus, Givat Ram, Jerusalem 91390, Israel ("**Yissum**") of the first part; and

THERAPIX BIOSCIENCES LTD., of 4 Ariel Sharon St. Givatayim, Israel; (the "**Company**"), of the second part;

(each of Yissum and the Company, a "**Party**", and collectively the "**Parties**")

WHEREAS: in the course of research conducted by Prof. Raphael Mechoulam (the "**Researcher**") and the late Prof. Itai Bab, at the University (as defined in Section 1 below), the Researcher developed technology comprising composition of CB2 agonist (HU-433) for various indications, as more fully described in the patents listed in **Appendix A** (collectively, the "**Existing Patents**"); and

WHEREAS: pursuant to the regulations of the University, the rights and title to all inventions, know-how and the results of research created by scientists of the University vest solely with Yissum, including the technology developed by the Researcher as aforesaid; and

WHEREAS: Yissum and the Company entered into a Material Transfer Agreement dated October 7, 2017 (the "**MTA Agreement**") pursuant to which Yissum transferred the Company the HU-433 compound for an evaluation (the "**Evaluation**"), and rights and title to any and all patents, patent applications, information, material, results, devices, and know-how created, generated or reduced to practice in the course of or arising from the performance of the Evaluation and related to the Materials and/or Yissum's Background Results (as such terms are defined in the MTA Agreement) (the "**Evaluation Results**") vest solely with Yissum; and

WHEREAS: the Company has represented to Yissum that (i) the Company is experienced in the development of products in the Field similar to those to be based on the inventions that are the subject of this Agreement; and (ii) either by itself or through third parties, it has the financial capacity and the strategic commitment to facilitate the development, production, marketing, sale and distribution of such products; and

WHEREAS: the Company is interested in the performance of research, by and under the supervision of the Researcher at the University, and is willing to finance the performance of such research in accordance with the terms of this Agreement; and

WHEREAS: the Company wishes to obtain an exclusive license from Yissum for the development and commercialization, in the Field, of the inventions covered by the Existing Patents and the Evaluation Results; and

WHEREAS: Yissum agrees to grant the Company such a license, all in accordance with the terms and conditions of this Agreement.

NOW THEREFORE THE PARTIES DO HEREBY AGREE AS FOLLOWS:

1. Interpretation and Definitions

1.1. The preamble and appendices to this Agreement constitute an integral part hereof and shall be read jointly with its terms and conditions.

1.2. In this Agreement, unless otherwise required or indicated by the context, the singular shall include the plural and *vice-versa*, the masculine gender shall include the female gender, "including" or "includes" shall mean including, without limiting the generality of any description preceding such terms and the use of the term "or" shall mean "and/or" and any reference to the term "sale" shall include the sale, lease, rental, or other disposal of any Product.

1.3. The headings of the Sections in this Agreement are for the sake of convenience only and shall not serve in the interpretation of the Agreement.

1.4. In this Agreement, the following capitalized terms shall have the meanings appearing alongside them, unless provided otherwise:

1.4.1. "**Affiliate**" shall mean any person, organization or other legal entity which controls, or is controlled by, or is under common control with, the Company. "**Control**" shall mean the holding fifty percent (50%) or more of (i) the equity, or (ii) the voting rights, or (iii) the right to elect or appoint directors.

1.4.2. "**Development Plan**" shall mean the written plan and timetable, a copy of which is attached to this Agreement as **Appendix C**, for the development and the commercialization of Products, including specific development milestones, prepared by the Company and approved by Yissum pursuant to Section 5.1 below.

1.4.3. "**Development Results**" shall mean the results of activities carried out by the Company or by third parties (other than the Researcher and his/her team or any other University employee) at the direction of the Company pursuant to the Development Plan, including any invention, patent or patent application, product, material, method, discovery, composition, process, technique, know-how, data, information or other result which do not form part of the Licensed Technology, and further including any governmental or regulatory filing submitted, or approval, license, registration, or authorization obtained, by the Company, an Affiliate or Sublicensee in respect of the Products, as well as any other information, data, material, results, devices and know-how arising from the performance of the Development Plan.

1.4.4. "**Field**" shall mean all therapeutic uses of HU-433 molecule (as such molecule is described in the Licensed Patents), for any and all indications except for ophthalmology which may be added pursuant to Section 2.9 below.

1.4.5. "**First Commercial Sale**" shall mean the first sale of a Product by the Company, an Affiliate or a Sublicensee after the receipt of any required regulatory approval to market and sell such Product. Notwithstanding the foregoing and for the avoidance of doubt, sales of Products for the purposes of clinical trials or other testing prior to a First Commercial Sale shall entitle Yissum to payment of consideration in accordance with Sections 7.2 (Royalties); 7.4 (Milestone Payments); and 7.5 (Sublicense Fee) of this Agreement, but shall not be considered a First Commercial Sale.

1.4.6. "**License**" shall have the meaning set forth in Section 3.1 below.

1.4.7. "**Licensed Patents**" shall mean (i) the Existing Patents, and any patent application that claims priority therefrom; as well as (ii) all divisions, continuations, continuations-in-part, re-examinations, reissues, renewals, registrations, confirmations, substitutions, or extensions, including European Supplementary Protection Certificates ("**SPCs**") (within the meaning of such term under Council Regulation (EU) No. 1768/92), and/or any other similar statutory protection, and any provisional applications, national, regional, PCT or similar applications and any and all patents issuing from, and patentable inventions, methods, processes, and other subject matter disclosed or claimed in, any or all of the foregoing.

1.4.8. "**Licensed Technology**" shall mean, the, the Licensed Patents, the Evaluation Results, the HU 433 Research Results, and Yissum's interest in any Joint Patent.

1.4.9. "**Net Sales**" shall mean:

(a) the gross sales price invoiced for sales of Products by the Company, an Affiliate or Sublicensee to a third party ; or

(b) the fair market value of non-monetary consideration received in connection with such sales; after deduction of: (i) discounts and return credits to the extent actually taken by third parties; and (ii) to the extent separately stated on purchase orders or invoices, sales and other applicable taxes, including VAT, customs, duties or other governmental charges levied on the production, sale, transportation, import or export, delivery, (but excluding income tax and the like) or paid by customers for transfer in full to applicable tax authorities; provided that such deductions shall be reasonable and directly related to the sale of Products that were awarded within the regular running of the business of the Company, Affiliate or Sublicensee. For the sake of clarity, any payment or rebate received by the Company, an Affiliate or Sublicensee from any governmental agency directly in relation to the sales shall be considered as Net Sales.

In the event of sales of Products made through a distributor, or marketing agent, where the Company, Affiliate or Sublicensee is entitled to receive from such distributor, or marketing agent, in addition to any fixed price, any further compensation for such transfer based upon the price at which the distributor or marketing agent sells Products to a third party, such further compensation, when received by the Company, Affiliate or Sublicensee from such distributor, or marketing agent, shall also be deemed "gross sales" for the purposes of this Agreement.

In the event of sales or deductions not made at "arms-length", then for the purpose of calculation of Royalties (as defined below) to Yissum, Net Sales shall be calculated in accordance with arms-length prices for sale of Products to an independent third party purchaser and arms-length deductions, to be determined by the current market conditions, or in the absence of such conditions, according to the assessment of an independent appraiser to be selected by the Parties.

With respect to sales by the Company or its Affiliate or Sublicensee, as applicable, to any Affiliate or Sublicensee of any of the foregoing, as the case may be, the term "Net Sales" shall mean the amount received by such Affiliate or Sublicensee on resale to an independent third party after deduction of the items specified above, to the extent applicable.

1.4.10. "**Product**" shall mean any product, system, device, material, method, process or service, the development, obtaining regulatory approvals (including clinical development, marketing and sales) manufacture, provision, marketing or sale of which, in whole or in part (i) uses, exploits, comprises, contains, improves upon or incorporates the Licensed Technology or the Development Results or any part thereof, or is otherwise covered thereby, or falls within the scope thereof, in whole or in part, or uses the Licensed Technology or the Development Results as a basis for subsequent modifications; or (ii) but for the License (as defined below) would infringe any claim of a Licensed Patent.

1.4.11. "**Representatives**" shall mean employees, researchers, officers, agents, subcontractors, consultants, and/or any other person or entity acting on a Party's behalf.

1.4.12. "**Research**" shall mean the research to be conducted by the Researcher during the Research Period on two distinct projects as follows: (i) synthesis of the HU433 molecule (the "**HU433 Research**") and (ii) a project to be determined by the Researcher, in its sole discretion that does not relate to the HU433 molecule (the "**Other Research**"); both pursuant to a Research Budget.

1.4.13. "**Research Budget**" shall mean the budget set forth in **Appendix B**.

1.4.14. "**Research Period**" shall mean a two (2) year period commencing from the effective Date.

1.4.15. "**HU433 Research Results**" shall mean any inventions, products, materials, compounds, compositions, substances, methods, processes, techniques, know-how, data, information, discoveries and other results of whatsoever nature, discovered or occurring in the course of, or arising from, the performance of the HU433 Research that is related to the HU433 molecule, including any patent applications and patents and, information, material, results, devices or know-how arising therefrom.

1.4.16. "**Other Research Results**" shall mean any inventions, products, materials, compounds, compositions, substances, methods, processes, techniques, know-how, data, information, discoveries and other results of whatsoever nature, discovered or occurring in the course of, or arising from, the performance of the Other Research that do not relate to the HU433 molecule, including any patent applications and patents and, information, material, results, devices or know-how arising therefrom.

1.4.17. "**Researcher**" shall mean Professor Raphael Mechoulam, or such other person as determined and appointed from time to time by Yissum, with the written agreement of the Company, to supervise and to perform the Research, if applicable.

1.4.18. "**Royalties**" shall have the meaning set forth in Section 7.2 below.

1.4.19. "**Subcontracting Agreement**" shall mean (i) a bona fide subcontracting agreement with a subcontractor in which the Company must grant the subcontractor the right to make use of the Licensed Technology on behalf of the Company, and for which use the Company is required to pay or otherwise compensate the subcontractor, including, but not limited to, manufacturing or developing any of the Products (or part thereof); or (ii) a bona fide arms-length research agreement, pursuant to which an academic or research institution is engaged for the purpose of performing research, on the Company's behalf, for the development of any of the Products (or part thereof); provided that in no event shall the consideration (if any) therefor comprise any Products; and further provided that such subcontracting agreement in (i) and (ii) above shall contain terms substantially as protective in relation to the Licensed Technology, as the terms of this Agreement; and the term "**Subcontractor**" shall be construed accordingly.

1.4.20. "**Sublicense**" shall mean any grant by the Company or its Affiliates of any of the rights granted under this Agreement or any part thereof; including the right to develop, manufacture, market, sell or distribute the Licensed Technology or any Product, for which grant the recipient of the Sublicense is required to pay the grantor of the Sublicense (or the grantor's related entity), excluding a Subcontracting Agreement and further excluding agreements with resellers, channels, or distributors that are operating under an agreement with Licensee or Sublicensee, or any Affiliate thereof, solely for the distribution and sale of a Product in its final form and paying fair market value for their purchase of the Product as a bona fide distributor or reseller, provided that the only license rights granted by the Licensee, Sublicensee or Affiliate, as applicable, to such reseller or distributor are distribution and sale (such distributors and resellers collectively: "**Distributors**").

1.4.21. "**Sublicense Consideration**" shall mean any proceeds or consideration or benefit of any kind whatsoever, whether monetary or otherwise, that the Company or an Affiliate actually receive from a Sublicensee as a result of the grant of a Sublicense or an option for a Sublicense and/or pursuant thereto, except for (i) amounts received by the Company or an Affiliate which constitute royalties based on sales by Sublicensees in respect of which the Company is required to pay Royalties to Yissum, (ii) research and development funding pursuant to a research and development plan and budget, a copy of which will be provided to Yissum at its request and provided that such funding is actually used to cover the actual cost for research and development of a Product performed under the Sublicense agreement, and (iii) any amounts received from a Sublicensee as a result of the purchase of debt or equity securities by a Sublicensee (but only with respect to the portion of payments not in excess of the market value of such securities).

1.4.22. "**Sublicense Fees**" shall have the meaning set forth in Section 7.5 below.

1.4.23. "**Sublicensee**" shall mean any third party to whom the Company or an Affiliate shall grant a Sublicense or an option for a Sublicense. For the sake of clarity, Sublicensee shall include any other third party (other than a Subcontractor and Distributors) to whom such rights shall be transferred or assigned, or who may assume control thereof by operation of law or otherwise, it being clarified that a change of control in the Company shall not be deemed a transfer or assignment of rights hereunder.

1.4.24. "**Territory**" shall mean worldwide.

1.4.25. "**University**" shall mean the Hebrew University of Jerusalem and each of its branches.

1.4.26. "**Valid Claim**" shall mean (i) a claim of: (a) any issued, unexpired patent which has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reexamination, reissue, disclaimer or otherwise, or (b) any patent application that has not been cancelled, rejected, withdrawn or abandoned without the possibility of appeal or re-filing. For the avoidance of doubt, the term "Valid Claim" shall include any extension of the exclusivity period under a claim of an issued patent included within the Licensed Technology through patent term extension, SPC, US Patent Term Extensions (PTEs), or any other arrangement whereby the exclusivity period of any such patent or any part thereof is extended.

2. Research

2.1. The Company hereby undertakes to finance performance of the Research in accordance with a Research Budget during the Research Period or any amendments thereof.

2.2. The Research shall be conducted by and under the supervision of the Researcher and in full coordination with the Company. Should the Researcher be unable to complete the Research for any reason, Yissum shall notify the Company of the identity of a suitable replacement researcher within thirty (30) days of the Researcher being unable to complete the Research. If the Company does not object in writing to the replacement researcher on reasonable grounds within twenty (20) days of this notification, the substitute researcher shall be deemed acceptable to the Company and all provisions of this Agreement applicable to the Researcher shall apply to such substitute researcher. Alternatively, the Company shall have the right to terminate the Research, provided that (i) no monies paid to Yissum for the Research in accordance with the Research Budget and pursuant to the schedule set forth in Section 2.4 below will be refundable; (ii) the Company shall be responsible for the payment of any accrued fees and expenses due to Yissum based on work duly performed up to the date of termination and those irrevocable commitments that were part of the Research Budget and entered into by Yissum prior to having received the Company's written notice of termination and (iii) the Company and Yissum shall not bear any liability for such termination.

2.3. For the avoidance of doubt, should the Company wish to place its employees in the laboratories of the Researcher on any campus of the University in connection with the Research or any other aspect of this Agreement it may do so after executing a separate agreement with Yissum setting out the terms of such placement.

2.4. As compensation to Yissum for the Research, subject to any earlier termination of the Research pursuant to Section 2.2 above, the Company shall pay Yissum the total sum seventy five thousand US Dollars ($75,000) inclusive of overhead but plus Value Added Tax as required by law, as follows: (i) twenty five thousand US Dollars (US$25,000) for the HU433 Research and (ii) fifty thousand US dollars (US$50,000) for the Other Research; payable as set forth in **Appendix B**.

2.5. Yissum shall have the right of first offer but without an obligation of the Company to accept, to conduct any additional research, which may be required by the Company to develop a Product, provided that there are employees of the University competent and available to perform such additional research.

2.6. For the avoidance of doubt, nothing herein shall prevent Yissum or the University or the Researcher from obtaining any finance or grants from other entities for non-commercial research regarding the Licensed Technology, provided that such entities may be granted with the same rights in the Licensed Technology, Research or Research Results reserved hereunder to Yissum or the University or the Researcher and provided that such rights are not prejudicial to the rights granted to the Company in this Agreement.

2.7. Yissum shall present the Company, within sixty (60) days of a request by the Company, with a written report from the Researcher summarizing the results of the HU433 Research Results in the form reasonable requested by the Company (the "**Research Report**") but in no event more than twice per year during the Research Period. The HU433 Research Results shall be automatically included in the Licensed Technology.

2.8. The Company shall have a right of first review of the Other Research Results for a period of ninety (90) days from the completion of the Other Research (the "**Review Period**"). If the Company is interested in obtaining such a license, the Company shall notify Yissum, in writing, within the Review Period (the "**Notice**"). In the event that Yissum receives a Notice within the Review Period, the Company and Yissum shall enter negotiations in good faith in order to reach an agreement with regard to the terms of the license. In the event that: (i) the Company fails to deliver a Notice to Yissum within the Review Period; or (ii) the Company notifies Yissum in writing that it is not interested in obtaining a license; or (iii) the Company delivers a Notice to Yissum within the Review Period, but the parties do not reach and finalize an agreement within ninety (90) days from the end of the Review Period (the "**Negotiations Period**"), Yissum shall be entitled to commercialize or otherwise grant third parties any right or title in and to the Other Research Results according to Yissum' sole discretion and without any further obligation to the Company.

2.9. In addition, in the event that the Company wishes at any time as of the Effective Date for a period of 90 days thereafter (the "**Option Period**") to obtain an exclusive license under the Licensed Technology for the field of ophthalmology, then it shall provide Yissum with notice in writing (prior to the end of the Option Period) and upon receipt of such notice, the Parties shall negotiate in good faith the terms of such additional license for a period of 90 days from such notice. During the Option Period and negotiations period as aforesaid, Yissum shall not solicit any offers for or grant any third party with rights that may circumvent the rights of the Company hereunder.

2.10. Nothing contained in this Agreement shall be construed as a warranty on the part of Yissum that any results or inventions will be achieved by the Research, or that the Research Results, if any, are or will be commercially exploitable. Yissum makes no warranties whatsoever as to the commercial or scientific value of the Research Results.

2.11. Should the Company choose, at its sole discretion, to (a) retain the services of the Researcher or any other employee of the University in connection with the Research or the License; or (b) grant any benefit, including cash payments or securities of any kind, to the Researcher or any other employee of the University, it shall do so only through a written agreement executed between the Company and Yissum. Any such agreement will require, among other things, that any intellectual property rights generated under such agreement will be governed by the terms of this Agreement.

3. The License

3.1. Subject to the full performance by the Company of its obligations in accordance with this Agreement and the provisions of Section 16, Yissum hereby grants the Company an exclusive license to make commercial use of the Licensed Technology, in order to develop, obtain regulatory approvals, manufacture, market, distribute or sell Products, all within the Field and the Territory only, subject to and in accordance with the terms and conditions of this Agreement (the "**License**").

3.2. Notwithstanding the provisions of Section 3.1, above, Yissum, on behalf of the University, shall retain the right (i) to make, use and practice the Licensed Technology for the University's own research and educational purposes; and (ii) to license or otherwise convey the Licensed Technology, in whole or in part, to any third party for research or commercial applications outside the Field. In the event Yissum receive requests for the Licensed Technology from researchers at academic and/or not-for-profit research organizations for use in non-commercial research in the Field, Yissum will forward the requests to the Company, and the Company, in consultation with the Researcher, will determine whether it is willing to supply Licensed Technology for such purpose. Any such disclosure or other supply of Licensed Technology shall be made pursuant to the Company's standard form confidentiality or material transfer agreement (as the case may be) and will acknowledge Yissum's contribution.

4. Term of the License

The License shall expire, if not earlier terminated pursuant to the provisions of this Agreement, 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. Should the periods referred to in Subsections (i) or (ii) expire in a particular country prior to the period referred to in Subsection (iii), above, the license in that country or those countries shall be deemed a license to the Know-How during such post-expiration period (the "**Term**").

Upon the expiration of the later of the periods set forth in Subsections (i) through (iii) above (and provided that the License has not been terminated prior thereto), the Company shall have a fully-paid non-exclusive license to the Know-How in the Field, and the Company shall have an irrevocable option to obtain an exclusive license in the Field to the Know-How by agreeing to pay Yissum [**] ([**]%) of the consideration set forth in Section 7.2 and 7.5 below, in respect of Net Sales and Sublicense Consideration received during the period of such license which shall continue for a period of five (5) years after termination of the later of the periods as referred to above and shall be renewed automatically for additional successive five (5) year periods, unless the Company or Yissum notifies the other Party in writing prior to the end of the then current five (5) year period that it does not wish the license to be renewed as aforesaid.

5. Development and Commercialization.

5.1. The Company undertakes, at its own expense, to use commercially reasonable efforts to carry out the development, regulatory, manufacturing and marketing work necessary to develop and commercialize Products in accordance with the Development Plan (including the Essential Development Milestones defined below) agreed by Yissum, a copy of which shall be incorporated into this Agreement as **Appendix C** within 45 (forty-five) days of the Effective Date, as such Development Plan may be amended, modified or replaced from time to time as determined by the Board of Directors of the Company (the "**Board**"), in its sole and absolute discretion, provided however that the Company shall amend any of the milestones set forth in **Appendix C** under the heading 'Essential Development Milestone' ("**Essential Development Milestones**") only if the Company first receives the written approval of Yissum for the particular amendment. All terms and conditions of the License and this Agreement shall apply to the modified Development Plan and subsequent Development Results. In the event that there is no Development Plan (including the Essential Development Milestones) prepared by the Company that meets Yissum's approval and is incorporated into this Agreement within 45 (forty-five) days of the Effective Date, then Yissum shall be entitled, at its sole discretion, to terminate without cause, with immediate effect, this Agreement and all rights of the Company hereunder, upon written notice to the Company of such termination.

5.2. The Parties shall establish a steering committee (the "**Committee**") to oversee the exercise of the License. Each Party shall be entitled to designate two (2) representatives to the Committee (the "**Committee Representatives**"), which shall meet at least twice per calendar year. The Committee Representatives shall be bound by the confidentiality arrangements set out in this Agreement. The Company shall consult with Yissum, via Yissum's Committee Representatives, in respect of significant decisions related to the exercise of the License. For the avoidance of doubt, the Committee shall be a forum for the exchange of information between the Parties with respect to the foregoing matters, shall act only in an advisory capacity and shall not have decision-making powers.

The Company shall, for the period of the License, (i) provide Yissum with periodic written reports ("**Development Reports**") not less than once per every six (6) months concerning all material activities undertaken in respect of the exercise of the License, (ii) keep Yissum informed on a timely basis concerning all material activities and changes to the Development Plan undertaken in respect of the exercise of the License, and (iii) at Yissum's reasonable request, from time to time, provide Yissum with further information relating to the Company's activities in exercise of the License. The Development Reports shall include detailed descriptions of the progress and results, if any, of: (a) the tests and trials conducted and all other actions taken by the Company pursuant to the Development Plan, and a summary of the Development Results and any other related work effected by the Company or by any Affiliate or Sub-Licensee during the six (6) month period prior to the report, (b) manufacturing, sublicensing, marketing and sales during the six (6) month period prior to the report; (c) the Company's plans in respect of the testing, undertaking of trials or commercialization of Products for the following six (6) months; and (d) projections of sales and marketing efforts following the First Commercial Sale. Development Reports shall also set forth a general assessment regarding the achievement of any milestones; the projected – or actual – completion date of the development of a Product and the marketing thereof; as well as a description of any corporate transaction involving the Products or the Licensed Technology. If progress in respect of a Product differs from that anticipated in its Development Plan or a preceding Development Report, the Company shall explain, in its Development Report, the reason therefor and shall prepare a modified Development Plan for Yissum's review. The Company shall also make reasonable efforts to provide Yissum with any reasonable additional data that Yissum requires to evaluate the performance of the Company hereunder.

5.3. Upon completion of the development of any Product, the Company undertakes to perform all commercially reasonable actions necessary to maximize Net Sales of such Product on a regular and consistent basis.

5.4. If the Company shall not meet one of the Essential Development Milestones within the timeframe set out in the Development Plan for the attainment of the said Essential Development Milestone, unless such delay is caused by (i) the requirements of a regulatory or other governmental authority; (ii) force majeure in accordance with Section 18.9, below; Yissum shall notify the Company in writing of the Company's failure to meet its obligations of diligence and shall allow the Company one hundred and twenty (120) days to cure such failure of diligence. If, to Yissum's reasonable satisfaction, the Company is diligently taking measures to cure such failure, Yissum may, at its sole discretion, notify the Company in writing that it is extending the period given to cure such failure by an additional period of up to sixty (60) days. The Company's failure to cure such failure, to Yissum's reasonable satisfaction, within the aforementioned cure period (or extended cure period) shall be a material breach of this Agreement, entitling Yissum to immediate termination under Section 16.3 below.

5.5. The Company shall perform all its activities hereunder in accordance with all applicable laws and regulations, and shall procure the receipt of all approvals and consents necessary for the performance of its obligations hereunder.

6. Sublicenses

6.1. The Company shall be entitled to grant one or more Sublicenses in accordance with the applicable terms and conditions of this Agreement, including the terms and conditions of this section 6, only after obtaining Yissum's written approval regarding the identity of the Sublicensee and the material terms of the Sublicense, such approval not to be unreasonably denied or withheld. In the event that a sublicense is a Pharmaceutical Sublicensee (as defined in Section 6.3), the prior written approval of Yissum shall not be required, provided however Yissum shall be notified in advance and in writing of the material terms of the Sublicense and any amendment thereof.

6.2. The Company shall provide Yissum with an executed copy of any Sublicense within ten (10) days of its execution. Any material amendments to a Sublicense other than a Sublicense with a Pharmaceutical Sublicensee, shall be subject to Yissum's prior written approval which shall not be unreasonably denied or withheld. The Company shall provide Yissum with an executed copy of such amendment to the Sublicense within ten (10) days of the execution of such amendment.

6.3. Any Sublicense shall be dependent on the validity of the License and shall terminate upon termination of the License, *provided*, *however*, that, for each Sublicense granted to a Pharmaceutical Sublicensee, upon termination of the License with the Company, if the Pharmaceutical Sublicensee is not then in breach of its Sublicense agreement with the Company such that the Company would have the right to terminate such Sublicense, Yissum shall be obligated, at the request of such Pharmaceutical Sublicensee, to enter into a new license agreement with any Pharmaceutical Sublicensee on substantially the same terms as those contained in the respective Sublicense agreement, provided that such terms shall be amended, if necessary, to the extent required to ensure that such agreement does not impose any obligations or liabilities (i) on the Company (without derogating from any liability due to the Company's breach or such other liabilities that survive the termination of the Agreement), or (ii) on Yissum which are not included in this Agreement, applied *mutatis mutandis*. "**Pharmaceutical Sublicensee**" shall mean a Sublicensee that is a company in the pharmaceutical industry with annual sales of at least $500,000,000 (Five Hundred Million US Dollars).

6.4. The Company shall ensure that any Sublicense shall include material terms that require the Sublicensee to comply with the terms of this Agreement, including Section 15 below, the breach of which terms shall be a material breach resulting in termination of the Sublicense. In such an event, the Company undertakes to take all reasonable steps to enforce such terms upon the Sublicensee, including the termination of the Sublicense. In all cases, the Company shall immediately notify Yissum of any breach of the material terms of a Sublicense, and shall copy Yissum on all correspondence with regard to such breach.

Furthermore, in the context of any Sublicense, the Company will obtain an agreement from the relevant Sublicensee (i) that such Sublicensee may only use the Licensed Technology and any related information received from the Company in connection with the further development and/or commercialization of a Product pursuant to the terms of the Sublicense agreement, and will keep same confidential; and (ii) naming Yissum as a third party beneficiary with the right to directly enforce the use and confidentiality provisions described in Subsection (i) above and the reporting provisions set out in Sections 6.5 and 8.2 below.

6.5. Without derogating from the generality of Section 6.4 above, the Company shall require each Sublicensee to provide it with regular written royalty reports that include at least the detail that the Company is required to provide pursuant to Section 8.2 below. Upon request, the Company shall provide such reports to Yissum.

6.6. Any act or omission of the Sublicensee which is not promptly remedied by the Company or the Sublicensee and which would have constituted a breach of this Agreement by the Company had it been an act or omission of the Company, and which the Company has not made best efforts to promptly cure, including termination of the Sublicense, shall constitute a breach of this Agreement by the Company.

6.7. For the avoidance of any doubt it is hereby declared that under no circumstance whatsoever shall a Sublicensee be entitled to assign such Sublicense or further Sublicense the License or any part thereof, provided, however, that a Pharmaceutical Sublicensee shall be entitled to sublicense its rights under such Sublicense agreement through multiple tiers to its Affiliates (through one or more tiers, provided that each tier is an Affiliate of the Pharmaceutical Sublicensee)(a "**Sub-Sublicense**"), without the prior written consent of Yissum; provided however that any such Sub-Sublicense shall be in compliance with the terms and conditions of this Agreement, including but not limited this Section 6.

7. License Consideration

In consideration for the grant of the License, the Company shall pay Yissum the following consideration during the term of the License as set forth in Section 4 above:

7.1. An irrevocable, non-creditable, and non-refundable License fee in the amount of [**], to be paid within thirty (30) days of the Effective Date, subject to receipt of proper tax invoice.

7.2. Royalties at the rates of [**]% ([**]) of Net Sales (the "**Royalties**"), subject to the Royalty Reductions set forth in section 7.3.

7.3. **Royalty Reductions**.

Notwithstanding the foregoing the following provisions shall apply with respect to reductions in the Royalties payments (the "**Reductions**"):

7.3.1. *Generic Competition*: In the event that during the Term of the License (as defined in Section 4 above), there is any Competition (as defined below) with respect to a particular Product in a particular country in which such Product is being sold, and for so long as such Generic Competition persists, the royalty amount payable to Yissum for sales of such Product (only) in such country shall be reduced by [**]% ([**]).

For purposes of illustration only, if Yissum would be entitled to receive the royalty amount of [**] if not for any royalty reduction, as aforementioned, then in the event that there is Generic Competition, then Yissum will be entitled to receive the royalty amount of [**].

For the purpose of this Section 7.3.1 only "Generic **Competition**" shall mean, with respect to a particular Product in a particular country, when (a) one or more Generic Product(s) are being marketed in such country; and (b) there are no Valid Claims covering such Product provided, however, that for defining a Generic Product in the United States the criteria will be either having no Valid Patent Claim covering the United States or having Paragraph IV certification or regulatory exclusivity in respect of such Product, in such country.

"**Generic Product**" shall mean a product (a) containing an active pharmaceutical ingredient or component that is equivalent to the active ingredient or component in a particular Product being sold in a particular country; and (b) that has obtained regulatory approval by means of establishing equivalence to such Product ; and (c) that is legally marketed in such country by an entity other than the Company, its Affiliates and/or Sublicensees; and (d) that at the end of the applicable calendar year, due to the marketing and sales of the Generic Product, there is a reduction in the volume of sales of such Product in such country by the Company, its Affiliates and/or Sublicensees, in comparison to the previous calendar year, by at least 30% (thirty percent).

In the event of Generic Competition in any particular calendar year for a particular Product in a particular country, then should there be deductions from royalty payments that the Company was entitled under this Section 7.3.1 to deduct, but did not deduct due to the need to compare product sales for that calendar year and the preceding calendar year, then such deductions will be rolled over and deducted from royalty amounts payable during the first quarter of the next calendar year for sales of such Product in such country.

7.3.2. *Offset for other payments*. In addition, in the event that the Company, Affiliate or Sublicensee pays to a third party amounts, whether by order by a court of competent jurisdiction, pursuant to a license agreement or otherwise, which result from such third party claiming that the utilization of the Licensed Technology in a Product infringes one or more patents or intellectual property owned by such third party that dominates the Licensed Technology, then [**]% of such amounts may be offset against any royalty owned to Yissum under this Agreement on Net Sales of such Product in such country, provided that in no event will the royalty payment made to Yissum be reduced below [**] ([**]%) of the amounts otherwise due to Yissum hereunder.

All reductions in Royalties combined, pursuant to this Section 7.3, shall, in aggregate, be capped at, and not exceed, [**]% ([**]) of the respective Royalty Rate.

7.4. Sublicense fees at a rate of [**]% ([**]) of Sublicense Consideration.

8. Reports and Accounting

8.1. The Company shall give Yissum written notice of any (i) Sublicense Consideration received; and (ii) First Commercial Sale made; within thirty (30) days of the particular event.

8.2. One (1) month after the end of each calendar quarter commencing from the earlier of (i) the First Commercial Sale; or (ii) the grant of a Sublicense or receipt of Sublicense Consideration, the Company shall furnish Yissum with a quarterly report ("**Periodic Report**"), certified as being correct by the chief financial officer of the Company, detailing the total sales and Net Sales effected during the preceding quarter, the total Sublicense Consideration received during the preceding quarter and the total Royalties and Sublicense Fees due to Yissum in respect of that period. Once the events set forth in Subsection (i) or (ii) above, have occurred, Periodic Reports shall be provided to Yissum whether or not Royalties and Sublicense Fees are payable for a particular calendar quarter. The Periodic Reports shall contain full particulars of all sales made by the Company, Affiliates or Sublicensees and of all Sublicense Consideration received, including a breakdown of the number and type of Products sold, discounts, returns, the country and currency in which the sales were made, invoice dates and all other data enabling the Royalties and Sublicense Fees payable to be calculated accurately.

8.3. On the date prescribed for the submission of each Periodic Report, the Company shall pay the Royalties and Sublicense Fees due to Yissum for the reported period, against a valid invoice issued by Yissum. All payments under this Agreement shall be computed and paid in US dollars, using the appropriate foreign exchange rate reported by the Bank of Israel on the last working day of the calendar quarter in respect of which the revenues are being reported. Payment of value added tax or any other tax, charge or levy applicable to the payment to Yissum of the consideration as detailed in Section 7 above, (except income tax, which shall be borne by Yissum), shall be borne by the Company and added to each payment in accordance with the statutory rate in force at such time. All payments made to Yissum by an Israeli entity shall be made without the withholding of any taxes, provided that Yissum shall supply such Israeli entity, to the extent required, with a valid tax certificate indicating an official exemption from tax withholding (פטור מניכוי מס במקור).). For the avoidance of doubt, if Yissum does not supply such certificate, the Israeli entity shall withhold taxes according to applicable law. All other payments to Yissum by non-Israeli entities shall be made without the withholding of any taxes. Payments may be made by check or by wire transfer to the following account:

Name of Bank: Hapoalim
Bank Key: 12
Bank's address: 1 Hamarpe Street, Jerusalem, Israel
Branch: Jerusalem Business Branch - 436
Bank account Number: 12-436-142-155001
Swift Code: POALILIT
IBAN: IL56-0124-3600-0000-0155-001 (for payment from Europe only)

8.4. The Company shall keep, and shall require its Affiliates and Sublicensees to keep, full and correct books of account in accordance with applicable Generally Accepted Accounting Principles as required by international accounting standards enabling the Royalties and Sublicense Fees to be calculated accurately. Starting from the first calendar year after the First Commercial Sale, or the first grant of a Sublicense, whichever occurs first, and until twenty four (24) months after the lapse of the term of the License, an annual report, authorized by a certified public accountant, shall be submitted to Yissum within ninety (90) days of the end of each calendar year, detailing Net Sales and Sublicense Consideration, Royalties and Sublicense Fees, both due and paid (the "**Annual Reports**"). The Annual Reports shall also include the Company's sales and royalty forecasts for the following calendar year, if available.

The Company shall, and shall require and cause its Affiliates and Sublicensees to, retain such books of account for five (5) years after the end of each calendar year during the period of this Agreement, and, if this Agreement is terminated for any reason whatsoever, for five (5) years after the end of the calendar year in which such termination becomes effective.

8.5. Yissum will either (i) allow the Company a credit against future Royalties or Sublicense Fees to be paid for Royalties or Sublicense Fees previously paid on account of Net Sales, as appropriate, that were reported as bad debts in the Company's annual audited financial statements; or (ii) if such bad debts are recorded by the Company in its annual audited financial statement after the Company's obligation to pay Royalties or Sublicense Fees has ceased, Yissum shall repay any Royalties or Sublicense Fees received on account of Net Sales that were reported as bad debts by the Company.

8.6. Yissum shall be entitled to appoint not more than two (2) representatives who must be independent certified public accountants or such other professionals as appropriate (the "**Auditors**") to inspect during normal business hours the Company's and its Affiliates' books of account, records and other relevant documentation to the extent relevant or necessary for the sole purpose of verifying the performance of the Company's payment obligations under this Agreement, the calculation of amounts due to Yissum under this Agreement and of all financial information provided in the Periodic Reports, provided that Yissum shall coordinate such inspection with the Company or Affiliate (as the case may be) in advance. In addition, Yissum may require that the Company, through the Auditors, inspect during normal business hours the books of account, records and other relevant documentation of any Sublicensees, to the extent relevant or necessary for the sole purpose of verifying the performance of the Company's payment obligations under this Agreement, the calculation of amounts due to Yissum under this Agreement and of all financial information provided in the Periodic Reports, and the Company shall cause such inspection to be performed. The Parties shall reconcile any underpayment or overpayment within thirty (30) days after the Auditors deliver the results of the audit. Any underpayment shall be subject to interest in accordance with the terms of Section 8.7 below. In the event that any inspection as aforesaid reveals any underpayment by the Company to Yissum in respect of any year of the Agreement in an amount exceeding five percent (5%) of the amount actually paid by the Company to Yissum in respect of such year, then the Company shall, in addition, pay the cost of such inspection.

8.7. Any sum of money due Yissum which is not duly paid on time shall bear interest from the due date of payment until the actual date of payment at the rate of annual LIBOR plus three percent (3%) per annum accumulated on a monthly basis.

9. Ownership

9.1. All right, title and interest in and to the Licensed Technology vest and shall vest solely in Yissum, and the Company shall hold and make use of the rights granted pursuant to the License solely in accordance with the terms of this Agreement.

9.2. All rights in the Development Results shall be solely owned by the Company, except to the extent that an employee of the University, including the Researcher, is considered an inventor of a patentable invention arising from the Development Results, in which case such invention and all patent applications and/or patents claiming such invention ("**Joint Patents**") shall be owned jointly by the Company and Yissum, as appropriate, and Yissum's share in such Joint Patents shall be automatically included in the Licensed Technology.

9.3. Upon the execution of this Agreement, the Company shall execute the letter of assignment attached to this Agreement as **Appendix D** concerning its interest in any Joint Patents that will provide that such interest will be irrevocably assigned to Yissum in the event that the Company is declared bankrupt, is voluntarily or involuntarily dissolved, or otherwise ceases operations.

10. Patents

10.1. Within thirty (30) days of the Effective Date the Company shall reimburse Yissum for all previous documented expenses and costs relating to the registration and maintenance of the Licensed Patents listed in **Appendix A** (the "**Historical Patent Costs**") which, as of the Effective Date, are approximately US $ 58,668 (Fifty eight thousands and six hundred and sixty eight US Dollars).

10.2. Yissum, in close coordination and cooperation with the Company, and at the Company's expense, shall be responsible for the filing, prosecution and maintenance of the Licensed Patents and the Joint Patents in the Territory, through Yissum's patent counsel; provided however that the Company may elect to file, prosecute and maintain the Joint Patents through a patent counsel selected by the Company and reasonably acceptable to Yissum (the "**Ongoing Patent Expenses**"). Each application and every patent registration shall be made and registered in the name of Yissum or, should the law of the relevant jurisdiction so require, in the name of the relevant inventors and then assigned to Yissum, provided that any application or registration relating to the Joint Patents shall be made and registered jointly in the name of Yissum and the Company. The Company agrees to have Yissum's patent counsel directly bill the Company for such expenses and shall directly pay such bills in accordance with patent counsel's directions.

10.3. Notwithstanding Sections 10.1 and 10.2 above, should Yissum grant a third party a license to some or all of the Licensed Patents outside the Field (a "**Third Party License**"), then, the Company's reimbursement obligation shall be reduced to a percentage of the Historical Patent Costs and Ongoing Patent Expenses going forward equal to the fraction 1/n+1, where "n" is the number of third parties to which a Third Party License has been granted (the "**Reduced Percentage**"). The Reduced Percentage shall be payable for so long as at least one such Third Party License remains in effect. In addition, following the grant of a Third Party License, the Company shall be entitled to credit for any Ongoing Patent Expenses and Historical Patent Costs that were previously paid by the Company in excess of the amount that would have been payable by the Company in accordance with the Reduced Percentage, such credit to be applied upon Yissum's receipt of the payments from the third party licensee and shall be applied against future payments of the Ongoing Patent Expenses and Historical Patent Costs that become due pursuant to this Agreement, for so long as such Third Party License remains in effect and Yissum receives payments from the third party licensee. By way of illustration only: (a) upon the grant of the first Third Party License by Yissum, the Company's reimbursement obligation shall be reduced to 50% of the Ongoing Patent Expenses going forward, and the Company shall be entitled to a reimbursement equal to 50% of the Ongoing Patent Expenses and Historical Patent Costs already paid by the Company up to such date.

10.4. The Company undertakes and warrants that no amounts utilized by the Company for such payment of Ongoing Patent Expenses or for the reimbursement of Yissum's past documented expenses and costs relating to the registration and maintenance of the Licensed Patents listed in **Appendix A** will be (i) funding provided by the Israeli Innovation Authority (formerly known as the Office of the Chief Scientist) at the Israeli Ministry of Economics (the "**OCS**"); (ii) funding that is earmarked as supplementary funding ("*mimun mashlim*") for an OCS approved project; or funding provided to the Company from any other governmental or regulatory institution of the State of Israel.

10.5. Notwithstanding the foregoing in Section 10.2, above, upon the execution of this Agreement, the Company shall deposit with Yissum the amount of $5,000 to secure the payment of the Ongoing Patent Expenses (the "**Expense Deposit**"). Should the Company fail to pay any amounts due in connection with the Ongoing Patent Expenses within thirty (30) days following receipt of Yissum's written request accompanied by a detailed account, Yissum shall be entitled to pay the unpaid expenses from the Expense Deposit. In the event that Yissum utilizes some or all of the Expense Deposit as set forth in this Section, it shall so notify the Company in writing. The Company shall be obligated to deposit with Yissum an amount equal to the difference between $5,000 and the balance in the Expense Deposit within thirty (30) days of its receipt of Yissum's notice. Upon termination or expiration of this Agreement, Yissum shall return to the Company the nominal amount of any remaining Expense Deposit that will not be required to cover Ongoing Patent Expenses for the period up until such termination or expiration.

10.6. Subject to the above, the Parties shall consult and make every effort to reach agreement in all respects relating to the manner of making applications for and registering the patents, including the time of making the applications, the countries where applications will be made and all other particulars relating to the registration and maintenance of the Licensed Patents. In the case of a disagreement between the Parties, the recommendations of the Patent Counsel handling the particular Licensed Patent shall be followed.

10.7. The Parties shall assist each other in all respects relating to the preparation of documents for the registration of any patent or any patent-related right upon the request of the other Party. Both Parties shall take all appropriate action in order to assist the other to extend the duration of a Licensed Patent or obtain any other extension obtainable under law, to maximize the cost-effective scope of the protection afforded by the Licensed Patents.

10.8. In the event that the Company is approached by a patent examiner or attorney in connection with any matter that is the subject matter of this Agreement, it shall give Yissum immediate notice of such approach. The Company shall only reply to such approaches after consultation with Yissum and subject to its consent, such consent not to be unreasonably withheld or delayed.

10.9. The Company, shall mark, and shall cause its Affiliates and Sublicensees to mark, all Products covered by one or more of the Licensed Patents with patent numbers (or the legend "patent pending") applicable to such Product. The Company shall take all reasonable action on its part to ensure that its Sublicensee complies with the provisions of this Section.

If at any time during the term of this Agreement the Company decides that it is undesirable, as to one or more countries, to file, prosecute or maintain any patents or patent applications within the Licensed Patents, it shall give at least ninety (90) days written notice thereof to Yissum, and upon the expiration of the ninety (90) day notice period (or such longer period specified in the Company's notice) the Company shall be released from its obligations to bear the expenses to be incurred thereafter as to such patent(s) or patent application(s). As of such time, such patent(s) or application(s) shall be removed from the Licensed Technology and Yissum shall be free to grant rights in and to such patent(s) or patent application(s) in such countries to third parties, without further notice or obligation to the Company, and the Company shall have no rights whatsoever to exploit such patent(s) or patent application(s) or with respect to such abandoned jurisdiction only, the Know-How related thereto). Notwithstanding the foregoing, the Company shall be required to bear the costs and expenses for filing, prosecuting and maintaining the Licensed Patents in at least the following jurisdictions: the United States, Israel, Japan, China, India, the United Kingdom, Germany, France, Italy and Spain (the "**Required Jurisdictions**"). Should the Company fail to do so in any one of the Required Jurisdictions, and such default is not cured within thirty (30) business days from the date notice of such failure is given to the Company by Yissum, Yissum shall be entitled to terminate this Agreement without any further notice and without any need to compensate the Company in any manner.

10.10. The foregoing does not constitute an obligation, representation or warranty, express or implied, on the part of Yissum that any patent or patent registration application will indeed be made or registered or be registerable in respect of the Licensed Technology or any part thereof, nor shall it constitute an obligation, representation, or warranty, express or implied, on the part of Yissum that a registered patent will be valid or afford any protection. For the avoidance of doubt, nothing in this Agreement constitutes an obligation, representation or warranty, express or implied, on the part of Yissum regarding the validity of or the protection afforded by any of the patents or patent registration applications detailed in **Appendix A** or regarding the commercial exploitability or any other value of the Licensed Technology or that the Licensed Technology will not infringe the rights of any third party.

11. Patent Rights Protection

11.1. The Company and Yissum shall each inform the other promptly in writing of any alleged infringements by a third party of the Licensed Patents in the Territory, together with any available written evidence of such alleged infringement.

11.2. To the extent permitted by applicable law, if the Company, its Affiliate or any Sublicensee makes (directly or indirectly), any assertion, application or claim, or initiates or supports (directly or indirectly) any action or proceeding, that challenges the validity, enforceability or scope of any of the Licensed Patents ("**Challenge Proceeding**"), Yissum will have the right, at any time following the commencement of the Challenge Proceeding, to terminate this Agreement and the Royalty rates specified in this Agreement will be tripled with respect to Net Sales of Products that are sold, leased or otherwise transferred during the course of such Challenge Proceeding, and the percentage due to Yissum in respect of Sublicense Consideration will be tripled with respect to Sublicense Consideration during such period. If the outcome of such Challenge Proceeding is a determination in favor of Yissum, (a) the Royalty rate with respect to Net Sales of Products and the percentage due to Yissum with respect to Sublicense Consideration will remain at such triple rate as aforesaid; and (b) Company will reimburse Yissum for all expenses incurred by Yissum (including reasonable attorneys' fees and court costs) in connection with such Challenge Proceeding. If the outcome of such Challenge Proceeding is a determination in favor of Company, Company will have no right to recoup any Royalties or Sublicense Fees paid before or during the course of such Challenge Proceeding.

11.3. The Company, its Affiliate or Sublicensee shall have the first right in its own name and at its own expense to initiate any legal action and enforce the Licensed Patents against any infringement of such Licensed Patents in the Field.

In the event of an infringement of the Licensed Patents which is both in the Field and outside the Field, Yissum shall decide which of its licensees shall be entitled to lead the legal action after consulting with the Company and giving reasonable consideration to the views of the Company in making such decision. In the event that Yissum decides that another licensee shall be entitled to lead the legal action, Yissum shall require such lead licensee to keep the Company reasonably apprised of all developments in the action and shall provide the Company with information and copies of all documents directly relevant to the proceedings, including, all documents filed with the courts by the parties to the legal action(s), and shall seek the Company's input on any substantive submissions or positions taken in the litigation that may adversely affect the Company and/or the License, it being agreed further that the grant of any rights and/or license to the infringing party that adversely affects the License shall be subject to the prior written consent of the Company, such consent not to be unreasonably delayed, denied or conditioned.

Before the Company, its Affiliate or its Sublicensee commences an action with respect to any infringement, the Company shall give careful consideration to the views of Yissum in making its decision whether or not to initiate any legal action and, if relevant, make these views known to its Affiliate or Sublicensee. The Company shall, or, if relevant, shall ensure that its Affiliate or Sublicensee shall, continuously keep Yissum apprised of all developments in the action and shall continuously provide Yissum with full information and copies of all documents relevant to the proceedings, including, all documents filed with the courts by the parties to the legal action(s) and all correspondence with the other parties to the proceedings, and shall seek Yissum's input and approval on any substantive submissions or positions taken in the litigation regarding the scope, validity or enforceability of the Licensed Patents.

If Yissum shall determine that the legal actions taken by the Company may adversely affect Yissum's rights hereunder, Yissum shall be entitled to appoint its own counsel at its own expense to represent it in such litigation; provided however that if the views of Yissum were not taken into consideration, as provided above, the Company shall reimburse Yissum for its reasonable expenses for such legal representation.

If the Company, its Affiliate or its Sublicensee elects to commence an action as described above and Yissum is a legally indispensable party to such action (being the registered owner of the infringed patent rights), Yissum, at the Company's expense, may be joined as a co-plaintiff, provided that all the following conditions shall be fulfilled:

(a) the Company shall continuously provide Yissum with full information and copies of all documents relevant to the proceedings, including, all documents filed with the courts by the parties to the legal action(s) and all correspondence with the other parties to the proceedings, as well as all drafts of written submissions relating to such legal action that are sent to the Company for review, and all Yissum's comments in respect thereof will be taken into account;

(b) any out of pocket expenses incurred by the Company or Yissum in connection with such action(s), including all legal and litigation related fees and expenses, all out of pocket expenses for external assistance required to comply with any discovery or other motions and any costs or amounts awarded to the counterparties in such action(s) shall be borne by the Company;

(c) if Yissum shall determine that a conflict of interest exists between the Company and Yissum, Yissum shall be entitled, at its own expense, to appoint its own counsel to represent it in such litigation and the Company shall make best efforts to ensure that such counsel chosen by Yissum is fully informed and receives all material necessary to adequately participate in such action; and

(d) the Company shall bear all costs, expenses and awards incurred by or awarded against Yissum, with respect to any action filed against Yissum alleging that an action initiated by the Company pursuant to the terms of this Section 11 was anticompetitive, malicious, or otherwise brought for an improper purpose, whether by a counterparty to such aforementioned action or by any third party.

If Yissum is not required by law to be joined as a co-plaintiff, Yissum, to the extent permitted by law, and at its own cost, may elect to join the action as a co-plaintiff at its own initiative and shall jointly control the action with the Company, its Affiliate or its Sublicensee. Irrespective of whether Yissum joins any such action as described above it shall provide reasonable cooperation to the Company, its Affiliate or its Sublicensee. The Company shall reimburse Yissum for any costs it incurs as part of an action brought pursuant to this Section where Yissum has not elected to join the action as a co-plaintiff at its own initiative.

11.4. If the Company, its Affiliate or its Sublicensee does not bring an action against an alleged infringer pursuant to Section 11.3, above, or has not commenced negotiations with said infringer for discontinuance of said infringement within one hundred and eighty (180) days after learning of said infringement, Yissum shall have the right, but not the obligation, to bring an action for such infringement at its own expense, and retain all proceeds from such action. In the event that Yissum has decided to bring an action for such infringement, the Company shall provide Yissum with any assistance reasonably required by Yissum with respect to such action. If the Company has commenced negotiations with said infringer for the discontinuance of said infringement within such one hundred and eighty (180) day period, the Company shall have an additional period of ninety (90) days from the end of the first one hundred and eighty (180) day period to conclude its negotiations before Yissum may bring an action for said infringement.

11.5. No settlement, consent judgment or other voluntary disposition of an infringement suit may be entered without the consent of Yissum, which consent shall not be unreasonably withheld, conditioned or delayed. For the avoidance of doubt and notwithstanding anything to the contrary herein, should Yissum bring an action as set forth in Section 11.4 above, it shall have the right to settle such action by licensing the Licensed Technology, or part of it, to the alleged infringer.

11.6. Any award or settlement payment resulting from an action initiated by the Company pursuant to this Section 11 shall be utilized, first to effect reimbursement of documented out-of-pocket expenses incurred by both Parties in relation to such legal action, and thereafter shall be paid to the Company and shall be deemed Sublicense Consideration received under this Agreement, in respect of which Sublicense Fees shall be due to Yissum.

11.7. If either Party commences an action and then decides to abandon it, such Party will give timely notice to the other Party. The other Party may continue the prosecution of the suit after both Parties agree on the sharing of expenses.

11.8. The Company shall use its best efforts at its own expense to defend any action, claim or demand made by any entity against the Company or Yissum in connection with rights in the Licensed Technology. Each Party shall notify the other immediately upon learning of any such action, claim or demand as aforesaid

12. Confidentiality

12.1. For the purposes of this Agreement (i) "**Yissum Confidential Information**" means this Agreement and the terms hereof and any and all reports, details, data, formulations, solutions, designs, and inventions and other information disclosed to the Company or any of its Representatives by Yissum or any of Yissum's Representatives in connection with the Licensed Technology, Yissum, the University, the Researcher and other Representatives of Yissum and/or the University, whether in written, oral, electronic or any other form, except and to the extent that that any such information: (a) was known to the Company at the time it was disclosed, other than by previous disclosure by or on behalf of Yissum, as evidenced by the Company's written records at the time of disclosure; (b) is in the public domain at the time of disclosure or becomes part of the public domain thereafter other than as a result of a violation by the Company or any of its Representatives of the confidentiality obligations herein; (c) is lawfully and in good faith made available to the Company by a third party who is not subject to obligations of confidentiality with respect to such information; or (d) is independently developed by the Company without the use of Yissum Confidential Information, as demonstrated by documentary evidence; and (ii) "**Company Confidential Information**" means this Agreement and the terms hereof and any and all reports, details, data, formulations, solutions, designs, and inventions and other information disclosed by or on behalf of the Company or any of the Company's Representatives under this Agreement, whether in written, oral, electronic or any other form, except and to the extent that any such information: (a) was known to Yissum or the University at the time it was disclosed, other than by previous disclosure by or on behalf of the Company, as evidenced by Yissum's or the University's written records at the time of disclosure; (b) is in the public domain at the time of disclosure or becomes part of the public domain thereafter other than as a result of a violation by Yissum or its Representatives of the confidentiality obligations herein; (c) is lawfully and in good faith made available to Yissum or the University by a third party who is not subject to obligations of confidentiality with respect to such information; or (d) is independently developed by Yissum or the University without the use of the Company Confidential Information, as demonstrated by documentary evidence.

12.2. Yissum Confidential Information. The Company undertakes that during the term of this Agreement and for a period of five (5) years subsequent thereto, it shall maintain full and absolute confidentiality of and shall not use the Yissum Confidential Information other than for the purposes of this Agreement. Except as otherwise set forth herein, the Company undertakes not to convey or disclose any of the Yissum Confidential Information to any third party without the prior written permission of Yissum. The Company shall be liable for its officers or employees or other Representatives maintaining absolute confidentiality of and not using or disclosing the Yissum Confidential Information except as expressly provided herein. The Company shall treat such Yissum Confidential Information with the same degree of care and confidentiality that it maintains or protect its own confidential information, but in any event, no less than a reasonable degree of care and confidentiality.

12.3. Notwithstanding the foregoing, the Company may only disclose the Yissum Confidential Information:

(a) to those of its Representatives who have a "need to know" such information as necessary for the exercise of its rights and/or performance of its obligations hereunder, provided that such Representatives are legally bound by agreements which impose similar confidentiality and non-use obligations to those set out in this Agreement. The Company shall be responsible for ensuring that its Representatives abide by such undertakings of confidentiality; and

(b) to any potential third party investor, including, any government, public foundation and/or private foundation, commercial partners or potential Sublicensees, in connection with seeking potential funding for the Company or the entering into a commercial collaboration or a Sublicense, provided that such potential third party has executed a confidentiality and non-use agreement which imposes similar obligations to those set out in this Agreement; and

(c) to any competent authority for the purposes of obtaining any approvals or permissions required for the exercise of the License and/or the implementation of this Agreement, or in the fulfillment of a legal duty owed to such competent authority (including a duty to make regulatory filings or to comply with any other reporting requirements); and

(d) to the extent required to be disclosed under any law, rule, regulation, court, or order of any competent authority (including any Stock Exchange), provided that, to the extent permissible, the Company promptly notifies Yissum thereof in order to enable Yissum to seek an appropriate protective order or other reliable assurance that confidential treatment will be accorded to such information (with the Company's assistance, if necessary), and such disclosure shall be made to the minimum extent required.

12.4. The Company Confidential Information. Yissum undertakes that during the term of this Agreement and for a period of five (5) years subsequent thereto, it shall maintain in confidence, and shall not use the Company Confidential Information other than for the purposes of this Agreement. Yissum undertakes not to convey or disclose any of the Company Confidential Information to any third party without the prior written permission of the Company. Yissum shall treat such Company Confidential Information with the same degree of care and confidentiality it maintains and protects its own confidential information, but in any event, no less than a reasonable degree of care and confidentiality.

12.5. Notwithstanding the foregoing, Yissum may only disclose the Company Confidential Information:

(a) to the University and to those of the Representatives of Yissum and/or the University who have a "need to know" such information as necessary for the exercise of Yissum's rights and/or performance of Yissum's obligations hereunder, provided that such Representatives are legally bound by agreements which impose similar confidentiality and non-use obligations to those set out in this Agreement; and

(b) to any competent authority in connection with the filing and prosecution of patent applications relating to the Licensed Technology, or in the fulfillment of a legal duty owed to any competent authority; and

(c) to the extent required to be disclosed under any law, rule, regulation, court, or order of any competent authority, provided that Yissum promptly notifies the Company thereof in order to enable the Company to seek an appropriate protective order or other reliable assurance that confidential treatment will be accorded to such information (with Yissum's assistance, if necessary), and such disclosure shall be made to the minimum extent required.

12.6. Each Party shall be responsible and liable to the other Party for any breach by its Representatives, Affiliates, Subcontractors, Sublicensees and investors of the undertakings of confidentiality set forth in this Section 12 as if such breach were a breach by the Party itself.

12.7. Without prejudice to the foregoing, the Company shall not mention the name of the University, Yissum or the Researcher, unless required by law, in any manner or for any purpose in connection with this Agreement, the subject of the Research or any matter relating to the Licensed Technology, without obtaining the prior written consent of Yissum, which will not be unreasonably withheld or delayed. Notwithstanding the foregoing, the mere statement of the fact that the Company is a party to, or that the Licensed Technology is subject to, this Agreement, shall not be deemed a prohibited disclosure hereunder.

12.8. Neither Party shall issue any press release or other media statement regarding the execution, existence or terms of this Agreement or any developments of the Licensed Technology without the prior written approval of the other Party.

12.9. The provisions of this Section shall be subject to permitted publications pursuant to Section 13 below.

13. Publications

13.1. Yissum shall ensure that no publications in writing, in scientific journals or orally at scientific conventions relating to the Licensed Technology, the Development Plan, the Development Results or the Product, which are subject to the terms and conditions of this Agreement, are published by it or the Researcher, without first seeking the consent of the Company.

13.2. The Company undertakes to reply to any such request for publication by Yissum within thirty (30) days of its receipt of a request in connection with the publication of articles in scientific journals, and within fourteen (14) days of its receipt of a request in connection with article abstracts. The Company may only decline such a request upon reasonable grounds, which shall be fully detailed in writing, requiring the postponement of such publication because it contains patentable subject matter for which patent protection should be sought, or the removal of any Company Confidential Information.

13.3. Should the Company decide to object to publication as provided in sub-Section 13.2, the publication shall be postponed for a period of not more than ninety (90) days from the date the publication was sent to the Company, to enable the filing of an appropriate patent application, or until the removal of the Company Confidential Information as requested by the Company. Thereafter, the publication will automatically be permitted.

13.4. The provisions of this Section 13 shall not prejudice any other right which Yissum has pursuant to this Agreement or at law.

13.5. For the avoidance of doubt, the prohibitions with respect to disclosure and publication set out in Sections 12 and 13 shall not apply to internal research and educational activities at the University for the Researcher and University employees provided that such persons are subject to written obligations of confidentiality substantially similar to those set forth in Section 12.

14. Representations by Yissum

14.1. This Agreement has been duly authorized by all necessary corporate action of Yissum and is a valid and binding corporate obligation of Yissum enforceable against it in accordance with its terms.

14.2. At the Effective Date, all right, title and interest in and to the Licensed Technology is owned by Yissum and neither Yissum, the Researcher nor any other person then acting on the behalf of either of them is licensing or granting any rights which contradict the License rights set forth in this Agreement to any person, or agreed to license to any person, the Licensed Technology in the Field.

14.3. To the knowledge of Yissum, at the Effective Date, Yissum has not received any written notice that any action or proceeding related to the Licensed Technology has been initiated or threatened against the University, Yissum and/or the Researcher, before any court, arbitration board or tribunal or administrative or other governmental agency, including by way of any letter of demand, legal suit or proceeding contesting the ownership of the Licensed Patents or the validity of the Licensed Patents, or claiming that the practice of the Licensed Patents or the Licensed Technology would infringe the rights of such third party.

15. Liability and Indemnity

15.1. TO THE EXTENT PERMITTED BY THE APPLICABLE LAW, EXCEPT AS EXPLICITLY SET OUT HEREIN, YISSUM MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THE LICENSED TECHNOLOGY. IN PARTICULAR, YISSUM MAKES NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, NOR DOES YISSUM REPRESENTS, WARRANTS OR GUARANTEES THAT THE USE OF THE LICENSED TECHNOLOGY WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER RIGHTS OF ANY THIRD PARTY. IN ADDITION, NOTHING IN THIS AGREEMENT MAY BE DEEMED A REPRESENTATION OR WARRANTY BY YISSUM AS TO THE VALIDITY OF ANY OF THE LICENSED PATENTS OR THEIR REGISTRABILITY OR OF THE ACCURACY, SAFETY, EFFICACY, OR USEFULNESS, FOR ANY PURPOSE, OF THE LICENSED TECHNOLOGY. YISSUM HAS NO OBLIGATION, EXPRESS OR IMPLIED, TO SUPERVISE, MONITOR, REVIEW OR OTHERWISE ASSUME RESPONSIBILITY FOR THE PRODUCTION, MANUFACTURE, TESTING, MARKETING OR SALE OF ANY PRODUCT. TO THE EXTENT PERMITTED BY APPLICABLE LAW, NEITHER YISSUM NOR THE RESEARCHER, NOR THE UNIVERSITY, NOR THE REPRESENTATIVES OF YISSUM AND/OR OF THE UNIVERSITY SHALL HAVE ANY LIABILITY WHATSOEVER TO THE COMPANY OR TO ANY THIRD PARTY FOR OR ON ACCOUNT OF ANY INJURY, LOSS, OR DAMAGE, OF ANY KIND OR NATURE WHETHER DIRECT OR INDIRECT, SUSTAINED BY THE COMPANY OR BY ANY THIRD PARTY, FOR ANY DAMAGE ASSESSED OR ASSERTED AGAINST THE COMPANY, OR FOR ANY OTHER LIABILITY INCURRED BY OR IMPOSED UPON THE COMPANY OR ANY OTHER PERSON OR ENTITY, DIRECTLY OR INDIRECTLY ARISING OUT OF OR IN CONNECTION WITH OR RESULTING FROM THIS AGREEMENT AND/OR THE EXERCISE OF THE LICENSE, INCLUDING, (i) THE PRODUCTION, MANUFACTURE, USE, PRACTICE, LEASE, OR SALE OF ANY PRODUCT; (ii) THE USE OF THE LICENSED TECHNOLOGY; OR (iii) ANY ADVERTISING OR OTHER PROMOTIONAL ACTIVITIES WITH RESPECT TO ANY OF THE FOREGOING.

15.2. EXCPET WITH RESPECT TO CLAIMS BY ANY THIRD PARTY FOR WHICH COMPANY IS OBLIGATED TO INDEMNIFY YISSUM UNDER SECTION 15.4 OR IN THE EVENT OF USE OF THE LICENSED TECHNOLOGY IN BREACH OF THIS AGREEMENT, IN NO EVENT SHALL EITHER PARTY, OR THE REPRESENTATIVES OF SUCH PARTY BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES OR TO ANY THIRD PARTY FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY THE OTHER PARTY OR ANY OF ITS AFFILIATES OR ANY THIRD PARTY, WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE OR TORT, OR OTHERWISE, ARISING OUT OF THIS AGREEMENT.

15.3. The Company shall be liable for any loss, injury or damage whatsoever caused directly or indirectly to or suffered by its employees or any Representatives of Yissum or the University (including the Researcher and his/her team), or to any third party by reason of the Company's acts or omissions pursuant to this Agreement or by reason of any use made by the Company, its Representatives, Affiliates, Subcontractors, and the Sublicensees and their respective business associates and customers of the Licensed Technology, the Development Results or any Product or exercise of the License, except to the extent such loss, injury or damage results directly from an uncured material breach of Yissum's obligations or representations hereunder.

15.4. The Company undertakes to compensate, indemnify, defend and hold harmless Yissum, the University, and any of their respective Representatives (including the Researcher and his/her team) (herein referred to jointly and severally as "**Indemnitees**") from and against any claim, investigation or liability including, product liability, damage, loss, costs and expenses, including legal costs, attorneys' fees and litigation expenses, incurred by or imposed upon the Indemnitees by reason of any acts or omissions of the Company, its Representatives, Affiliates, Subcontractors, and the Sublicensees, or which derive from the development, manufacture, marketing, sale, use or other exploitation, or sublicensing (as applicable) of any Product, or Licensed Technology, or the exercise of the License unless such loss, injury or damage resulting directly uncured material breach of obligations or representations hereunder of an Indemnitee.

The Company shall ensure that its Sublicensees shall provide undertakings of indemnification which shall also be given also in favor of, and shall be actionable by Yissum, the University and any director, officer or employee of Yissum or of the University, and by the Researcher.

15.5. The Company shall procure and maintain, at its sole cost and expense, policies of comprehensive general liability insurance in amounts not less than (i) $2,000,000 per incident and $2,000,000 annual aggregate, commencing as of the date and for such period that any Product is being tested in clinical trials by the Company, its Affiliate or Sublicensee prior to commercial sale; and (ii) $4,000,000 per incident and $4,000,000 annual aggregate during the period that any Product is being commercially distributed or sold Company, its Affiliate or Sublicensee. Such policy shall name the Indemnitees as additional insureds. The policy or policies so issued shall include a "cross-liability" provision pursuant to which the insurance is deemed to be separate insurance for each named insured (without right of subrogation as against any of the insured under the policy, or any of their representatives, employees, officers, directors or anyone in their name). Such comprehensive general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for the Company's indemnification obligations under this Section 15. If the Company elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of a $250,000 annual aggregate), such self-insurance program shall include assets or reserves which have been actuarially determined for the liabilities associated with this Agreement and must be reasonably acceptable to Yissum.

The minimum amounts of insurance coverage required above shall not be construed to create a limit of the Company's liability with respect to its indemnification obligations under this Section 15.

15.6. The Company shall provide Yissum with written evidence of such insurance upon request. The Company shall provide Yissum with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance. If the Company does not obtain replacement insurance providing comparable coverage within such fifteen (15) day period, Yissum shall have the right to terminate this Agreement effective at the end of such fifteen (15) day period without notice or any additional waiting periods.

15.7. The Company shall maintain, at its own expense, liability insurance as set forth in Section 15 above, beyond the expiration or termination of this Agreement as long as a Product relating to or developed pursuant to this Agreement is being commercially distributed or sold by the Company, an Affiliate or a Sublicensee, and thereafter as required by applicable laws.

16. Termination of the Agreement

16.1. Unless otherwise agreed by the Parties in writing, this Agreement shall terminate upon the occurrence of the later of the following: (i) the date of the expiry of the Term pursuant to Section 4 above; or (ii) if the Company elects to obtain an exclusive license to the Know-How pursuant to Section 4 above - the date of expiry of the period of such exclusive license.

16.2. Without prejudice to the Parties' rights pursuant to this Agreement or at law, either Party may terminate this Agreement by written notice to the other in any of the following cases:

16.2.1. immediately upon such written notice, if: (i) the other Party passes a resolution for voluntary winding up or a winding up application is made against it and not set aside or suspended within ninety (90) days; or (ii) a receiver or liquidator is appointed for the other Party and has not been removed within ninety (90) days; or (iii) the other Party enters into winding up or insolvency or bankruptcy proceedings which have not been set aside or suspended within ninety (90) days.
Each of the Parties undertakes to notify the other within seven (7) days if any of the abovementioned events occur; or

16.2.2. upon breach of this Agreement, where such breach has not been remedied within thirty (30) days from the breaching Party's receipt of written notice from the non-breaching Party requiring such remedy.

16.2.3. The Company shall be entitled to terminate this Agreement for convenience upon ninety (90) days prior written notice provided that immediately on or before the date of such termination the Company ceases or terminates on a world-wide basis: (a) all exploitation and use of the technology covered by or claimed in the Licensed Technology, whether by the Company, an Affiliate, a Sublicensee, or any contractor, distributor, reseller or agent and (b) all marketing and sales of all Products.

16.2.4. Yissum, at its sole discretion, shall be entitled to terminate this Agreement, without cause, with immediate effect, upon written notice to the Company in the event that a Development Plan (including the Essential Development Milestones) prepared by the Company and meeting Yissum's approval, has not been incorporated into this Agreement within 45 (forty-five) days of the Effective Date as set out in Section 5.1 above.

16.3. In addition to the above, and without prejudice to Yissum's rights pursuant to this Agreement or at law, Yissum shall be entitled to terminate this Agreement immediately upon written notice to the Company in the following circumstances:

16.3.1. failure or a delay of more than one hundred and twenty (120) days, or such extended period as provided in Section 5.4 above, in meeting the Essential Development Milestones as provided in Section 5 above;

16.3.2. if an attachment is made over the majority of the Company's assets or if execution proceedings are taken against the Company and the same are not set aside within sixty (60) days of the date the attachment is made or the execution proceedings are taken or the Company seeks protection under any laws or regulations, the effect of which is to suspend or impair the rights of any or all of its creditors, or to impose a moratorium on such creditors and such act is not cancelled within sixty (60) days of the performance thereof; or

16.3.3. if the Company, its Affiliate or a Sublicensee initiates, supports or makes a Challenge Proceeding as detailed in Section 11.2 above.

16.4. Upon termination of this Agreement for any reason (including termination for convenience and termination without cause), other than the expiration of its term, the License shall terminate, the Licensed Technology and all rights included therein shall revert to Yissum, and Yissum shall be free to enter into agreements with any other third parties for the granting of a license or to deal in any other manner with such right as it shall see fit at its sole discretion.

The Company shall return or transfer to Yissum, within fourteen (14) days of termination of the License, all material, in soft or hard copy, provided by Yissum or Yissum's Representatives and relating to the Licensed Technology or Products connected with the License, and it may not make any further use thereof. In case of termination as set out herein the Company will not be entitled to any reimbursement of any amount paid to Yissum under this Agreement. Yissum shall be entitled to conduct an audit in order to ascertain compliance with this provision and the Company agrees to allow access to Yissum or its representatives for this purpose.

16.5. The Company will prepare and present all regulatory filings necessary or appropriate in any country and will obtain and maintain any regulatory approval required to market Products in any such country, at all its own expense. Company will solely own all right, title and interest in and to all such regulatory approvals and filings; provided, however, that (1) Company will provide copies thereof to Yissum on an on-going basis; and (2) without derogating from Company's assignment undertaking in this Section 16.5 below, upon termination of the License (in whole or in part) for any reason other than due to an uncured breach by Yissum (as set forth in Section16.2.2 above), Company agrees that Yissum shall have the right, on its own or via third parties, to reference, cross-reference, review, have access to, incorporate and use all documents and other materials filed by or on behalf of Company and its Affiliates with any regulatory authority in furtherance of applications for regulatory approval in the relevant country with respect to Products.

Upon the termination of the Agreement for any reason (including termination for convenience and termination without cause), other than the expiration of its term or due to an uncured breach by Yissum (as set forth in Section 15.2.2 above), the Company shall transfer and assign to Yissum all of the Development Results and any information and documents, in whatever form, relating thereto, including any data, results, regulatory information (including applications, registrations, licenses, authorizations, approvals and all clinical studies, tests, and manufacturing batch records relating to a Product, and all data contained in any of the foregoing) and files that relate to the Licensed Technology or the Product(s), with the exclusion of Development Results which are directly applicable to other products of the Company (the "**Excluded Development Results**") or intellectual property of the Company existing prior to the Effective Date or developed independently of this Agreement (collectively, the "**Assigned Development Results**"); provided however that Yissum shall have a non-exclusive, worldwide, royalty free, limited in purpose license to use the Excluded Development Results for the sole purpose of demonstrating the feasibility of the Licensed Technology in the re-commercialization of the Licensed Technology to other third parties, and subject to such third parties being bound to confidentiality provisions regarding such Excluded Development Results. The Company shall fully cooperate with Yissum to effect such transfer and assignment and shall execute any document and perform any acts required to do so.

Without derogating from the force and effect of the foregoing assignment undertaking, the Parties acknowledge and agree that if under applicable law the aforesaid assignment undertaking will not be fully enforceable, then the part (if any) of such undertaking which is enforceable shall remain in full force and effect, and the part (or whole) which is not enforceable shall be automatically replaced with an irrevocable grant by the Company to Yissum, binding upon all of the Company's acquirers, successors and assignees, of an unrestricted, perpetual, irrevocable, worldwide, royalty-free, license to use, exploit, transfer and sublicense (on a multi-tier basis) the Assigned Development Results, for any and all purposes and uses. To the extent permitted by applicable law, such license will be exclusive, *provided, however*, that the foregoing assignment shall be subject to any conditions preventing or governing such transfer and assignment set out in the applicable laws and regulations governing grants received by the Company and used in generation of the Assigned Development Results ("**Grant Transfer Conditions**"), in which case the Company will not be required to transfer and assign the Assigned Development Results as contemplated above *unless and until* Yissum either (i) agrees in writing to assume all obligations required by the Grant Transfer Conditions, or (ii) reach another arrangement with the grantors of the grants which absolves the Company of any liability to such grantors with respect to the transfer or assignment of the Assigned Development Results.

Notwithstanding anything to the contrary in Section 11 (Confidentiality) or elsewhere in this Agreement, Yissum (on its own or via third parties) shall be entitled to freely exploit the Assigned Development Results without any obligation of confidentiality to the Company.

16.6. In the event that Yissum commercializes any of the Assigned Development Results assigned and transferred in accordance with Section 16.5, through a license or otherwise, Yissum shall pay the Company a royalty equal to 15% (fifteen percent) of Net Licensor Receipts as defined below , until such time as the Company shall have received, in aggregate, two (2) times the full amount of the documented capital investment actually expended out-of-pocket by the Company in order to generate the Assigned Development Results as certified by external independent auditors agreed upon by the Parties, less any amounts received or receivable by the Company from third parties in connection with the Licensed Technology or the Assigned Development Results prior to the transfer of the Assigned Development Results to Yissum (the "**Development Reimbursement Amounts**"). The Development Reimbursement Amounts shall be paid by Yissum on a quarterly basis, within thirty (30) days of the end of the calendar quarter in which the Net Licensor Receipts were received. The Company shall have the rights granted to Yissum pursuant to Section 8, *mutatis mutandis*, in respect of the Net Licensor Receipts. For purposes of this Section 16.6, the following terms shall have the following meanings:

"Net Licensor Receipts" shall mean Licensor Receipts less Licensor Expenses;

"Licensor Receipts" shall mean all amounts in cash and other consideration actually received by Yissum solely in respect from the grant of a license to a third party under the Assigned Development Result (but not other technology licensed together therewith) ; except for (a) any amounts received for sponsored research and fees for the provision of services; and (b) any academic research grants; and

"Licensor Expenses" shall mean (a) payments actually incurred by Yissum in accordance with detailed budgets and research workplans included in sponsored research or research and license agreements relating to the Assigned Development Results; and (b) any out-of-pocket expenses paid by Yissum in connection with enabling the receipt of such Licensor Receipts. (including, without limitation, unreimbursed patent costs, and all attorney's fees and expenses and other costs and expenses in connection with the negotiation and conclusion of such license.

16.7. Notwithstanding the foregoing, neither the termination of this Agreement for any reason nor the expiration of the License shall release the Company from its obligation to carry out any financial or other obligation which it was liable to perform prior to the Agreement's termination or the License's expiration.

In addition, Sections 8, 9, 12, 13, 14, 15, 16, 17 and 19 shall survive the termination of this Agreement to the extent required to effectuate the intent of the Parties as reflected in this Agreement.

17. Law

17.1. The provisions of this Agreement and everything concerning the relationship between the Parties in accordance with this Agreement shall be governed exclusively by Israeli law without application of any conflict of law principles that direct that the laws of another jurisdiction apply and jurisdiction shall be granted to the competent court in Tel-Aviv exclusively except that Yissum may bring suit against the Company in any other jurisdiction outside the State of Israel in which the Company has assets or a place of business.

17.2. Each Party agrees that any breach or threatened breach of the terms and conditions of this Agreement governing confidentiality or the exploitation and use of the Licensed Technology may cause irreparable harm, that may be difficult to ascertain and that monetary damages may not afford an adequate remedy. Accordingly, in addition to all other rights and remedies that may be available to the non-breaching Party under this Agreement or by law, such Party shall be entitled to seek, in the courts and under the law mutually agreed to in Section 17.1 above, injunctive relief without proof of damages.

18. Miscellaneous

18.1. Relationship of the Parties. It is hereby agreed and declared between the Parties that they shall act in all respects relating to this Agreement as independent contractors and there neither is nor shall there be any employer-employee or principal-agent relationship or partnership relationship between the Company (or any of its employees) and Yissum. Each Party will be responsible for payment of all salaries and taxes and social welfare benefits and any other payments of any kind in respect of its employees and officers, regardless of the location of the performance of their duties, or the source of the directions for the performance thereof.

18.2. Assignment. No Party may transfer or assign or endorse its rights, duties or obligations pursuant to this Agreement to another, without the prior written consent of the other Parties, which consent shall not be unreasonably denied, conditioned or delayed, except that the Company shall be entitled to assign its rights and obligations under this License Agreement to an Affiliate without requiring to obtain the prior written consent of Yissum, provided, however, that in the event of such assignment (i) the Affiliate shall undertake in writing to be bound by all the terms and conditions of this Agreement, and (ii) any such assignment shall not derogate from the Company's obligations which have accrued prior to the date of such assignment. In addition, the Company may assign this Agreement and its rights hereunder without the consent of Yissum to an acquirer acquiring all or substantially all of its assets or shares, provided that such acquirer shall agree in writing to be bound to Yissum by all of the terms of this Agreement.

18.3. No waiver. No waiver by any Party, whether express or implied, of its rights under any provision of this Agreement shall constitute a waiver of such Party's rights under such provisions at any other time or a waiver of such Party's rights under any other provision of this Agreement. The failure or delay of a Party to claim the performance of an obligation of another Party shall not be deemed a waiver of the performance of such obligation or of any future obligations of a similar nature.

18.4. Representation by Legal Counsel. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in drafting this Agreement. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.

18.5. Legal Costs. Each Party shall bear its own legal expenses involved in the negotiation and drafting of this Agreement.

18.6. Disclosure of Agreements with Researcher. The Company shall disclose to Yissum any existing agreement or arrangement of any kind with the Researcher and or any representative of the Researcher, and shall not enter into any such agreement or arrangement without the prior written consent of Yissum.

18.7. Taxes. Monetary amounts mentioned in this agreement do not include value added tax ("**VAT**"), or any duties or other taxes. Each Party shall itself be responsible to pay the taxes for which it is liable under the law.

18.8. Severability. The provisions of this Agreement are severable and, in the event that any one or more of the provisions or part of a provision contained in this Agreement shall, for any reason, be held by any court of competent jurisdiction to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision or part of a provision of this Agreement; but such provision shall be modified as set out below and the balance of this Agreement shall be interpreted as if such provision were so modified. The Parties shall negotiate in good faith in order to agree on the terms of an alternative provision which complies with applicable law and achieves, to the greatest extent possible, the same effect as would have been achieved by the invalid, illegal or unenforceable provision. In the event that the Parties fail to agree within thirty (30) days, the head of the Israeli Bar Association (on his/her own or via a representative that he/she appoints) ("**Deciding Expert**") will determine the text of the alternative provision, and each Party shall bear its own costs and the Parties shall equally bear the fees and expenses of the Deciding Expert. Each Party agrees that the determination of the Deciding Expert will be non-appealable, final and binding.

18.9. Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached the Agreement for failure or delay in fulfilling or performing any term of this Agreement to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party and without fault of such Party, including fires, earthquakes, floods, embargoes, wars, acts of war (whether war is declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances (except of such Party's personnel), acts of God or acts, omissions or delays in acting by any governmental authority provided that the nonperforming Party uses commercially reasonable efforts to avoid or remove such causes of nonperformance and continues performance under this Agreement with reasonable dispatch whenever such causes are removed. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance and when they cease to do so.

18.10. Counterparts. This Agreement may be executed in any number of counterparts (including counterparts transmitted by facsimile and by electronic mail), each of which shall be deemed an original, but all of which taken together shall be deemed to constitute one and the same instrument.

18.11. Binding Effect. This Agreement shall be binding upon the Parties once executed by both Parties and shall enter into force and become effective as of the later of the signature dates.

18.12. Entire Agreement. This Agreement constitutes the full and complete agreement between the Parties and supersedes any and all agreements or understandings, whether written or oral, concerning the subject matter of this Agreement, and may only be amended by a document signed by both Parties.

19. Notices

All notices and communications pursuant to this Agreement shall be made in writing and sent by facsimile, electronic mail or by registered mail or served personally at the following addresses:

To Yissum at:

Yissum Research Development Company
of the Hebrew University of Jerusalem Ltd.
P.O. Box 39135,
Jerusalem 91390
Israel
Facsimile: 972-2-6586689
Email: bob.trachtenberg@yissum.co.il

To the Company at:
Therapix Biosciences Ltd.
4 Ariel Sharon St.
Givatayim, Israel
Facsimile: 972-3-616-7056
Email: elran@therapixbio.com

or such other address furnished in writing by one Party to the other. Any notice served personally shall be deemed to have been received on the day of service, any notice sent by registered mail as aforesaid shall be deemed to have been received seven (7) days after being posted by prepaid registered mail. Any notice sent by facsimile or electronic mail shall be deemed to have been received by the next business day after receipt of confirmation of transmission (provided that any notice terminating this Agreement which is sent by electronic mail shall be followed by a notice sent in any other manner provided herein).

IN WITNESS WHEREOF THE PARTIES HAVE SET THEIR HANDS

YISSUM		**THERAPIX BIOSCIENCES LTD.**	
By:	/s/ Yaron Daniely	By:	/s/ Ascher Shmulewitz
Name:	Dr. Yaron Daniely	Name:	Dr. Ascher Shmulewitz
Title:	CEO of Yissum	Title:	CEO of Therapix
Date:	July 29, 2018	Date:	July 30, 2018
By:	/s/ Ariela Markel	By:	/s/ Adi Zuloff-Shani
Name:	Ariela Markel	Name:	Dr. Adi Zuloff-Shani
Title:	VP Licensing of Yissum	Title:	CTO of Therapix
Date:	July 29, 2018	Date:	July 30, 2018

I the undersigned, Prof. Raphael Mechoulam, have reviewed, am familiar with and agree to all of the above terms and conditions. I hereby undertake to cooperate fully with Yissum in order to ensure its ability to fulfill its obligations hereunder, as set forth herein.

/s/ Raphael Mechoulam	July 30, 2018
Prof. Raphael Mechoulam	Date signed

Appendix A

LICENSED PATENTS

Appendix B

YISSUM

By: /s/ Yaron Daniely
Name: Dr. Yaron Daniely
Title: CEO of Yissum
Date: July 29, 2018

By: /s/ Ariela Markel
Name: Ariela Markel
Title: VP Licensing of Yissum
Date: July 29, 2018

THERAPIX BIOSCIENCES LTD.

By: /s/ Ascher Shmulewitz
Name: Dr. Ascher Shmulewitz
Title: CEO of Therapix
Date: July 30, 2018

By: /s/ Adi Zuloff-Shani
Name: Dr. Adi Zuloff-Shani
Title: CTO of Therapix
Date: July 30, 2018

Appendix C

THE DEVELOPMENT PLAN (including the Essential Development Milestones)

[***To be prepared by the Company, subject to Yissum approval; for incorporation into this Agreement within 45 days of the Effective Date***]

YISSUM		**THERAPIX BIOSCIENCES LTD.**	
By:	/s/ Yaron Daniely	By:	/s/ Ascher Shmulewitz
Name:	Dr. Yaron Daniely	Name:	Dr. Ascher Shmulewitz
Title:	CEO of Yissum	Title:	CEO of Therapix
Date:	July 29, 2018	Date:	July 30, 2018
By:	/s/ Ariela Markel	By:	/s/ Adi Zuloff-Shani
Name:	Ariela Markel	Name:	Dr. Adi Zuloff-Shani
Title:	VP Licensing of Yissum	Title:	CTO of Therapix
Date:	July 29, 2018	Date:	July 30, 2018

Appendix D

JOINT PATENT ASSIGNMENT LETTER

ASSIGNMENT AGREEMENT

Made as a Deed

This ASSIGNMENT AGREEMENT (the "**Agreement**") is made this July 31, 2018, by and between Yissum Research Development Company of the Hebrew University of Jerusalem Ltd., Hi-Tech Park, Edmond J. Safra Campus, Givat Ram, Jerusalem, Israel on the one hand ("**Yissum**") and Therapix Biosciences Ltd. of 4 Ariel Sharon St. Givatayim, Israel, on the other hand (the "**Company**"). Yissum and the Company shall be referred each as a "**Party**", and together as the "Parties".

WHEREAS, on July 29, 2018, the Parties signed a Research and License Agreement (the "**R&L Agreement**"), according to which the Company received, among other things, a License to the Licensed Patents; and

WHEREAS, pursuant to the R&L Agreement, certain inventions have been or shall/may be registered jointly in the name of Yissum and the Company and shall be regarded as Joint Patents; and

WHEREAS, the Parties have agreed that, upon the occurrence of certain Events (as defined below), the Company shall assign and transfer to Yissum its title and ownership in and to the Joint Patents and thereafter Yissum shall become the sole and exclusive owner of such Joint Patents; all in accordance with the terms and conditions of this Agreement;

NOW THEREFORE THE PARTIES DO HEREBY AGREE AS FOLLOWS:

1. **Preamble**

1.1 The recitals hereto constitute an integral part hereof.

1.2 The headings of the sections in this Agreement are for the sake of convenience only and shall not serve in the interpretation of the Agreement.

1.3 All capitalized terms not defined herein shall have the meaning ascribed to such terms in the R&L Agreement.

1.4 In this Agreement the following expressions shall have the meanings appearing alongside them, unless the context otherwise requires:

"Effective Date" shall mean the date of occurrence of the earliest of the Events.

"Event(s)" shall mean a situation in which: (i) the Company passes a resolution for voluntary winding up or a winding up application is made against it and not set aside or suspended within ninety (90)days; or (ii) a receiver or liquidator is appointed for the Company and has not been removed within ninety (90) days; or (iii) the Company enters into winding up or insolvency or bankruptcy proceedings which have not been set aside or suspended within ninety (90)days; or (iv) the Company ceases operations for a consecutive period of 180 days ; or) a Joint Patent has become a Relinquished Patent.

"**Intellectual Property Rights**" shall mean any and all rights relating to intellectual property, including without limitation, all inventions, patents and patent applications, including all re-issuances, continuations, continuations-in-part, divisions, revisions, extensions and re-examinations thereof.

"Relinquished Patent" shall mean a Joint Patent for which the Company fails to pay the expenses of the filing, prosecution, maintenance or any activity required by the patent office, relating thereto, in accordance with the Company's obligations under the R&L Agreement.

2. **Assignment of Joint Patents**.

2.1 Upon the Effective Date, the Company shall assign, convey and transfer to Yissum, its successors and assigns, the entire right, title and interest and benefits in and to any Joint Patent(s), including all Intellectual Property Rights therein. Notwithstanding the foregoing, in case the Event relates solely to a Relinquished Patent, the aforementioned assignment shall relate only to such Relinquished Patent. Notwithstanding the foregoing, any assignment hereunder shall be subject, to any conditions governing such transfer and assignment set out in the applicable laws and regulations governing grants received by the Company and used in generation of the Joint Patent(s).

2.2 Subsequent to an assignment pursuant to this Agreement, the Company or its successors, legal representatives or assigns, at Yissum's sole cost and expense, shall notify Yissum, its successors, legal representatives and assigns, of any facts known to it regarding said Joint Patents, testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing, reissue and foreign applications, make all rightful oaths, and generally do everything possible to assist Yissum, its successors, legal representatives and assigns, to obtain and enforce proper protection, full ownership and rights of use for said Joint Patents in all countries.

2.3 In the event the Company, its successors, legal representatives or assigns fail to execute and deliver such documents and instruments promptly upon Yissum's request, Yissum is hereby authorized and appointed attorney-in-fact of and for the Company to make, execute and deliver any and all such documents and instruments.

3. **Governing Law and Jurisdiction**. The provisions of this Agreement and everything concerning the relationship between the Parties in accordance with this Agreement shall be governed by the laws of the State of Israel and exclusive jurisdiction shall be granted to the appropriate courts in Tel Aviv, Israel.

4. **Miscellaneous**. This Agreement supersedes any prior understanding, agreement, practice or contract, oral or written, between the Parties with respect to the matters covered by this Agreement. This Agreement may not be modified except by written instrument signed by all Parties hereto. This Agreement may be executed in counterparts, each of which shall be deemed an original, but which together shall constitute one and the same instrument. This Agreement shall be binding upon the Parties' heirs, executors, administrators, successors, and assigns. The invalidity of any provision of this Agreement shall not result in the invalidity of the entire Agreement.

AS WITNESS THE HANDS OF THE PARTIES:

Yissum Research Development Company
of the Hebrew University of Jerusalem Ltd.
Hi-Tech Park, Edmond J. Safra Campus,
Givat Ram, P.O.B 39135, Jerusalem 91390, Israel

By: /s/ Ariela Markel
Name: Ariela Markel
Title: VP Licensing of Yissum
Date: July 29, 2018

Therapix Biosciences Ltd.
4 Ariel Sharon St. Givatayim, Israel

By: /s/ Ascher Shmulewitz
Name: Dr. Ascher Shmulewitz
Title: CEO of Therapix
Date: July 31, 2018

By: /s/ Adi Zuloff-Shani
Name: Dr. Adi Zuloff-Shani
Title: CTO of Therapix
Date: July 31, 2018

Exhibit 12.1

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13a-14(a) or 15d-14(a)

I, Ascher Shmulewitz, certify that:

1. I have reviewed this annual report on Form 20–F of Therapix Biosciences Ltd.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent function):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: May 15, 2019

/s/ Ascher Shmulewitz

Ascher Shmulewitz, M.D., Ph. D
Interim Chief Executive Officer

Exhibit 12.2

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13a-14(a) or 15d-14(a)

I, Oz Adler, certify that:

1. I have reviewed this annual report on Form 20–F of Therapix Biosciences Ltd.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent function):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: May 15, 2019

/s/ Oz Adler
Oz Adler
Chief Financial Officer

Exhibit 13.1

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350

In connection with the filing of the Annual Report on Form 20-F for the period ended December 31, 2018 (the "Report") by Therapix Biosciences Ltd. (the "Company"), the undersigned, as the Chief Executive Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2019

/s/ Ascher Shmulewitz
Ascher Shmulewitz, M.D., Ph. D
Interim Chief Executive Officer

Exhibit 13.2

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350

In connection with the filing of the Annual Report on Form 20-F for the period ended December 31, 2018 (the "Report") by Therapix Biosciences Ltd. (the "Company"), the undersigned, as Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2019

/s/ Oz Adler
Oz Adler
Chief Financial Officer

Exhibit 15.1

Kost Forer Gabbay & Kasierer
2 Pal-Yam Blvd. Brosh Bldg.
Haifa 3309502, Israel

Tel: +972-4-8654000
Fax: +972-3-5633439
ey.com

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (File No. 333-225773) pertaining to Therapix Biosciences Ltd. (the "Company") Israeli Share Option Plan (2005) and Israeli Share Option Plan (2015), and the Registration Statement on Form F-3 (File No. 333-225745) of our report dated May 15, 2019, with respect to the consolidated financial statements of the Company and its subsidiaries, included in the annual report (Form 20-F) for the year ended December 31, 2018.

/s/ KOST FORER GABBAY & KASIERER

Haifa, Israel
May 15, 2019

KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global