UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)
☒ 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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-37521

INTEC PHARMA LTD.

(Exact name of Registrant as specified in its Charter)

Israel	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
12 Hartom Street Har Hotzvim, Jerusalem	**9777512**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: +972-2-586-4657

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

Ordinary Shares, no par value	**The Nasdaq Capital Market**
(Title of each class)	**(Name of each exchange on which registered)**

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

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. 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 Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). YES ☒ NO ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the ordinary shares on the Nasdaq Capital Market on June 30, 2018, was $145,373,536.

The number of shares of Registrant's ordinary shares outstanding as of February 22, 2019: 33,232,988.

DOCUMENTS INCORPORATED BY REFERENCE

None

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ABOUT THIS ANNUAL REPORT

All references to "we," "us," "our," "Intec", "the Company" and "our company", in this Annual Report on Form 10-K, or our Annual Report, are to Intec Pharma Ltd. and its U.S. subsidiary Intec Pharma Inc., unless the context otherwise requires. All references to "ordinary shares" and "share capital" refer to ordinary shares and share capital of Intec. All references to "Israel" are to the State of Israel. Our historical results do not necessarily indicate our expected results for any future periods. Any discrepancies in any table between totals and sums of the amounts listed are due to rounding. Unless otherwise indicated, or the context otherwise requires, references in this Annual Report to financial and operational data for a particular year refer to the fiscal year of our Company ended December 31 of that year.

In this Annual Report, "NIS" means New Israeli Shekel, and "$," "US$" and "U.S. dollars" mean United States dollars.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements about our expectations, beliefs or intentions regarding, among other things, our product development efforts, business, financial condition, results of operations, strategies, plans and prospects. In addition, from time to time, we or our representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as "believe," "expect," "intend," "plan," "may," "should," "anticipate," "could," "might," "seek," "target," "will," "project," "forecast," "continue" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. These forward-looking statements may be included in, among other things, various filings made by us with the Securities and Exchange Commission, or the SEC, press releases or oral statements made by or with the approval of one of our authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the factors summarized below:

- we are a clinical stage biopharmaceutical company with a history of operating losses, are not currently profitable, do not expect to become profitable in the near future and may never become profitable;
- our independent registered public accounting firm has expressed substantial doubt regarding our ability to continue as a going concern;
- because of our limited operating history, we may not be able to successfully operate our business or execute our business plan;
- we face continuous technological change, and developments by competitors may render our products or technologies obsolete or non-competitive. If our new or existing product candidates are rendered obsolete or non-competitive, our marketing and sales will suffer and we may never be profitable;
- we license our core technology on an exclusive basis from Yissum (Hebrew University), and we could lose our rights to this license if a dispute with Yissum arises or if we fail to comply with the financial and other terms of the license;
- if we fail to adequately protect, enforce or secure rights to the patents which were licensed to us or any patents we may own in the future, the value of our intellectual property rights would diminish and our business and competitive position would suffer;
- our product candidates are at various stages of preclinical and clinical development and may never be commercialized;
- we cannot be certain that the results of our potential Phase III clinical trials, even if all endpoints are met, will support regulatory approval of any of our product candidates for any indication;
- our product candidates are subject to extensive regulation and are at various stages of regulatory development and may never obtain regulatory approval;
- we are subject to anti-kickback laws and regulations. Our failure to comply with these laws and regulations could have adverse consequences to us; and
- potential political, economic and military instability in the State of Israel, where some of our senior management, our head executive office, research and development, and manufacturing facilities are located, may adversely affect our results of operations.

We believe these forward-looking statements are reasonable; however, 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. We discuss many of these risks in this Annual Report in greater detail under the heading "Risk Factors" and elsewhere in this Annual Report. Given these uncertainties, you should not rely upon forward-looking statements as predictions of future events.

All forward-looking statements attributable to us or persons acting on our behalf speak only as of the date hereof and are expressly qualified in their entirety by the cautionary statements included in this Annual Report. We undertake no obligations to update or revise forward-looking statements to reflect events or circumstances that arise after the date made or to reflect the occurrence of unanticipated events. In evaluating forward-looking statements, you should consider these risks and uncertainties.

EXPLANATORY NOTE

Market data and certain industry data and forecasts used throughout this Annual Report were obtained from market research databases, consultant surveys commissioned by us, publicly available information, reports of governmental agencies and industry publications and surveys. Industry surveys, publications, consultant surveys commissioned by us and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable. We have relied on certain data from third-party sources, including internal surveys, industry forecasts and market research, which we believe to be reliable based on our management's knowledge of the industry. Statements as to our market position are based on the most currently available data. While we are not aware of any misstatements regarding the industry data presented in this Annual Report, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "Risk Factors" in this Annual Report. Notwithstanding the foregoing, we remain responsible for the accuracy and completeness of the historical information presented in this Annual Report, as of the date on the front cover of this Annual Report.

PART I

Item 1. Business.

Historical Background and Corporate Structure

Intec Pharma Ltd. was established and incorporated in Israel on October 23, 2000 as a private Israeli company under the name Orly Guy Ltd. In February 2001, our name was changed to Intec Pharmaceuticals (2000) Ltd. Our research and development activities began originally through a private partnership, Intec Pharmaceutical Partnership I.P.P, a general Israeli partnership, formed on September 21, 2000. Its operations were transferred in full to us at the beginning of 2002 in return for the allocation of shares in our company to the partners in the partnership, pro rata with their ownership in the partnership. In March 2004, we changed our corporate name to Intec Pharma Ltd. In February 2010, we successfully completed an initial public offering in Israel on the Tel Aviv Stock Exchange, or TASE and in August 2015 we completed an initial public offering in the U.S. In September 2017, we incorporated a wholly-owned subsidiary, Intec Pharma Inc., in the State of Delaware. In August 2018, we voluntarily delisted from the TASE.

In connection with our initial public offering in Israel in February 2010, we raised approximately NIS 35.3 million before issuance costs and issued 783,969 ordinary shares and registered warrants (Series 1) to purchase 313,588 of our ordinary shares. As of the date of this Annual Report, all warrants issued in our initial public offering in Israel have expired.

In connection with our initial public offering in the U.S., we raised gross proceeds of approximately $34.0 million before deducting underwriting discounts and commissions and other offering expenses. In August 2017, we completed an underwritten follow-on public offering in the U.S. in which we raised gross proceeds of approximately $57.5 million before deducting underwriting discounts and commissions and other offering expenses and in April 2018, we completed another underwritten follow-on public offering in the U.S. in which we raised gross proceeds of approximately $37.5 million before deducting underwriting discounts and commissions and other offering expenses.

Effective January 1, 2019, we ceased reporting as a "foreign private issuer" as defined in Rule 3b-4 of the Exchange Act, and became subject to the rules and regulations under the Securities Exchange Act of 1934, as amended, or Exchange Act, applicable to U.S. domestic issuers. As a result, we are filing an Annual Report on Form 10-K beginning with the fiscal year ended December 31, 2018. Our annual reports for prior years were filed on Form 20-F.

We are an "emerging growth company," under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible to, and intend to, take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not "emerging growth companies" such as reduced disclosure obligations regarding executive compensation and not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. We will remain an emerging growth company until the earliest of: (i) the last day of the fiscal year during which we have total annual gross revenues of $1.07 billion or more, (ii) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our ordinary shares pursuant to an effective registration statement (i.e., December 31, 2020) (iii) the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt or (iv) the date on which we are deemed a "large accelerated issuer" as defined in Regulation S-K of the Securities Act of 1933, as amended, or the Securities Act.

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common shares held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure, are exempt from the auditor attestation requirements of Section 404, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

Our principal executive offices are located in Har Hotzvim at 12 Hartom Street, Jerusalem, Israel 9777512 and our telephone number is (+972) (2) 586-4657. Our website address is http://www.intecpharma.com. The information contained on, or that can be accessed through, our website is neither a part of nor incorporated into this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

We use our investor relations website (http://ir.intecpharma.com) as a channel of distribution of Company information. The information we post through this channel may be deemed material. Accordingly, investors should monitor our website, in addition to following our press releases, SEC filings and public conference calls and webcasts. The contents of our website are not, however, a part of this Annual Report.

Overview

We are a clinical stage biopharmaceutical company focused on developing drugs based on our proprietary Accordion Pill platform technology, which we refer to as the Accordion Pill. Our Accordion Pill is an oral drug delivery system that is designed to improve the efficacy and safety of existing drugs and drugs in development by utilizing an efficient gastric retention, or GR, and specific release mechanism. Our product pipeline currently includes several product candidates in various clinical trial stages. Our leading product candidate, Accordion Pill Carbidopa/Levodopa, or AP-CD/LD, is being developed for the indication of treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients. We have successfully completed a Phase II clinical trial for AP-CD/LD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients and have agreed with the U.S. Food and Drug Administration, or FDA, on the remaining clinical development program for AP-CD/LD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, including the main principles of the single required pivotal Phase III clinical trial in advanced Parkinson's disease patients.

We are currently conducting a pivotal Phase III clinical for AP-CD/LD for the treatment of advanced Parkinson's disease known as the ACCORDANCE study. In April 2016, we enrolled the first patient in the ACCORDANCE study and in October 2018, we completed enrollment. We currently expect to release top-line results in mid-2019. In our correspondence with the FDA, the FDA previously agreed that an acceptable regulatory pathway for AP-CD/LD would be to submit a new drug application, or NDA, pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA which is a streamlined approval pathway that may accelerate the time to commercialize and decrease the costs of FDA approval for AP–CD/LD, as compared to those typically associated with a new chemical entity, or NCE.

In February 2019, we announced that AP-CD/LD met the primary endpoint in a pharmacokinetic, or PK, study comparing the AP-CD/LD 50/500mg dosed three times daily, the most common dose used in our on-going ACCORDANCE study, to 1.5 tablets of CD/LD immediate release (Sinemet™) 25/100 dosed five times per day in Parkinson's disease patients.

We have invested in the commercial scale manufacture of AP-CD/LD, for which we are in partnership with LTS Lohmann Therapie-Systeme AG, or LTS. In December 2018, the large commercial scale production line was delivered to LTS in Andernach, Germany. We are in the process of installing and connecting all the ancillary equipment and expect to begin the validation, bioequivalency and stability studies needed for approval of our commercial production processes in the coming months. After preliminary discussions with the FDA in anticipation of filing for marketing approval of AP-CD/LD, we remain confident we are on track to submit a New Drug Application, or NDA, for approval of AP-CD/LD in mid- to late-2020, assuming positive topline data in the Accordance Study in mid-2019.

In addition, we have initiated a clinical development program for our Accordion Pill platform with the two primary cannabinoids contained in cannabis sativa, which we refer to as AP-Cannabinoids. We are formulating and testing cannabidiol, or CBD, and 9-tetrahydrocannabinol, or THC, for the treatment of various pain indications. AP-Cannabinoids are designed to extend the absorption phase of CBD and THC, with the goal of more consistent levels for an improved therapeutic effect which may address several major drawbacks of current methods of treatment, such as short duration of effect, delayed onset, variability of exposure, variability of the administered dose and adverse events that correlate with peak levels. In March 2017, we initiated a Phase I single-center, single-dose, randomized, three-way crossover clinical trial in Israel to compare the safety, tolerability and PK of AP-THC/CBD, with Sativex ®, an oral buccal spray containing CBD and THC that is commercially available outside of the United States. Initial results demonstrate that the Accordion Pill platform is well-suited to safely deliver CBD and THC with significant improvements in exposure compared with Sativex. In December 2018, we initiated a PK study of AP-THC. We have completed the dosing of the AP-THC PK study and the data is in the process of being analyzed by a third party contract research organization per protocol. However, upon raw data review, the delivery of THC does not appear to meet our full program expectations. We await the full dataset and the statistical analysis to determine our next steps.

In December 2018, we reported that we successfully developed an Accordion Pill for a Novartis proprietary compound that met the required *in vitro* specifications set forth in a feasibility agreement with Novartis. We have mutually agreed to proceed with the program and plan to enter the clinic with a first-in-human PK study in the first half of 2019. We believe continued success with this program further validates the platform, confirms our technical abilities to build custom APs and paves the way for additional collaborative agreements.

Our Accordion Pill Platform Technology

We believe that our Accordion Pill technology has the potential to improve the performance of approved drugs and drugs in development, including Levodopa, by providing several distinct advantages, including, but not limited to:

- increasing efficacy of the drug incorporated into the Accordion Pill;
- improving safety of the drug incorporated into the Accordion Pill by reducing the side effects of such drugs;
- reducing the number of daily administrations required to achieve the same or superior therapeutic effect as the non-Accordion Pill version of such drugs; and
- expanding the intellectual protection period of the drug incorporated into the Accordion Pill.

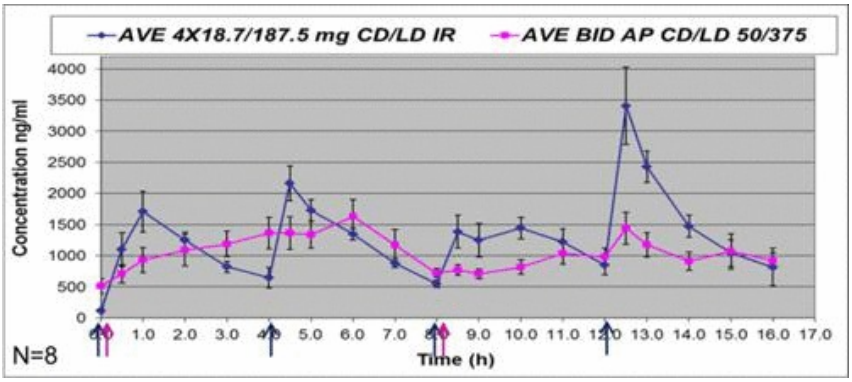
Our anticipated ability to submit NDAs pursuant to Section 505(b)(2) for our existing pipeline and future products increases the likelihood of accelerating the time to commercialization of our products and decreasing costs when compared to those typically associated with NCEs.

Our Accordion Pill platform technology is designed to increase the time that drugs are retained in the stomach as compared to other oral dosage forms, such as tablets and capsules. This capability is particularly important to drugs with a narrow absorption window, or NAW, which are absorbed mainly in the upper part of the gastrointestinal, or GI, tract. Regular controlled-release formulations of such drugs currently on the market sometimes fail to provide an efficient solution, as once the regular dosage form has passed the drug's NAW in the upper gastrointestinal, or GI, tract, the drug is not, or is very poorly, absorbed in the distal parts of the GI tract. The Accordion Pill platform technology is also designed for drugs with low solubility, which do not efficiently dissolve in the GI tract, and drugs with low permeability, which do not efficiently penetrate the intestinal wall and reach the blood stream, such as Biopharmaceutics Classification System, or BCS, Class II (low solubility, high permeability) and Class IV (low solubility, low permeability) drugs. According to The AAPS Journal published by the American Association of Pharmaceutical Scientists, of the top 200 oral drugs in the United States, Great Britain, Spain and Japan in 2006, approximately 30% to 35% were BCS Class II drugs and approximately 5% to 10% were BCS Class IV drugs. Further, according to The AAPS Journal in 2011 approximately 90% of new molecular entities in development were either Class II or Class IV drugs. Poorly soluble drugs are sometimes characterized by low bioavailability, which is strongly affected by the drug's solubility. In addition, the extent of absorption of poorly soluble drugs can be dose dependent, leading to non-linear PK behavior. The Accordion Pill's efficient GR and specific release mechanism prolongs the absorption phase of drugs with an NAW, which can result in significantly more stable plasma levels. In addition, the Accordion Pill has demonstrated an enhancement of the absorption of a poorly soluble, BCS Class II/IV drug in a crossover PK clinical study in 12 healthy volunteers. For poorly soluble drugs, we believe that our technology acts through the gradual delivery of an undissolved drug by the Accordion Pill in the stomach, which allows for the complete dissolution of the drug dose in the stomach over the delivery period. The gradual passage of the drug from the stomach to the upper part of the GI tract enables an increase in the amount of the drug that can be dissolved and thus absorbed, in the upper small bowel. In addition, we believe that bile secretion in the upper part of the GI tract also improves the intestinal environment for better absorption. Finally, the significant dilution of the drug solution in the small bowel caused by prolonged delivery increases the amount of the drug available for absorption.

Our clinical trials to date have demonstrated that the Accordion Pill is retained in the stomach for eight to 12 hours, as compared to significantly shorter time periods, typically as little as two to three hours, when using other solid dosage forms. The efficient GR and the predetermined release profile for each specific drug associated with our Accordion Pill technology demonstrated a significant improvement in PK, which is the drug plasma level over time and a corresponding improvement in efficacy and safety.

The following chart depicts the Accordion Pill's capability to improve the PK of Levodopa, which is a drug characterized by a narrow absorption window:

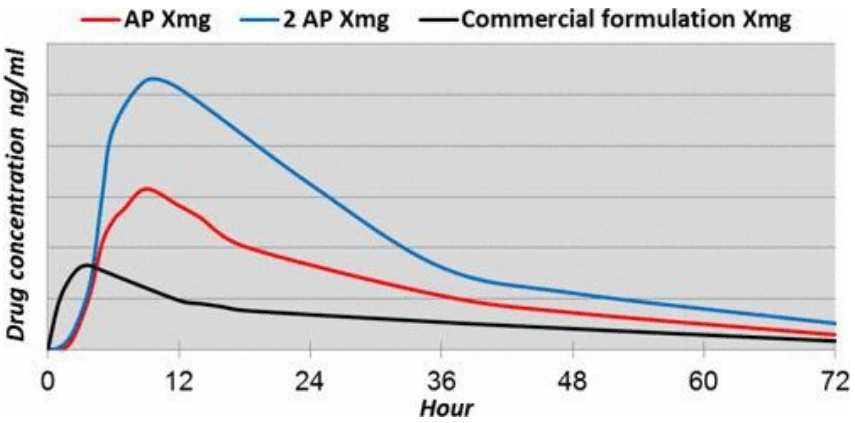
AP-CD/LD Phase II clinical trial — more stable Levodopa levels with statistically significant reduced peak-to-trough fluctuations



Levodopa plasma levels in n=8 advanced Parkinson's disease patients following twice daily, or b.i.d, administration (eight hours apart) of AP-CD/LD 50/375 versus four times daily, or q.i.d, administration (four hours apart) of a commercial Carbidopa/Levodopa formulation (equivalent daily Levodopa dose). The PK study was performed on day seven, following six days of drug administration at home. No Levodopa medication was allowed for ten hours before the first administration at day seven. The PK results showed that the peak to trough ratio, which measures the maximum average concentration relative to the minimum average concentration of LD plasma levels, was reduced from 29.9 to 3.2 with the AP-CD/LD. Demonstration of the clinical benefits of these peak to trough ratios are being further studied and confirmed in the ACCORDANCE study.

The following chart depicts the Accordion Pill's capability to improve the PK of a BCS Class II/IV drug combined with our Accordion Pill technology that is currently on the market and is characterized with poor solubility:

PK results with the Accordion Pill with a BCS Class II/IV drug that is currently available on the market in 12 healthy volunteers

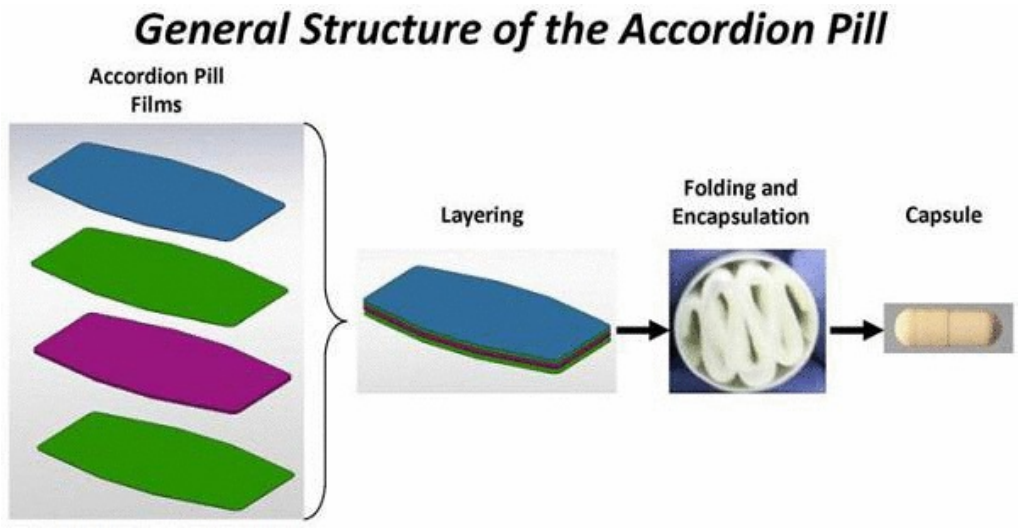


The results of our clinical trial have demonstrated approximately a 100% increase in bioavailability in 12 healthy volunteers with our Accordion Pill technology, as compared to the commercial formulation of the drug. Furthermore, the results demonstrated that the increase in bioavailability obtained when administering one Accordion Pill and two Accordion Pills was proportional to the increase in dosage, or linear absorption, whereas the commercial formulation does not show linear absorption in these dosage ranges.

Although there is no assurance that these results will be repeated in other instances, we believe that these results are important because the enhancement of bioavailability of poorly soluble drugs is one of the main challenges facing the pharmaceutical industry.

Our Accordion Pill technology enables us to combine active pharmaceutical ingredients, or APIs, which are also referred to as drugs, and inactive ingredients that are included in the FDA's list of approved inactive ingredients, into pharmaceutical-grade, biodegradable polymeric films, welded into a planar structure, folded into the shape of an accordion and placed inside of a capsule. While in the stomach, the capsule dissolves and the Accordion Pill unfolds and releases the drug in a predetermined profile. In order to provide optimum results for each drug, each Accordion Pill drug differs and will likely differ in several ways, including composition, structure and properties.

The diagram below illustrates the general structure of the Accordion Pill:



All of the ingredients in the Accordion Pill (active and inactive) are combined physically, not chemically, thus maintaining the chemical composition of the active ingredients.

The Accordion Pill has a drug release mechanism that is independent of the gastric retention mechanism. It can combine both immediate and controlled release profiles, as well as more than one drug. We have demonstrated that the Accordion Pill has the ability to carry a drug load of up to 550 mg. We have also demonstrated that the Accordion Pill fully degrades in the intestine once it is expelled from the stomach.

Our Product Pipeline

Our product pipeline currently includes several product candidates in various clinical trial stages. Our leading pipeline product, AP-CD/LD, is focused on leveraging our Accordion Pill technology to improve the efficacy and safety of an approved drug for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients. We have agreed with the FDA on the remaining clinical development program for AP-CD/LD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, including the main principles of our ongoing ACCORDANCE study, a pivotal Phase III clinical for AP-CD/LD for the treatment of advanced Parkinson's disease. In April 2016, we enrolled the first patient in the ACCORDANCE study and in October 2018, we completed enrollment. We currently expect to release top-line results in mid-2019. See "— Current Regulatory Status of AP-CD/LD." We also initiated a new clinical development program for our Accordion Pill platform with the two primary cannabinoids contained in cannabis sativa, which we refer to as AP-Cannabinoids. We are formulating and testing CBD, and THC, for the treatment of various pain indications. The AP-Cannabinoids are currently in Phase I.

In addition, in December 2018, we reported that we successfully developed an Accordion Pill for a Novartis proprietary compound that met the required *in vitro* specifications set forth in a feasibility agreement with Novartis. We have mutually agreed to proceed with the program and plan to enter the clinic with a first-in-human PK study in the first half of 2019. We believe continued success with this program further validates the platform, confirms our technical abilities to build custom APs and paves the way for additional collaborative agreements.

Our Business Strategy

We plan to leverage our Accordion Pill technology platform to become a leading specialty pharmaceutical company focused on developing, manufacturing and commercializing improved proprietary versions of approved and development stage drugs for the treatment of various diseases.

We intend to continue to develop our existing product candidates while reviewing other drug candidates that may also benefit from our platform technology. We seek to create global partnerships to assist us in the development and marketing of our products and may also independently commercialize certain products in the U.S. We believe that our approach will allow us to continue to advance our current product candidates and should allow us to avoid dependency on a small number of drugs.

Using this approach, we have advanced our product candidates into various stages of clinical development. Specific elements of our current strategy include the following:

- ***Continue to advance our current pipeline by developing improved versions of drugs with reduced side effects and that enhance the efficacy of existing drugs***. We expect that our products will potentially offer significant advantages over the original versions of the drugs. Results from our completed Phase II clinical trial demonstrate that AP-CD/LD can improve motor function in patients suffering "off time" episodes. "Off time" refers to debilitating periods of decreased motor and non-motor functions. We are pursuing the development and approval of AP-CD/LD under the Section 505(b)(2) pathway, which allows us to rely in part upon FDA's prior findings of safety or efficacy for an approved CD/LD reference drug. In October 2018, we completed patient enrollment in our Phase III ACCORDANCE Study and expect to report top-line results in mid-2019. If our pivotal Phase III clinical trial is successful, we intend to submit an NDA for regulatory approval in the United States.

- ***Utilize the 505(b)(2) regulatory pathway to leverage extensive existing clinical and regulatory experience with the original drugs and bring our improved versions of these drugs to market more quickly***. An NDA submitted under Section 505(b)(2) of the FDCA may be permitted to reference FDA's prior conclusions regarding the safety and effectiveness of that previously approved drug, or rely in part on data in the public domain. This may expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate to submit an NDA. As the FDA has previously agreed that our lead product, AP-CD/LD, would likely be eligible to file under Section 505(b)(2), assuming the successful completion of the ACCORDANCE study, we believe that there is a strong likelihood that our future products would similarly qualify. The factors related to this qualification are expected to reduce the time and costs associated with clinical trials when compared to a traditional NDA for an NCE. We also believe the strategy of targeting drugs with proven safety and efficacy provides a better prospect of clinical success of our proprietary development portfolio as compared to de novo drug development. We estimate that the average time to market and cost of clinical trials for our products could be less than that required to develop a new drug.

- ***Use our expertise with our platform technology to evaluate drug development and commercialization opportunities***. We continuously seek attractive product candidates to develop and commercialize. We intend to focus on product candidates that we believe would be synergistic with our Accordion Pill technology. We intend to use our expertise in our technology and our pharmacological expertise to grow our product candidate portfolio.

- ***Seek attractive partnership opportunities***. We believe that our Accordion Pill technology can be applied to many drugs that have already been approved by the FDA, as well as developmental stage drugs. We believe that the proprietary rights provided by our Accordion Pill technology, together with the clinical and compliance benefits, will be attractive to potential partners. We are seeking to build a portfolio of commercially attractive partnerships in a blend of co-developments and licenses. Where possible, we are seeking partnerships that allow us to participate significantly in the commercial success of each of the drugs. Although we are currently developing most of our current pipeline, we are looking to partner with the owners of rights to patented drugs in order to develop Accordion Pill versions of those drugs, and we may seek strategic partners to market our Accordion Pill products worldwide. We may also seek arrangements with third parties to assist in the development and commercialization of our products. These arrangements will allow us to share the high development cost, minimize the risk of failure and enjoy our partners' marketing capabilities, while also enabling us to treat a more significant number of patients.

- ***Develop products that target significant commercial opportunities***. Our existing product candidates are intended to target diseases that have major global markets. Our intent is to continue to develop products that present significant market opportunities by leveraging our Accordion Pill technology.

- ***Maintain a prominent intellectual property position***. We believe our licensed and proprietary patents and patent applications provide and will provide broad and comprehensive coverage for the use of our Accordion Pill technology for the treatment of certain diseases, focusing on BCS Class II/IV and NAW drugs, or drugs where longer retention in the upper GI tract could improve efficacy and absorption and reduce side effects. We seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that we believe are important to the development of our business. We also rely on know-how and continuing technological innovation to develop and maintain our proprietary position. We have submitted and intend to continue to submit patent applications for various Accordion Pill and drug combinations that we develop.

AP-CD/LD for the Treatment of Parkinson's Disease Symptoms in Advanced Parkinson's Disease Patients

Parkinson's disease

Parkinson's disease is a progressive, degenerative disease characterized by movement symptoms such as involuntary tremor or trembling in the hands, arms and legs; muscle rigidity of the limbs and trunk; slowness of and a decline in movement; and impaired balance and coordination. In its advanced stages, the disease causes comprehensive dysfunction of the patient's bodily systems, including difficulties in swallowing, speech disorders and significant mental decline. Parkinson's disease results from a continuing loss of dopamine-producing nerve cells. Dopamine is required for normal functioning of the central nervous system and smooth, coordinated function of the body's muscles and movement. According to the National Parkinson's Foundation, the symptoms of Parkinson's disease appear when approximately 60–80% of dopamine-producing cells are damaged.

Although there is presently no cure for Parkinson's disease, there are a number of medications that provide relief from the symptoms. Dopamine replacement therapy with Levodopa is generally considered to be the most effective treatment for Parkinson's disease. After 50 years of clinical use, Levodopa therapy still offers the best symptomatic control of Parkinson's disease and is the most widely used therapy. Levodopa is converted into dopamine in the brain and is usually administered with Carbidopa, which helps prevent Levodopa from converting to dopamine outside the brain. Levodopa helps reduce tremor, stiffness and slowness and helps improve muscle control, balance and walking. Virtually all Parkinson's disease patients will require Levodopa therapy during the course of their disease.

Parkinson's disease patients typically experience a satisfactory response to initial treatment with Levodopa. However, at later stages of Parkinson's disease, there is a decline in the capacity of the nigrostriatal dopaminergic system, or the brain pathways that moderate control of voluntary movement, to synthesize, store, and release dopamine. Therefore, the dopaminergic system becomes more and more dependent on dopamine from external sources, such as Levodopa treatment.

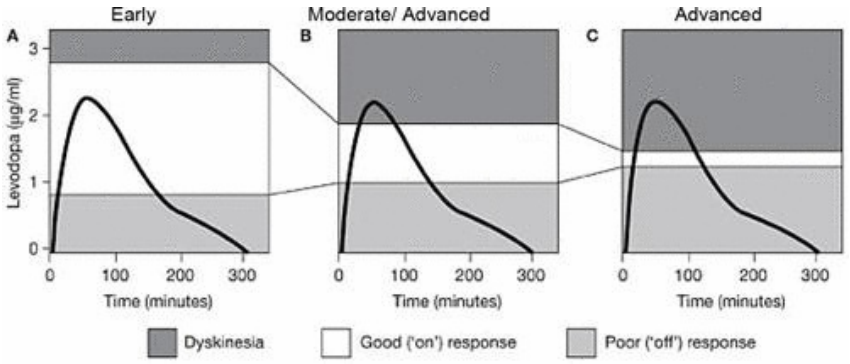
As the disease progresses, it becomes increasingly difficult to control the symptoms adequately by Levodopa treatment, and patients develop motor complications, for the following reasons:

- The duration of the response after each Levodopa dose declines, resulting in a "wearing off" effect, wherein the clinical benefits of Levodopa are lost until the next dose reaches therapeutic levels.

- The patients suffer from longer periods in which Levodopa does not provide symptom relief and patients' movements are severely restricted (i.e., off time).

- When Levodopa doses are increased to address the loss of clinical benefit, involuntary movements or troublesome dyskinesia emerges.

Recent studies have reported that up to 50% of patients show the onset of motor fluctuations within two years of starting conventional Levodopa therapy. For many patients with advanced Parkinson's disease, the repeated emergence of off states can occupy up to one-third or more of a typical waking day. The loss of consistent symptomatic control from Levodopa is a major challenge for the long-term management of Parkinson's disease. When Parkinson's disease patients experience "wearing off" between Levodopa doses, this short-duration response occurs in parallel to the drug's peripheral PK profile. Therefore, with the evolution of these short-duration responses, improving the consistency in Levodopa's plasma levels becomes the major factor for improving symptom control.



Oral Levodopa formulations currently on the market do not provide satisfactory consistent Levodopa plasma levels. There are two major challenges to maintaining consistency in Levodopa plasma levels: (i) the very short half-life of Levodopa (approximately 90 minutes) and (ii) the fact that Levodopa's absorption is confined to the upper part of the GI tract (i.e., it has an NAW). For drugs with an NAW, conventional controlled release formulations are limited in providing long-acting performance, as once the drug has passed through the upper GI tract, it will no longer be absorbed. These factors result in high peak-to-trough ratios of Levodopa in the plasma, namely high variability of the concentration of the drug in the blood, rather than a consistent level being maintained, reducing the clinical benefits of Levodopa therapy. Providing stable Levodopa plasma levels is therefore a major unmet need for the long-term management of Parkinson's disease.

Key opinion leaders interviewed by Global Data, a market research provider, summarized the unmet needs in Parkinson's disease treatment to include, among others, greater efficacy in reducing motor complications, reducing side effects and reducing pill burden.

Market. According to a 2018 report by Global Data, Parkinson's disease is the second most common chronic progressive neurodegenerative disorder in the elderly after Alzheimer's disease, affecting 1%–2% of individuals worldwide over the age of 65 and the annual growth of Parkinson's disease cases in individuals over the age of 65 from 2016 to 2026, in the Seven Major Markets, is estimated to be 2.28%. According to Global Data, in 2016 the market for pharmaceutical treatments for Parkinson's disease was approximately $3.1 billion a year in the Seven Major Markets growing to $8.8 billion by 2026. According to a 2016 Global Burden of Disease Study there are approximately 6.1 million people worldwide who suffer from Parkinson's disease.

We have also conducted, together with leading consultants, market assessment of AP-CD/LD for the treatment of the symptoms associated with advanced Parkinson's disease. The assessment indicates there is a substantial market for AP-CD/LD with hundreds of thousands of patients suffering with Parkinson's disease appropriate for AP-CD/LD treatment.

Our Solution — AP-CD/LD

AP-CD/LD, our lead product candidate, is in development for the treatment of Parkinson's disease symptoms. AP-CD/LD is an Accordion Pill that contains the generic drugs Carbidopa and Levodopa, which are currently approved for the treatment of Parkinson's disease symptoms. We have successfully completed a Phase II clinical trial, and the FDA has permitted us to initiate a Phase III clinical trial of AP-CD/LD. On May 5, 2015, we held an end of Phase II meeting with the FDA for AP-CD/LD. We reached an agreement with the FDA on the remaining clinical development program for AP-CD/LD and are currently conducting a pivotal Phase III clinical trial, the ACCORDANCE Study.

AP-CD/LD – Clinical Trials

Phase II Clinical Trial

Our Phase II clinical trial with AP-CD/LD was a multi-center, open-label, randomized, crossover, active control trial that included five groups. Overall, 60 patients completed the trial per protocol, in several medical centers in Israel. The Phase II clinical trial assessed safety, PK and pharmacodynamics/efficacy in patients with various stages of Parkinson's disease compared with their current Levodopa treatment. Each group of the clinical trial was deemed to initiate upon the first patient enrolling in a group and to be completed upon the conclusion of data analysis. The initiation and completion dates for groups 1, 3, 4, 5 and 6 were August 2009 – December 2009, April 2010 – August 2010, December 2010 – July 2011, August 2011 – November 2011 and December 2011 – October 2012, respectively. The following table details the structure, design and purpose of the Phase II clinical trial:

Group Number	Trial Design	Trial Purpose	Population	N (PP)	Test Treatment	Treatment and Duration*
Group 1	Open-label, multi-dose, multi-center, randomized	2-way crossover comparative PK trial	Early-stage PD patients	12	AP-CD/LD 50/250 mg	b.i.d for 7 days
Group 2	This trial was originally planned in early non-fluctuators with a dose of 50/375 mg b.i.d. In light of the satisfactory PK results with 50/250 mg b.i.d in this population, the higher dose was considered unnecessary and therefore the trial was not performed.					
Group 3	Open-label, multi-dose, multi-center, randomized	2-way crossover comparative PK and PHDS trial	Advanced PD patients	10[a]	AP-CD/LD 50/375 mg	b.i.d for 7 days
Group 4**	Open-label, multi-dose, multi-center, randomized	2-way crossover comparative PHDS trial	Advanced PD patients	16	AP-CD/LD 50/375 mg	b.i.d for 21 days
Group 5[b]**	Open-label, multi-dose, multi-center, randomized	2-way crossover comparative PHDS trial	Advanced PD patients	4	AP-CD/LD 50/500 mg	b.i.d for 21 days
Group 6**	Open-label, multi-dose, multi-center, randomized	2-way crossover comparative PHDS trial	Advanced PD patients	18	AP-CD/LD 50/500 mg	b.i.d for 21 days

a Eight patients completed the PK trial.
b Group 5 was terminated early due to low enrollment.

d = days; PP = Per Protocol; N = number of subjects; PD = Parkinson's disease; PHDS = pharmacodynamics.

* Not including add-on dosing of immediate release Carbidopa/Levodopa, if needed.
** Compared against each patient's optimized current Levodopa treatment.

Pharmacokinetic Results

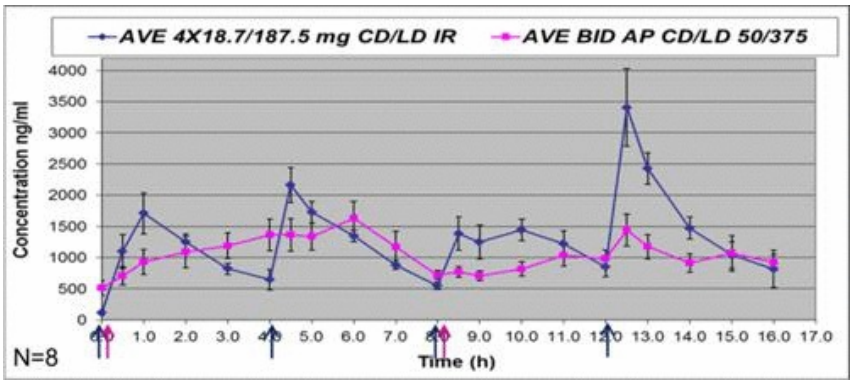
Group 1 of our Phase II clinical trial with AP-CD/LD was conducted with 12 male and female patients with non-fluctuating Parkinson's disease. The crossover design included the following treatment arms: (i) AP-CD/LD 50/250 mg administered b.i.d and (ii) immediate release CD/LD 25/250 mg administered by half tablet q.i.d, resulting in a total daily dosage of 50/500mg. The treatments were administered for six days, with the seventh day consisting of PK testing. On the PK day of the control period, patients were given an additional 50 mg of Carbidopa (12.5 mg q.i.d) to achieve the recommended daily 70 – 100 mg dose of Carbidopa. Immediately following the PK testing on day seven, the patients crossed over to the other treatment to repeat the seven day process. This study concluded that (i) the bioavailability of Levodopa when administered via AP-CD/LD was similar to the immediate release reference; (ii) AP-CD/LD provided more stable plasma levels of Levodopa, with reduced peak-to-trough ratio, when compared to the immediate release reference; and (iii) AP-CD/LD provided higher morning Levodopa plasma levels than the immediate release reference.

Group 3 of our Phase II clinical trial with AP-CD/LD was conducted with ten male and female patients with advanced, fluctuating Parkinson's disease, of which eight completed the PK trial per protocol. The crossover design included the following treatment arms: in the AP-CD/LD treatment arm, the AP-CD/LD 50/375 mg was administered b.i.d for six at home days of treatment with up to an additional three add-on immediate release Carbidopa/Levodopa, as needed, and on day seven, b.i.d administration of AP-CD/LD 50/375 mg. In the control arm, the patient's current treatments were administered for six at home days and, on the seventh day, they were given immediate release Carbidopa/Levodopa 18.75/187.5 mg q.i.d, resulting in a total dosage of 75/750 mg. On the seventh day of each treatment regime, we conducted PK testing. Immediately following the PK testing on day seven, the patients were crossed over to the other treatment to repeat the seven day process.

These trials concluded that (i) the PK of AP-CD/LD demonstrated an efficient controlled-release profile, with significantly more stable Levodopa levels; (ii) the Levodopa absorption phase was increased more than six-fold versus the control treatment; (iii) the b.i.d administration of AP-CD/LD provided daily coverage of therapeutic Levodopa plasma levels; (iv) the peak-to-trough ratio in Levodopa plasma levels was half of those of the control; (v) the morning, or pre-first dose, Levodopa plasma levels of AP-CD/LD, were significantly higher than the control; and (vi) Levodopa's high bioavailability was preserved when using AP-CD/LD.

The following figure displays the concentrations of Levodopa in plasma of patients over time, comparing AP-CD/LD (pink) to the reference treatment (blue):

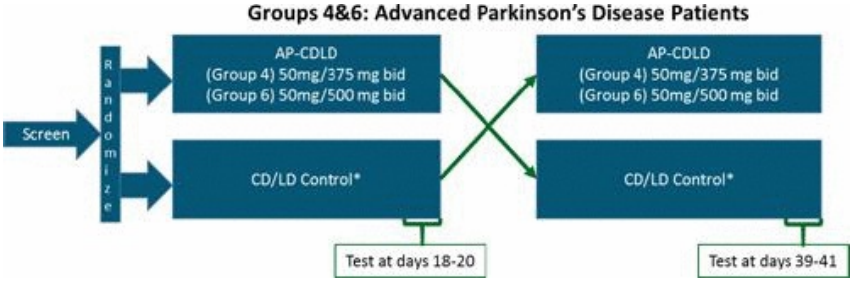
AP-CD/LD Phase II clinical trial — more stable Levodopa levels with statistically significant reduced peak-to-trough fluctuations



The PK results showed that peak to trough ratio, which measures the maximum average concentration relative to the minimum average concentration of LD plasma levels, was reduced from 29.9 to 3.2 with the AP-CD/LD. Cmax/Cmin with the AP-CD/LD was 5.8. The average LD plasma levels during time 0-16 hours was 1,038 ng/ml.

Pharmacodynamics Results

The following figure sets forth the structure of the Phase II clinical trial for Groups 4 and 6:



* Patient's optimized CD/LD regimen.

CD/LD = Carbidopa/Levodopa

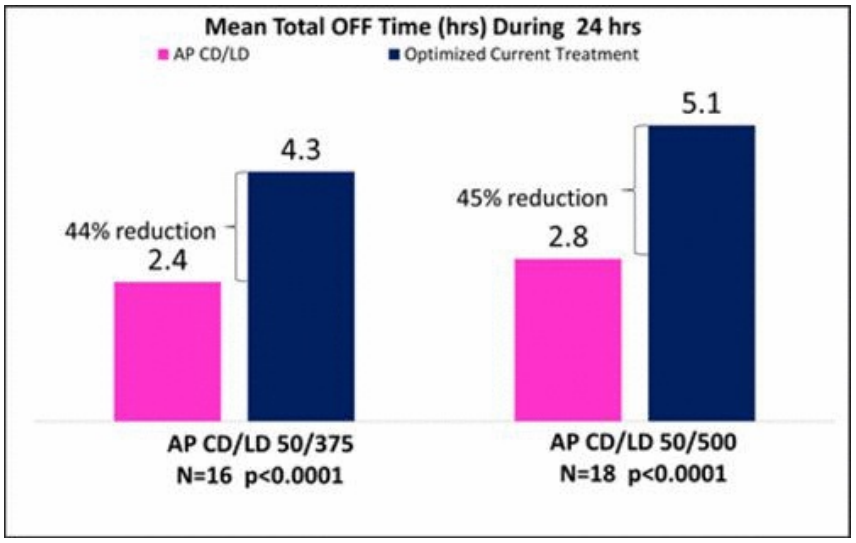
Groups 3, 4 and 6 of our Phase II clinical trial examined the pharmacodynamic effects of AP-CD/LD. Each group assessed the effects in patients with advanced Parkinson's disease; ten, 16 and 18 patients completed the trials per protocol in Groups 3, 4 and 6, respectively. Groups 3 and 4 tested AP-CD/LD in the 50/375 mg strength, administered b.i.d. with additional CD/LD immediate release tablets if needed; Group 6 tested the 50/500 mg strength administered b.i.d. with additional CD/LD immediate release tablets if needed. In these three trials, AP-CD/LD was compared to the patients' current Levodopa treatment (including a dopamine decarboxylase inhibitor, such as Carbidopa). All three groups were cross-over, with Group 3 receiving the treatments as described above and Groups 4 and 6 receiving each of their current treatment and AP-CD/LD for 21 days, with the second tested treatment starting immediately after completion of the first. In Groups 4 and 6, off time, on time and dyskinesia were assessed by patient-completed home diaries during days 18 through 20 of each arm.

Because Levodopa is usually prescribed for long-term treatment, three weeks of treatment with AP-CD/LD was sufficient to demonstrate statistically significant improvements in the primary endpoint, as well as most of the secondary endpoints. The statistical significance of a result was captured by the associated "p-value", or the estimated probability that the observed effect was by chance. A "p-value" of less than 0.05 implied that there was less than a 5% probability that the observed effect was by chance, and was generally accepted as a statistically significant event.

These studies demonstrated that (i) total off time was decreased when taking AP-CD/LD versus the control, by 44% and 45% in Groups 4 and 6, respectively (statistically significant $p<0.0001$); (ii) improvements in off time and on time without troublesome dyskinesia did not come at the expense of an increase of on time with troublesome dyskinesia, and, moreover, with the AP-CD/LD 50/500 mg troublesome dyskinesia was decreased by 0.5 hours (statistically significant $p = 0.002$); (iii) the effect of AP-CD/LD on total off time and on time with troublesome dyskinesia resulted in a total increase of "good" on time (i.e., without troublesome dyskinesia) of 2.1 and 2.7 hours per day in Groups 4 and 6, respectively (statistically significant $p<0.0001$); (iv) the improvements in treating symptoms with AP-CD/LD were achieved with fewer daily doses; and (v) the improvements in treating symptoms with AP-CD/LD correlate with stable Levodopa plasma levels throughout the day with appropriate therapeutic levels of the drug.

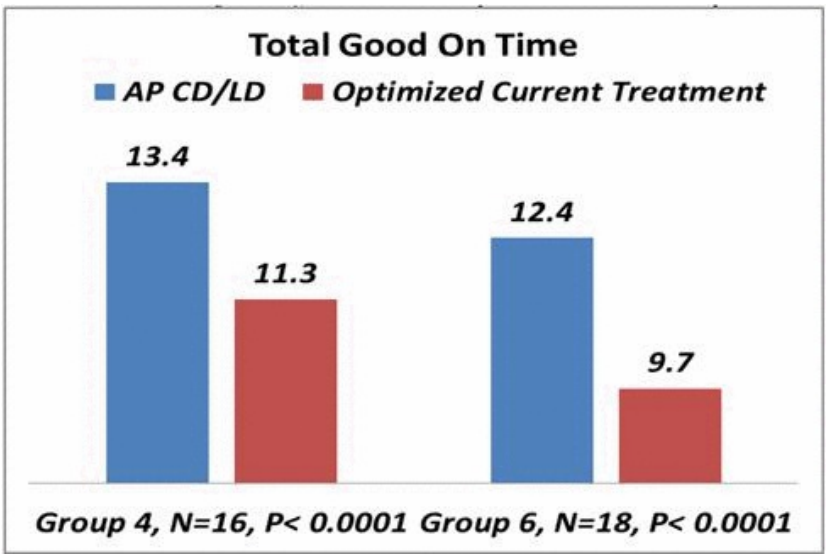
The figure below reflects the mean total off time in hours over a 24 hour period during days 18 through 20 of Groups 4 and 6. The average total off time was reduced by 1.9 hours and 2.3 hours with AP-CD/LD 50/375 mg (Group 4) and 50/500 mg (Group 6), respectively. This reduction is statistically significant (p<0.0001).

AP-CD/LD – Significant reduction of total off time compared to current Levodopa treatment



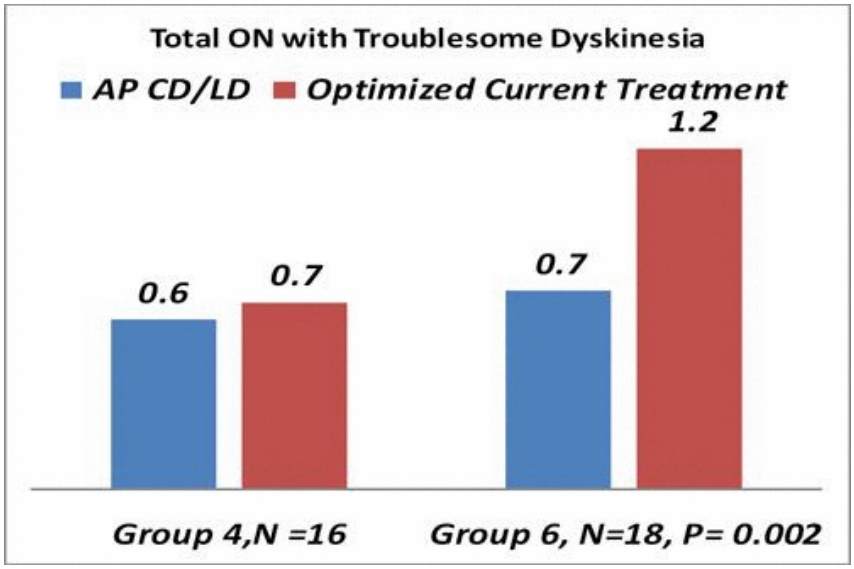
The figure below reflects the mean total "good" on time (on time without troublesome dyskinesia) in hours over a 24 hour period during days 18 through 20 of Groups 4 and 6. The average total "good" on time was increased by 2.1 hours and 2.7 hours with AP-CD/LD 50/375 mg (Group 4) and 50/500 mg (Group 6), respectively. This reduction is statistically significant (p<0.0001).

AP-CD/LD – Increase of total "good" on time compared to current Levodopa treatment



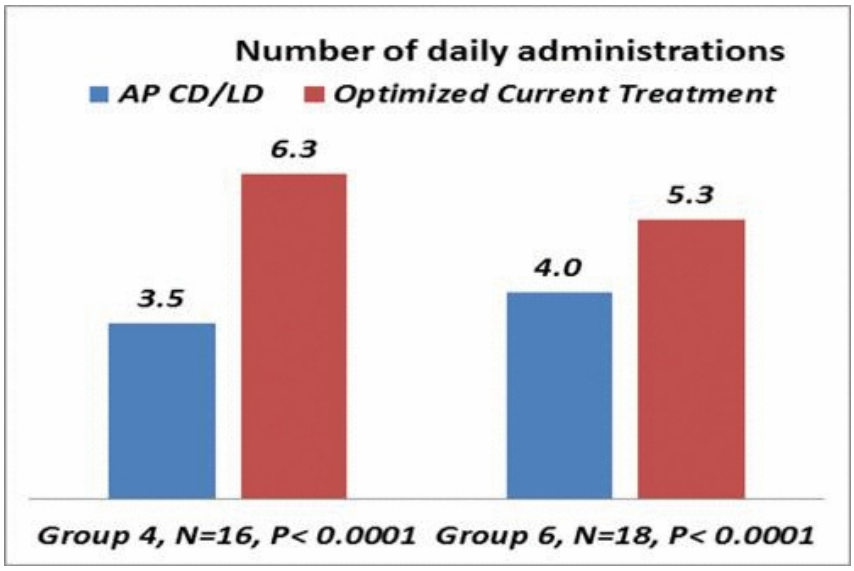
The figure below reflects the mean total on time with troublesome dyskinesia in hours over a 24 hour period during days 18 through 20 of Groups 4 and 6. On time with troublesome dyskinesia was not changed and decreased by 0.5 hours (p = 0.002) with AP-CD/LD 50/375 mg (Group 4) and 50/500 mg (Group 6), respectively.

AP-CD/LD – Reduction of total on time with dyskinesia compared to current Levodopa treatment



Finally, the figure below displays the mean number of daily Levodopa administrations of the treatments in Groups 4 and 6.

AP-CD/LD –Number of daily Levodopa administrations compared to current Levodopa treatment*



* In the administration of the AP-CD/LD arm, patients received b.i.d AP-CD/LD pills and were allowed to take additional commercially available immediate release Carbidopa/Levodopa formulations, as add-ons when needed. As seen in the figure above, patients took, in addition to the b.i.d AP-CD/LD pills, one-and-a-half to two commercially available immediate-release Carbidopa/Levodopa formulations, in Groups 4 and 6, respectively.

Demonstration of the clinical benefits of these peak to trough ratios will be further studied and confirmed in the ACCORDANCE study.

Phase I Clinical Trials

We conducted four Phase I clinical trials - three to assess the PK profile of Levodopa when administered in several formulations and one to measure the GR time of our Accordion Pill without an active ingredient.

The first PK trial was conducted with early formulations in 24 healthy volunteers to assess the PK profile of Levodopa when administered in the following three forms: (i) in an Accordion Pill with a dosage of 75/300 mg; (ii) in the immediate release form currently on the market, Sinemet; and (iii) in the controlled release form currently on the market, Sinemet CR. This group underwent a partially randomized open trial compared with immediate release Sinemet and controlled release Sinemet. The trial results indicated a significant prolongation of Levodopa's mean residence time, or MRT, in the blood when administered with the Accordion Pill compared with the Sinemet and Sinemet CR. Furthermore, the study showed the level of Levodopa received with the Accordion Pill reached treatment-relevant levels.

The second PK trial was conducted with early formulations in 23 healthy volunteers to assess the PK profile of Levodopa when administered in the following two forms: (i) an Accordion Pill in two formulations, 75/300 mg and 50/200 mg; and (ii) in the currently marketed immediate release form, Sinemet. This was a randomized open trial, compared with immediate release Sinemet. The trial results indicated a very significant increase in the MRT of Levodopa in the blood when administered with the Accordion Pill in both formulations, and a very significant prolongation of the absorption phase (up to 12 hours) of Levodopa was demonstrated when administered with the Accordion Pill compared with Sinemet (two hours).

The third PK trial was conducted with the AP-CD/LD 50/500 mg Phase II formulation in 18 healthy volunteers to assess the PK profile of Levodopa when administered in the following two forms: (i) AP-CD/LD 50/500 mg; and (ii) the currently marketed immediate release form, Sinemet. This was a randomized open trial, compared with immediate release Sinemet. The trial results indicated that the absorption phase of Levodopa was increased to approximately ten hours when administered with the Accordion Pill compared to approximately two hours with Sinemet.

The GR Phase I clinical trial was a MRI study conducted with 17 Parkinson's patients to measure the GR time of the Accordion Pill without an active pharmaceutical ingredient. This trial was a non-randomized open trial comparison of a few formulations. The results indicated that GR of over 13 hours can be achieved in these patients using all three formulations.

Safety

AP-CD/LD was tested for safety on Göttingen minipigs in accordance with the FDA's guidelines. The study was 180 days and a subgroup of minipigs were kept for recovery for an additional 30 days without receiving any treatments. This study included the following four arms: AP-CD/LD 50/400 mg three times daily, AP-CD/LD 50/500 mg b.i.d, a Carbidopa/Levodopa reference (Sinemet) and a placebo. The study was completed in March 2014. The study evaluated (i) animal wellbeing as represented by behavior, food consumption and weight, (ii) microscopic and macroscopic organ pathology, (iii) ophthalmic evaluation and (iv) electrocardiograms of the miniature pigs, which is the recording of the electrical activity of the heart. This study's results form an additional basis regarding the safety of AP-CD/LD.

In the Phase I and Phase II clinical trials, AP-CD/LD was well-tolerated with no serious adverse events that were related to the study drug. Adverse events were generally mild in severity and resolved without intervention. The most common adverse events reported included nausea, vomiting, diarrhea, abdominal pain, chest pain and fatigue, which are known adverse events associated with Levodopa treatment.

Current Regulatory Status of AP-CD/LD

On May 5, 2015, we held an end of Phase II meeting with the FDA for AP-CD/LD. We reached an agreement with the FDA on the remaining clinical development program for AP-CD/LD, and the following are the main principles of the single required pivotal Phase III clinical trial:

- A multicenter, randomized, double-blind, double-dummy, parallel, active-controlled trial, comparing the efficacy and safety of AP-CD/LD to Sinemet IR, an immediate release CD/LD, which is a conventional Levodopa medication for the treatment of Parkinson's disease symptoms that is currently on the market.
- The total treatment period for each patient is 25 weeks, composed of:
    - Six weeks open-label titration/ conversion/ optimization of Sinemet IR (all patients);
    - Six weeks open-label titration/ optimization of AP-CD/LD (all patients); and
    - 13 weeks double-blind, double-dummy active comparator period, in which approximately half of the patients are randomized to AP-CD/LD and half of the patients are randomized to Sinemet IR.
- The primary efficacy endpoint is the change from baseline to endpoint in the percent of daily off time during waking hours, based on Hauser home diaries.

In October 2018, we completed enrollment in our ACCORDANCE Study with a total of 462 patients entered into the Sinemet titration period. After the multiple titration and optimization steps, 320 patients were then randomized into the 13-week double-blinded portion of the study.

As part of our agreement with FDA regarding the approval of the AP-CD/LD product, we committed to perform additional safety studies on the first 100 patients with a predefined safety stopping rule related to gastric ulcers. These additional safety evaluations involved endoscopy procedures that would detect whether the AP was causing gastric ulcers of a predefined size that might be of medical concern. By the time the safety study completed enrollment of 123 patients, we were able to obtain evaluable paired gastroscopies (endoscopy procedures prior to AP treatment and at end of treatment) on 64 patients who completed all stages of the study. At the second scheduled periodic meeting of the independent data monitoring committee (DMC) in February 2018, the DMC determined that based on available results, there did not appear to be a significantly increased rate of the prespecified gastric ulcers defined in the safety charter. At that meeting, the DMC recommended to continue the ACCORDANCE study without modification. The DMC will continue to monitor adverse events of special interest, and also recommended we submit its comments and findings to the FDA, which we have done. No further endoscopic procedures are planned.

Consistent with International Council for Harmonisation of Technical Requirements for Human Use (ICH) guidelines, we are also required to submit evidence of the adequate safety experience of at least 100 patients receiving AP-CD/LD for one year, with at least 50% receiving the highest proposed dose of AP-CD/LD. This is a standard requirement for drugs intended for long-term treatment of non-life-threatening conditions. We are collecting this long-term safety data, from our on-going open label extension of the ACCORDANCE study.

We also agreed, at the FDA's request, to conduct an additional bioavailability study to compare the PK between Sinemet IR and the to-be-marketed formulation of AP-CD/LD as the formulation of AP-CD/LD has changed from our previously completed comparative bioavailability study. We currently intend to conduct this study during 2019. The FDA also strongly suggested that we conduct additional dissolution testing and we anticipate doing so.

In addition, in February 2019 we announced the results of a new PK study to determine the performance of the to-be-marketed formulation of AP-CD/LD when dosed three time per day (t.i.d). The objective of this open-label, crossover PK study was to compare the plasma levodopa variability in 12 Parkinson's disease patients treated with standard levodopa therapy and with AP-CD/LD 50/500 mg t.i.d. On day one, all participants received 1.5 tablets of standard Sinemet 25/100 mg five times at approximately three-hour intervals. Plasma was collected for PK determination at 30-minute intervals for 16 hours in the clinic. This period provided the reference PK profile for Sinemet. On days two through seven, PD patients were treated at home with AP-CD/LD 50/500 mg capsules dosed t.i.d., at approximately five-hour intervals. On day eight, participants returned to the clinic and PK assessments were repeated as described above. The primary outcome measure in this study was the fluctuation index $[(C_{max}-C_{min})/C_{avg}]$ in plasma levodopa concentration at steady state (between hours four and 16.) The key secondary endpoint was the levodopa coefficient of variation.

AP-CD/LD 50/500 mg TID met its primary endpoint demonstrating significantly less variability than standard oral CD/LD when dosed 5x/ day in the levodopa fluctuation index ($p<0.005$) (see the table below). These results were supported by the findings of significant outcomes on each of the prespecified sensitivity analyses. Similar results were observed for the key secondary endpoint of coefficient of variation of plasma levodopa levels ($p<0.047$). AP-CD/LD was very well tolerated with no reported adverse events.

	Primary Endpoint: Levodopa Fluctuation Index at Steady State (4-16 Hours)		
Treatment/ Difference	**Mean Value**	**95% Confidence Interval**	**p-Value**
Sinemet (IR-CD/LD)	**2.22**	**1.82 – 2.62**	**--**
Accordion AP-CD/LD	**1.59**	**1.23 – 1.95**	**--**
Difference	**0.63**	**0.24 – 1.03**	**0.005**

Phase III ACCORDANCE Study

The Phase III ACCORDANCE clinical trial of AP-CD/LD is a multi-center, global, randomized, double-blind, double-dummy, active-controlled, parallel-group study in adult subjects with advanced PD. The study is evaluating the safety and efficacy of AP-CD/LD compared with immediate release CD/LD (IR-CD/LD; Sinemet) as a treatment for the symptoms of PD.

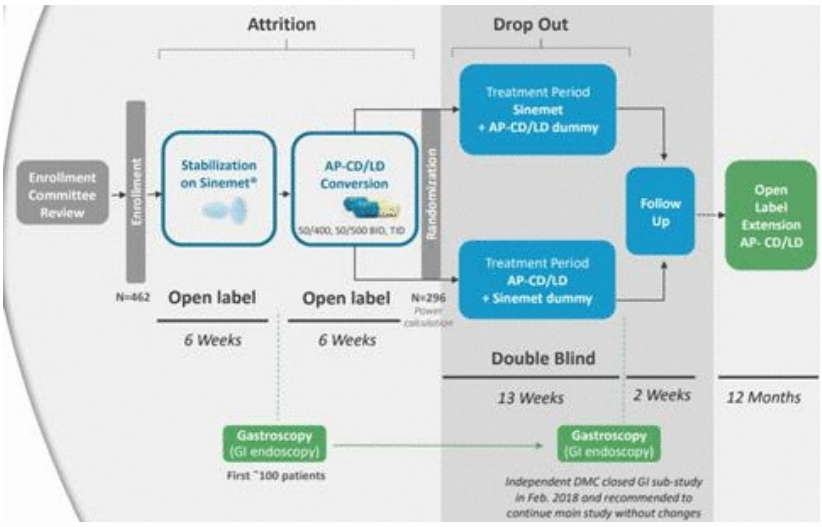
The study enrolled a total of 462 patients into the Sinemet titration period. After the multiple titration and optimization steps, 320 patients were then randomized into the 13-week double-blinded portion of the study. The study is being conducted at approximately 90 clinical sites throughout the U.S., Europe and Israel.

Preliminary analysis of the baseline data for the enrolled population shows:

- Average age at study entry was 63 and 65% of enrolled patients were male;
- Entering patients had a diagnosis of PD for 8.8 years on average;
- The average daily levodopa dose for patients upon entering the blinded portion of the study was in excess of 800 mg and the most common Accordion Pill dose was AP-CD/LD 50/500mg three times per day;
- Average daily OFF time for patients upon entering the study was approximately 6.1 hours; and
- Approximately 31% of patients were enrolled in the U.S.

Prior to the 13-week randomized portion of the study, the ACCORDANCE study had two open label periods of 6 weeks each during which all patients in these open label periods were first stabilized and optimized on the active comparator, Sinemet, and then on AP-CD/LD. All patients completing the 13-week randomized period are eligible to continue in an OLE study in which they will receive treatment with AP-CD/LD for up to an additional 12 months. To date, more than 90% of eligible patients have elected to enter an open label extension study.

The following is an illustration of the study design:



The primary efficacy endpoint of the study is the change from baseline to endpoint in the percentage of daily off time during waking hours based on Hauser home diaries. The study is 90% powered to be statistically significant for a one-hour difference in off time between Sinemet and AP-CD/LD.

Secondary endpoints currently include change from baseline to endpoint in "on time" without troublesome dyskinesia during waking hours, CGI-I at endpoint as recorded by physician and patient and change from baseline through endpoint in the Unified Parkinson's Disease Rating Scale (UPDRS) Score parts 2 and 3.

We expect to report topline results from the ACCORDANCE Study in mid-2019.

Development of Accordion Pills with additional drugs

We are continuously evaluating the possibilities of developing Accordion Pills with various additional specific drugs for its pipeline. In August 2016, we announced the initiation of a new clinical development program for the Accordion Pill platform with the two primary cannabinoids contained in *Cannabis Sativa*, Cannabidiol (CBD) and 9-Tetrahydrocannabinol (THC), for treatment of various pain indications. The *Cannabis sativa* plant is used in treatment of chronic pain and a variety of other indications. Previous clinical studies conducted using the whole plant or specific extracts generated evidence of the cannabis analgesic activity. Furthermore, extracts containing known amounts of the active plant driven compounds (mainly THC and CBD) or diverse synthetic THC derivatives are promising treatments for painful conditions that do not respond properly to currently available treatments, such as chronic, neuropathic, and inflammatory pain.

We believe that AP-Cannabinoids hold the potential to address several major drawbacks of current methods of use and treatment with cannabis and cannabinoids, such as short duration of effect, delayed onset, variability of exposure, variability of the administered dose and adverse events that correlate with peak levels. AP-Cannabinoids are designed to extend the absorption phase of CBD and THC, with the goal of more consistent levels, for an improved therapeutic effect. We believe that the cannabis market has significant commercial potential and is projected to represent approximately 10% of the specialty pharmaceutical market by 2020, or a market of at least $20 billion.

In August 2017, we announced the results of a Phase I clinical trial that compared the safety, tolerability and PK of AP-THC/CBD with Sativex ®. This Phase I trial is a single-center, single-dose, randomized, three-way crossover study in Israel to compare the safety, tolerability and PK of two formulations of AP-CBD/THC with Buccal Sativex® in 21 normal healthy volunteers. The results showed that patients in the Accordion Pill CBD/THC arm demonstrated significant improvements in exposure to CBD (290% to 330%) and THC (25% to 50%) compared with Sativex®. The median time to peak concentration was 2-3 times longer than Sativex and absorption was significantly higher. Additionally, the formation of THC metabolites was meaningfully reduced, and the drug had a good safety profile and was well-tolerated with no serious adverse events reported. Sativex® is a commercially available oral buccal spray containing CBD and THC. Following the Phase 1 clinical trial, we evaluated the program and decided as a next step to develop two new Accordion Pills containing only the individual cannabinoid components, namely CBD and THC.

We recently commenced a Phase 1 PK study of AP-THC. The study is a single-center, single-dose, randomized, open-label three-way crossover study to investigate the PK, safety and tolerability of AP-THC in up to 18 normal healthy volunteers and we dosed the first patient in January 2019. We have completed the dosing of the AP-THC PK study and the data is in the process of being analyzed by a third party contract research organization per protocol. However, upon raw data review, the delivery of THC does not appear to meet our full program expectations. We await the full dataset and the statistical analysis to determine our next steps.

We successfully completed a Phase II clinical trial for Accordion Pill Zaleplon, or AP–ZP, in November 2011 under an IND that we submitted to the FDA for AP–ZP as a treatment for the induction and maintenance of sleep in patients suffering from insomnia. The FDA also agreed that AP-ZP could also benefit from the streamlined pathway available through filing an NDA pursuant to Section 505(b)(2) of the FDCA. The FDA indicated in written correspondence to us that we may be able to design the development program for AP–ZP in a manner that would allow us to obtain sufficient data for the NDA submission for AP–ZP in one pivotal Phase III clinical trial. The details of such a trial were not determined or confirmed with the FDA. We are currently focusing on the development of, and are employing almost all of our resources toward, AP-CD/LD and AP-Cannabinoids. We are not currently developing or seeking a partner to develop AP-ZP and we have not presently budgeted any funds toward its development. In the future, we may consider viable partnership opportunities for this product candidate.

In addition, in March 2016, we completed a Phase I clinical trial for one of our product candidates that is being developed for the prevention and treatment of gastroduodenal and small bowel NSAID induced ulcers. The PK results demonstrated in the Phase I trial were within the well-defined safety levels of the drug. At this time, we have not presently budgeted any funds toward the development of this product candidate.

In January 2018, we also entered into a feasibility and option agreement with Novartis Pharmaceutical to explore using the Accordion Pill platform for a proprietary Novartis compound. Following potentially successful feasibility studies, including a Phase I PK study, Novartis has the option to enter into negotiations with respect to a potential licensing agreement for employing Intec Pharma Accordion Pill technology. In December 2018, we reported that we successfully developed an Accordion Pill for the Novartis proprietary compound that met the required *in vitro* specifications set forth in a feasibility and option agreement with Novartis. We have mutually agreed to proceed with the program and plan to enter the clinic with a first-in-human PK study in the first half of 2019.

Manufacturing

We currently manufacture the Accordion Pill in our production and packaging facility located in Har Hotzvim, in Jerusalem, Israel, in the same building as our offices. This production and packaging facility was granted the Certificate of GMP Compliance of Manufacturer from the Israeli Ministry of Health in August 2018. This certificate applies in Israel, as well as in the EU, in accordance with the Conformity Assessment and Acceptance of Industrial Products (CAA) agreement between the EU and Israel. The certificate is valid until August 2021.

We have the capacity to manufacture the required quantities for the ACCORDANCE study. Our fully automated assembly line enables us to manufacture approximately two to three million capsules annually. With respect to the future commercialization of the AP-CD/LD, we have decided to rely on a third-party manufacturer. Establishing a manufacturing facility to produce commercial quantities of our products will require a substantial investment by any party intending to manufacture our products.

In March 2018, we entered into a Term Sheet for Manufacturing Services with LTS, for the commercial manufacture of AP-CD/LD, which was subsequently superseded in December 2018 by a Process Development Agreement. Under the agreement, LTS will exclusively manufacture and supply us with AP-CD/LD capsules using our proprietary Accordion Pill production technology in LTS' manufacturing facility in Andernach, Germany subject to the execution and terms of a manufacturing and supply agreement to be negotiated and entered into between us and LTS. The large-scale automated production line for manufacturing AP-CD/LD capsules, or the Production Line, will be owned by us with LTS operating and maintaining the Production Line and owning the other production equipment for AP-CD/LD. Under the agreement, we are responsible for compensating LTS for certain development activities and we agreed to bear the costs incurred by LTS to acquire the other production equipment for AP-CD/LD, or Production Equipment, (which are estimated to total approximately seven million Euros and as of December 31, 2018 we transferred payments of approximately 4.3 million Euros); however such amount is required under the agreement to be later reimbursed to us by LTS in the form of a reduction in the purchase price of the AP-CD/LD capsules. In addition, upon our decision to not continue with the project or commercialization of the product, LTS has the right to (i) purchase the Production Equipment from us in which case LTS is required to pay to us the share of the cost of the Production Equipment paid by us less up to two million Euros for upgrade costs of LTS's facility invested by LTS or (ii) transfer such Production Equipment to us in which case we are required to pay LTS up to two million Euros for upgrade costs of LTS's facility invested by LTS. In addition, we may under certain circumstances be required to pay to LTS up to one million Euros for certain upgrade costs of LTS' facility invested by LTS upon the earlier of the announcement of our Phase III results or October 31, 2019. The agreement shall continue in force unless earlier terminated or upon the termination of any future manufacturing agreement. The agreement contains several termination rights which are expected to be included in a definitive manufacturing and supply agreement, including, among others, in the cases of bankruptcy, breach by either party, change of control of either of the parties, or the sale or licensing by us of the Accordion Pill to a third party.

In December 2018, the Production Line was delivered to LTS in Andernach, Germany. We are in the process of installing and connecting all the ancillary equipment and expect to begin the validation, bioequivalency and stability studies needed for approval of our commercial production processes in the coming months. After preliminary discussions with the FDA in anticipation of filing for marketing approval of AP-CD/LD, we remain confident we are on track to submit a NDA for approval of AP-CD/LD in mid- to late-2020, assuming positive topline data in the Accordance Study in mid-2019.

We have received Israeli government grants for certain of our research and development activities. The terms of these grants may require us to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. We may be required to pay penalties in addition to the repayment of the grants in case we decide to manufacture outside of Israel. With respect to the manufacturing of the AP-CD/LD, the Israel Innovation Authority, or IIA (formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry, or the OCS) approved our request to transfer 100% of the manufacturing rights to such product, which was developed under one of the IIA funded programs, to a non-Israeli manufacturer. As a result, we will be required to pay the IIA royalties from revenue generated from the AP-CD/LD product candidate at an increased rate and up to an increased cap amount. The IIA noted that the approval granted was exceptional and that the IIA will not approve manufacturing additional product candidates out of Israel.

The FDA will likely condition granting any marketing approval, if any, on a satisfactory on-site inspection of our manufacturing facilities. See "Item 1A. Risk Factors — Risks Related to the Clinical Development, Manufacturing and Regulatory Approval of Our Product Candidates — Our product candidates are manufactured through a compounding, film casting and assembly process, and if we or one of our materials suppliers encounters problems manufacturing our products or raw materials, our business could suffer."

Our manufacturing process consists of the following stages: compounding, which includes manufacturing of solutions and/or suspensions; film casting, which involves manufacturing of specific layers of films, including films containing the applicable drug; assembly and capsulation, which is processing and folding the films into an accordion shape and capsulation; and packaging, which entails packaging the pills in plastic bottles or blister packs.

Raw Materials and Supplies

With the exception of three inactive ingredients, we believe the raw materials that we require to manufacture AP-CD/LD and AP–Cannabinoids, as well as the raw materials that we require for our research and development operations relating to our products, are widely available from numerous suppliers and are generally considered to be generic pharmaceutical materials and supplies. Except as described below, we do not rely on a single supplier for the current production of any product in development or for our research and development operations relating to our products.

We usually contract with suppliers in Israel and worldwide to purchase the materials required for the research and development operations of our products. All the materials required in the research and development operations of our products are off-the-shelf pharmaceutical products; special production or special requirements are not required to order these materials. We have no written agreements with most of our suppliers. Rather, we submit purchase orders to our suppliers from time to time and as required.

Three of our inactive ingredients used in our products have only one supplier of each such ingredient. The three suppliers are each large, well-established suppliers (BASF, the Dow Chemical Company and Evonik), and most of the pharmaceutical industry relies on these suppliers when they need to purchase certain pharmaceutical products such as these inactive ingredients. To avoid a shortfall of these materials, we usually purchase sufficient material in advance for a period of at least one year. The pharmaceutical industry usually relies on these three manufacturers as suppliers of specific materials. The prices of these commonly used raw materials are not volatile.

Marketing and Sales

We do not currently have any marketing or sales capabilities. We intend to license to, or enter into strategic alliances with, companies in the pharmaceutical business, which are equipped to market and/or sell our products, if any, through their well-developed marketing and distribution networks. We may establish marketing and/or sales forces in the future in addition to licensing arrangements or strategic alliances.

Competition

The pharmaceutical and drug delivery technologies industries are characterized by rapidly evolving technology, intense competition and a highly risky, costly and lengthy research and development process. Adequate protection of intellectual property, successful product development, adequate funding and retention of skilled, experienced and professional personnel are among the many factors critical to success in the pharmaceutical industry.

Assertio Therapeutics, Inc. (formerly known as Depomed Inc.) has several products on the market based on its GR technology. Several companies have reported research projects related to systems designed for GR including Teva Pharmaceutical Industries, Avadel Pharmaceuticals, Merrion Pharmaceuticals, Sun Pharma and others, all of which develop products delivered orally that are designed for GR. We are not aware of any approved drug delivery system currently on the market that is similar to the Accordion Pill, nor are we aware of any product candidates that are similar to our Accordion Pill with respect to mechanism of action.

Other drug delivery technologies, other drugs on the market, new drugs under development (including drugs that are in more advanced stages of development in comparison to our product pipeline) and additional drugs that were originally intended for other purposes, but were found effective for the indications we target, may all be competitive to the current products in our pipeline. In fact, some of these drug delivery systems and drugs are well-established and accepted among patients and physicians in their respective markets, are orally bioavailable, can be efficiently produced and marketed, and are relatively safe and inexpensive. Moreover, other companies of various sizes engage in activities similar to ours, including large pharmaceutical companies, such as Pfizer and Novartis, who have established in-house capabilities for the development of drug delivery technologies. Most, if not all, of our competitors have substantially greater financial and other resources available to them. Competitors include companies with marketed products and/or an advanced research and development pipeline.

Current Treatments on the Market and in Development for Parkinson's Disease

The current common treatments for Parkinson's disease include Levodopa (usually used in conjunction with other drugs such as Carbidopa), which is currently the standard and most efficient Parkinson's medication used, and dopamine agonists, such as bromocriptine, pergolide, pramipexole and ropinirole, as well as MAO inhibitors and COMT inhibitors. However, Levodopa therapy is associated with "wearing-off", a condition in which a treatment's effects diminish over time as the disease progresses, and dyskinesia, or involuntary disturbing movements.

We believe our direct competition will include other technologies designed to address the need for more stable Levodopa levels. As such, AP-CD/LD will compete against other Levodopa-based Parkinson's drugs that are already on the market, such as Sinemet, a combination of Levodopa and Carbidopa, which is sold by Merck, as well as generic Sinemet, which is sold by various generic manufacturers. In addition, other technologies and drug delivery systems designed to address the Levodopa blood concentration problem currently exist. To our knowledge, based on publicly-filed documents, press releases and published studies, we believe the companies described below would be our primary competition with respect to AP-CD/LD.

Novartis and Orion combine Levodopa and Carbidopa with Comtan (entacapone), a drug that inhibits the clearance of Levodopa from the blood, thereby slowing the rapid drop in the Levodopa level in the blood. Additional drug candidates that are developed by Bial and Orion are based on the same approach.

Solvay Pharmaceuticals, which has been acquired by AbbVie Inc., introduced a drug delivery system based on implanting a tube in the duodenum area attached to an external pump that releases Levodopa formulation directly to the NAW. This product has been approved for marketing in the United States and Europe. The invasive nature of implanting a tube in patients, most of whom are elderly, as well as various difficulties related to the system, are certain disadvantages of this technology.

Impax Laboratories, which has merged with Amneal Pharmaceuticals, has developed a product, Rytary™, or IPX066, a continuous release Levodopa capsule formulation. The product was launched in April 2015. In addition, Amneal is developing IPX203, a new extended-release oral capsule formulation of carbidopa and levodopa, as a potential treatment for symptoms of Parkinson's disease. IPX203 has commenced a Phase III clinical trial.

Civitas Therapeutics, Inc., which was acquired by Acorda Therapeutics, Inc. in September 2014, has developed a product, INBRIJA™, or CVT-301, a self-administered, adjunctive, as needed, inhaled oral Levodopa, for the ability to rapidly and predictably treat "off" episodes as they occur. In December 2018, Acorda announced that the FDA approved INBRIJA™ for intermittent treatment of OFF episodes in people with Parkinson's disease treated with carbidopa/levodopa.

NeuroDerm Ltd., which was acquired by Mitsubishi Tanabe Pharma Corporation in October 2017, has the following subcutaneous product candidates, ND0612H and ND0612L for the treatment of patients suffering from Parkinson's disease. These product candidates have completed Phase II clinical trials.

Other technologies for delivering Levodopa, such as through the skin (transdermal administration) using a patch, injections or inhalations, as well as new formulations and chemical modifications of Levodopa and/or complementary drugs, currently exist and might compete with AP-CD/LD as well, but, to our knowledge, these technologies, formulations and modifications have not yet been submitted for approval.

Government Regulation

In the United States, the FDA regulates pharmaceuticals under the FDCA, and its implementing regulations. These products are also subject to other federal, state, and local statutes and regulations, including federal and state consumer protection laws, laws protecting the privacy of health-related information, and laws prohibiting unfair and deceptive acts and trade practices.

The process required by the FDA before a new drug product may be marketed in the United States generally involves the following: completion of extensive preclinical laboratory tests and preclinical animal studies, performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations; submission to the FDA of an IND which FDA must allow to become effective before human clinical trials in the US may begin; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication; and submission to the FDA of an NDA for the drug, after completion of all pivotal clinical trials. An IND is a request for authorization from the FDA to administer an investigational drug product to humans.

Clinical trials that involve the administration of the investigational drug to human subjects are conducted under the supervision of qualified investigators in accordance with current Good Clinical Practice, or cGCP which is intended to protect the rights, safety and welfare of humans participating in research and assure the quality, reliability and integrity of data collected. A protocol for each clinical trial conducted in the US, or other protocols under IND even not conducted in the US, and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's Institutional Review Board, or IRB, before the trials may be initiated, and the IRB must monitor the trial until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Clinical trials are usually conducted in three phases. Phase I clinical trials are normally conducted in small groups of healthy volunteers to assess safety and tolerability. After an acceptable dose has been established, the drug is administered to small populations of patients (Phase II) to look for initial signs of efficacy in treating the targeted disease or condition and to continue to assess safety. Phase III clinical trials are usually multi-center, double-blind controlled trials in hundreds or even thousands of subjects at various sites to assess as fully as possible both the safety and effectiveness of the drug.

The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the trial subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by a data safety monitoring board, or DSMB. This group of experts reviews unblinded data from clinical trials and provides authorization for whether or not a trial may move forward at designated check points. A DSMB may order a trial halted if it believes that the risk to subjects is unacceptable or the product is so effective as to make it unethical to administer placebos or alternate treatments to the non-treatment arms. The sponsor may also suspend or terminate a clinical trial based on evolving business reasons.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of an NDA requesting approval to market the product in the US for one or more indications. The NDA must be accompanied by a substantial user fee, which may be waived in certain circumstances. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. FDA has sixty days from the applicant's submission of an NDA to either accept the NDA for filing or issue a refusal-to-file letter if it finds that the application is not sufficiently complete to permit substantive review.

Once the NDA submission has been accepted for filing, the FDA's goal is to review standard applications within ten months of filing. However, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities involved in the production of the product, as well as inspections of selected clinical trial sites for data integrity, it may issue an approval letter or, instead, a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the application is not ready for approval in its present form. A Complete Response Letter may require additional clinical data or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing, or any combination thereof. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with restrictive indications, labeling that includes particular risk information, or a risk evaluation and mitigation strategy, or REMS, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase IV clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

After regulatory approval of a drug product is obtained, we would be required to comply with a number of post-approval requirements. As a holder of an approved NDA, we would be required to report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and manufacturing procedures must continue to conform to current Good Manufacturing Practices, or cGMP after approval, which includes, among other things, maintenance of a stability program. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive, and record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of product out of specification results and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We produce, and expect to continue to produce, the quantities of our product candidates required for our clinical trials, and we do not yet have a need to produce our product candidates for commercial purposes. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers or licensees that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary withdrawal of the product's approval, seizure, or FDA-initiated judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

In addition, as the NDA holder, we will be responsible for legal and regulatory compliance for advertising and promotion of the drug product. We are required to provide to the FDA copies of all drug promotion at the time of first use, and to ensure that all information disseminated conforms to the product's approved labeling and other FDA regulations and policies.

505(b)(2) Applications

We intend to submit NDAs for our proposed products, assuming that the clinical data justify submission, under Section 505(b)(2) of the FDCA, assuming the FDA agrees with our assessment that a given proposed product qualifies for review under that section. If the FDA disagrees with that assessment or revises its decision at a later date, we would be compelled to file under section 505(b)(1), which is the normal route used for traditional new drugs where the data relied upon for the NDA filing have been developed by the sponsor during its clinical trials. In contrast, Section 505(b)(2) permits the filing of an NDA when 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. The applicant may rely on published literature and the FDA's findings of safety and effectiveness based on certain pre-clinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the changes from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. The abbreviated Section 505(b)(2) approval pathway increases the likelihood that the timeframe and costs associated with commercializing products will be lower than under a typical Section 505(b)(1) approval pathway.

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information. When an Abbreviated New Drug Application, or ANDA, applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant. This same procedure that applied to an ANDA applicant also applies to an NDA applicant under Section 505(b)(2).

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for the patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Marketing Exclusivity

A Section 505(b)(2) NDA applicant may be eligible for its own regulatory exclusivity period, such as three-year exclusivity. A Section 505(b)(2) NDA applicant for a new condition of use, or change to a marketed product, such as a new extended release formulation for a previously approved product, may be granted a three-year market exclusivity if one or more clinical studies, other than bioavailability or bioequivalence studies, were essential to the approval of the application and were conducted or sponsored by the applicant. Should this occur, the FDA would be precluded from approving any other application for the same new condition of use or for a change to the drug product that was granted exclusivity until after that three-year exclusivity period has run. Additional exclusivities may also apply.

Reimbursement

We face uncertainties over the pricing of pharmaceutical products. Sales of our product candidates will depend, in part, on the extent to which the costs of our product candidates will be covered by third-party payors, such as federal health programs, commercial insurance and managed care organizations. These third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, foreign governments and third party payors have shown significant interest in implementing cost-containment programs, including price controls, pricing transparency disclosure obligations, restrictions on reimbursement and requirements for substitution of generic products. 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 payors do not consider our products to be cost-effective compared to other therapies, they may not cover any of our products after approved 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.

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably. In the United States, the Medicare Prescription Drug, Improvement and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and certain others. Prior to MMA, Medicare did not cover most outpatient prescription drugs. MMA created a new voluntary Part D, which covers outpatient drugs for Medicare beneficiaries and is administered by private insurance plans that operate partially at-risk under contract with the Centers for Medicare & Medicaid Services, or CMS. These private Part D plans have incentives to keep costs down. MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of certain outpatient drugs that will be covered in any therapeutic class.

In recent years, Congress has considered further reductions in Medicare reimbursement for drugs administered by physicians. CMS has issued and will continue to issue regulations to implement the law which will affect Medicare, Medicaid and other third-party payors. Medicare, which is the single largest third-party payment program and which is administered by CMS, covers prescription drugs in one of two ways. Medicare part B covers outpatient prescription drugs that are administered by physicians and Medicare part D covers other outpatient prescription drugs, but through private insurers. Medicaid, a health insurance program for the poor, is funded jointly by CMS and the states, but is administered by the states; states are authorized to cover outpatient prescription drugs, but that coverage is subject to caps and to substantial rebates. CMS also has the authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. While the MMA and implementing regulations apply primarily to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended, or the Affordable Care Act, which was amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA became law in the United States, 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 health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. As amended, the PPACA expanded manufacturers' rebate liability to include covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, increased the minimum rebate due for innovator drugs (both single source drugs and innovator multiple source drugs) from 15.1% of average manufacturer price, or AMP to 23.1% of AMP or the difference between the AMP and best price, whichever is greater. The total rebate amount for innovator drugs is capped at 100.0% of AMP. The PPACA and subsequent legislation also narrowed the definition of AMP. Furthermore, the PPACA imposes a significant annual, nondeductible fee on companies that manufacture or import certain branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. The PPACA likely will continue to put pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. The PPACA remains subject to continuing legislative scrutiny, including efforts by Congress to repeal and amend a number of its provisions, as well as administrative actions delaying the effectiveness of key provisions. In addition, there have been lawsuits filed by various stakeholders pertaining to certain portions of the PPACA that may have the effect of modifying or altering various parts of the law. Efforts to date to amend or repeal the PPACA have generally been unsuccessful.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, then President Obama signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of an amount greater than $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Bipartisan Budget Act of 2015, signed into law on November 2, 2015, increased the rebates that generic drug manufacturers are obligated to pay under the Medicaid program by applying an inflation-based rebate formula to generic drugs that previously only applied to brand name drugs. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

In the fourth quarter of 2018, the Trump Administration announced initiatives that it asserted are intended to result in purportedly lower drug prices. The first initiative, announced on October 15, 2018, involved the plan for a new federal regulation that would require pharmaceutical manufacturers to disclose the list prices of their respective prescription drugs in their television advertisements for their products if the list price is greater than $35. With respect to the second initiative, on October 25, 2018, the CMS gave Advance Notice of Proposed Rulemaking to propose the implementation of an "International Pricing Index" model for Medicare Part B drugs and biologicals (single source drugs, biologicals, and biosimilars). Public comments were due on December 31, 2018 with a proposed rule theoretically being offered as early as spring 2019 with target implementation of a 5 year pilot program beginning in spring 2020. On January 31, 2019, the U.S. Department of Health and Human Services, or HHS, Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. While these initiatives have not been put into effect, we are not in a position to know at this time whether they will ever become law or what impact the enactment either of these proposals would have on our business.

Various states, such as California, have also taken steps to consider and enact laws or regulations that are intended to increase the visibility of the pricing of pharmaceutical products with the goal of reducing the prices at which we are able to sell our products. Because these various actual and proposed legislative changes are intended to operate on a state-by-state level rather than a national one, we cannot predict what the full effect of these legislative activities may be on our business in the future.

Although we cannot predict the full effect on our business of the implementation of existing legislation, including the PPACA or the enactment of additional legislation pursuant to healthcare and other legislative reform, we believe that legislation or regulations that would reduce reimbursement for or restrict coverage of our products could adversely affect how much or under what circumstances healthcare providers will prescribe or administer our products.

Additionally, in some countries, particularly the countries comprising the EU the pricing of pharmaceuticals and certain other therapeutics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product andidate to other available therapies.

DEA

Our AP-Cannabinoids product candidates for treatment of various pain indications, uses CBD or THC. These products are quite distinct from crude herbal "medical marijuana," and we intend to seek FDA approval for these products in accordance with the customary FDA approval process and based on adequate and well-controlled clinical studies. However, the active ingredients in our products are defined as controlled substances under the federal Controlled Substances Act of 1970, or CSA. Under the CSA, the Drug Enforcement Administration of the United States Department of Justice, or DEA, places each drug that has abuse potential into one of five categories. The five categories, referred to as Schedules I-V, carry different degrees of restriction. Each schedule is associated with a distinct set of controls that affect manufacturers, researchers, healthcare providers, and patients. The controls include registration with the DEA, labeling and packaging, production quotas, security, recordkeeping, and dispensing. Schedule I is the most restrictive, covering drugs that have "no accepted medical use" in the United States and that have high abuse potential.

If and when any of our product candidates receive FDA approval, the DEA will make a scheduling determination and place the product in a schedule other than Schedule I in order for it to be prescribed to patients in the United States. Accordingly, our ability to ultimately commercialize the product will depend in part on the ultimate scheduling classification determination by DEA for our product.

The FDA has stated that it will continue to facilitate the work of companies interested in bringing safe, effective, and quality products to market, including scientifically-based research concerning the medical uses of products derived from marijuana and the FDA has approved synthetic compositions of the active ingredients found in marijuana. However, the use and abuse of controlled substances is currently subject to political and social pressures from certain constituencies related to their usage which could result in additional difficulty with respect to the approval of AP-Cannabinoids as a prescription pharmaceutical. For example, the FDA or DEA may require us to generate more clinical data about the potential for abuse than that which is currently anticipated, which could increase the cost and/or delay the launch of our product. In addition, DEA scheduling may limit our ability to achieve market share in the United States due to restricted access and the disinclination of some physicians to prescribe more restrictive scheduled controlled substances. For example, Schedule II drugs may not be refilled without a new prescription. These factors may limit the commercial viability of AP-Cannabinoids in the United States.

Most countries are parties to the Single Convention on Narcotic Drugs 1961, which governs international trade and domestic control of narcotic substances, including the compounds in our AP-Cannabinoids product candidates. Countries may interpret and implement their treaty obligations in a way that creates a legal obstacle to our obtaining approval to market our AP-Cannabinoids product candidates. Approval to market in these countries could require amendments or modifications to existing laws and regulations that such countries would be unwilling to undertake or may cause material delays in any marketing approval.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our current and future activities with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers are subject to healthcare regulation and enforcement by the federal government and the states in which we conduct our business. Applicable federal and state healthcare laws and regulations include the following:

- The federal healthcare Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good, item, facility or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid.

- The federal Anti-Inducement Act which prohibits persons from offering remuneration to beneficiaries to induce them to use a particular item or service payable in whole or in part by Medicare or Medicaid.

- The Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law, and its corresponding regulations, prohibit physicians from referring patients for designated health services (including outpatient drugs) reimbursed under the Medicare or Medicaid programs to entities with which the physicians or their family members have a financial relationship or an ownership interest, subject to narrow regulatory exceptions, and prohibits those entities from submitting claims to Medicare or Medicaid for payment of items or services provided to a referred beneficiary.

- The federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government.

- Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

- The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services.

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government.

- A PPACA provision, generally referred to as the Physician Payments Sunshine Act or Open Payments Program, imposes reporting requirements for applicable drug and device manufacturers of covered products with regard to payments or other transfers of value made to physicians and teaching hospitals, and certain investment/ownership interests held by physicians and their immediate family members in the reporting entity. These disclosures are publicly disclosed by the Centers for Medicare &Medicaid Services, or CMS.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. Although we believe our business practices are structured to be compliant with applicable laws, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our past or present operations, including activities conducted by our sales team or agents, are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, exclusion from third party payor programs, such as Medicare and Medicaid, debarment, imprisonment, integrity obligations and other compliance oversight, and the curtailment or restructuring of our operations. If any of the physicians, providers or entities with whom we do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusion from government funded healthcare programs.

Many aspects of these laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations which increases the risk of potential violations. In addition, these laws and their interpretations are subject to change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and damage our reputation.

In addition, from time to time in the future, we may become subject to additional laws or regulations administered by the U.S. Federal Trade Commission, or FTC, or by other federal, state, local or foreign regulatory authorities, to the repeal of laws or regulations that we generally consider favorable or to more stringent interpretations of current laws or regulations. We are not able to predict the nature of such future laws, regulations, repeals or interpretations, and we cannot predict what effect additional governmental regulation, if and when it occurs, would have on our business in the future. Such developments could, however, require reformulation of certain products to meet new standards, recalls or discontinuance of certain products not able to be reformulated, additional record-keeping requirements, increased documentation of the properties of certain products, additional or different labeling, additional scientific substantiation, additional personnel or other new requirements. Any such developments could have a material adverse effect on our business.

The growth and demand for electronic commerce, or eCommerce, could result in more stringent consumer protection laws that impose additional compliance burdens on online retailers. These consumer protection laws could result in substantial compliance costs and could interfere with the conduct of our business.

There is currently great uncertainty in many states whether or how existing laws governing issues such as property ownership, sales and other taxes, and libel and personal privacy apply to the Internet and commercial online retailers. These issues may take years to resolve. For example, tax authorities in a number of states, as well as a Congressional advisory commission, are currently reviewing the appropriate tax treatment of companies engaged in online commerce and new state tax regulations may subject us to additional state sales and income taxes. New legislation or regulation, the application of laws and regulations from jurisdictions whose laws do not currently apply to our business, or a change in application of existing laws and regulations to the Internet and commercial online services could result in significant additional taxes on our business. These taxes could have an adverse effect on our results of operations.

Intellectual Property

Our success depends, at least in part, on our ability to protect our proprietary technology and intellectual property, and to operate without infringing or violating the proprietary rights of others. We rely on a combination of patent, trademark, trade secret and copyright laws, know-how, intellectual property licenses and other contractual rights (including confidentiality and invention assignment agreements) to protect our proprietary technology and intellectual property, including related intellectual property rights.

Patents

As of December 31, 2018, we own or exclusively license six families of patents to use within our field of business (families IN-1, IN-3, IN-7, IN-8, IN-11 and IN-21). Four of the patent families (IN-1, IN-3, IN-7 and IN-11) have granted patents registered in various countries, as detailed below. One family (IN-8) has granted patents in force in the US, Japan and Israel, which we plan to allow to lapse by non-payment of future renewal fees. With the exception of the first family of patents (IN-1) three families (IN-3, IN-7 and IN-11) have active pending applications under examination. The sixth patent family (IN-21) currently comprises of recently filed pending applications in 21 jurisdictions, including the United States, European Patent Office, Israel, China, Japan, Russia, Australia, Canada, and other countries. Our patents and patent applications generally relate to gastroretentive drug delivery devices for oral intake, the integration of the drugs into our delivery devices and their production, and our patents and any patents that issue from our pending patent applications are expected to expire at various dates between 2020 and 2037. We also rely on trade secrets to protect certain aspects of our technology. The following discussion describes certain patents/patent applications which we consider to be our material patents and patent applications.

IN-1 and Yissum License Agreement

The patent family, IN-1, that we exclusively license from Yissum (i.e., Gastroretentive Controlled Release Pharmaceutical Dosage Forms) pursuant to the license agreement described below, or the License Agreement covers gastroretentive system/device for controlled release of an active ingredient in the GI tract. This patent does not cover the implementation of the accordion technology with respect to any particular drug or in a manner that is readily manufactured commercially, but it broadly covers folded gastroretentive forms, and forms the basis for the accordion technology in its most basic form. The system is intended mainly for drugs with NAW, drugs that act locally in the digestive system and drugs whose active receptors are in the upper part of the GI tract. The system is intended for clinical use in humans and in animals. The patent is issued in the United States, Israel, Japan, Australia, Canada, South Africa, the United Kingdom and six other European countries, and expires in 2020.

In the License Agreement, Yissum granted us an exclusive license for developing, manufacturing and marketing of products based, directly or indirectly, on the IN-1 patent, the know-how and research results defined therein. Under the provisions of the License Agreement, as amended, Yissum may not transfer its rights in the patent without our prior written consent. In consideration of the license, we have undertaken to pay Yissum royalties equaling 3% of the total net revenues from the sale of products based on Yissum's patent and royalties equal to 15% of any payment or benefit whatsoever received by us from any sublicensee. At the current time we have not commenced sales and have not granted any sublicenses to any third parties. The parties to the License Agreement are entitled to terminate the agreement in case of bankruptcy or receivership of the other party, or a material breach (including in respect of any payment obligations) that is not cured within 30 days. The License Agreement will remain in effect until the later of the expiration date of the patent or 15 years from the first commercial sale on the basis of the license. We have the right to assign our rights in the License Agreement with the prior consent of Yissum, not to be unreasonably withheld, and we are entitled to grant sublicenses under the licensed intellectual property of Yissum to third parties in our sole discretion, and any sublicensee(s) thereunder will not be required to assume any undertaking towards Yissum.

IN-3

An additional patent family (i.e., Method and Apparatus for Forming Delivery Devices for Oral Intake of an Agent), which we refer to as IN-3, covers various methods for making and folding the gastroretentive drug delivery system, and for folding it in an accordion configuration allowing its integration into an ordinary oral capsule, which are suitable for commercial manufacturing in mass quantities. The IN-3 family patents, will expire in 2027, except for the first United States patent of this family, which will expire in 2028. We consider our proprietary process for folding and cutting the films forming the drug delivery system for integration in an accordion-like configuration into an ordinary oral capsule to be material to our business. We have four granted patents in the U.S. and an additional pending patent application in connection with IN-3, as well as granted patents in Israel (three patents), Europe (two granted patents validated in more than 15 countries and a pending divisional application), Canada and Japan. Importantly, the second IN-3 patents granted in the U.S. and in Europe cover a specific embodiment of the Accordion Pill, particularly suitable for insoluble or poorly soluble drugs. Similar divisional applications have been filed in other countries and patents for these have already been granted in Israel and Japan.

IN-7

An additional patent family (for "frameless" Accordion Pill, specifically but not limited to Levodopa as the active drug) that we consider material to our business is referred to as IN-7. The accordion technology covered by our other patents may sometimes need to be specifically adapted for a given drug that might benefit from prolonged gastroretentive release. Thus, the layered structure of an Accordion Pill may be varied and specially designed by reference to factors that are unique to any given drug and indication, such as the quantity of active ingredient desired to be released, the length of time over which the active drug is released, the relative solubility of a particular drug molecule, and other factors. IN-7 patents/patent applications relate to a special Accordion Pill, which is "frameless", and is suitable for carrying various active drugs, including but not limited to Levodopa, optionally in combination with Carbidopa. The IN-7 patent family relates to the Accordion Pill dosage form, the main feature of which is the uniform inner drug-containing layer, which allows for, but does not require, high load of the drug, while maintaining the requisite structural or mechanical strength of the Accordion Pill. This patent family includes patents/patent applications filed in the United States, the European Patent Office, Japan and several other countries in April 2009. We have four granted U.S. patents for an Accordion Pill with specific claims to Carbidopa/Levodopa as the active ingredient(s) (IN-7), which will be in force until April 17, 2029, and have been granted IN-7 patents in China, Japan, Hong Kong, Canada, Europe, (validated in over 30 countries), Israel, South Africa and South Korea. Applications in Europe, Israel and China (divisional) and in India are pending.

An additional patent family, related to IN-7, which we refer to as IN-11, seeks protection for an Accordion Pill containing Levodopa that is specifically formulated for treatment of Parkinson's disease in a specific treatment regimen. We have been granted two United States patents, and have pending applications in Canada, EPO, India and Israel. Any granted patent of IN-11 will expire in November 2031.

IN-21

This patent family is directed to Accordion Pill comprising cannabinoid/s as active drugs (including THC and CBD, separately or in combination) currently includes pending patent applications in 21 jurisdictions, including the US, EPO, Israel, China, Republic of Korea, Canada, India, Japan, Australia, New Zealand, Russia, Brazil, Mexico and others. Patents to be granted on these applications will expire in 2037.

General

We intend to submit patent applications for each Accordion Pill and/or drug combination that we develop. The patent outlook for companies like ours is generally uncertain and may involve complex legal and factual questions. Our ability to maintain and consolidate our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or any patent applications that we license will result in the issuance of any patents. Our issued patents and those that may be issued in the future, or patents that we exclusively license, may be challenged, narrowed, circumvented or found to be invalid or unenforceable, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. We cannot be certain that we were the first to invent the inventions claimed in our owned patents or patent applications, or that Yissum was the first to invent the invention claimed in the patent that we exclusively license from Yissum. In addition, our competitors may independently develop similar technologies or duplicate any technology developed by us, and the rights granted under any issued patents may not provide us with any meaningful competitive advantages against these competitors. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

Trademarks

We rely on trade names, trademarks and service marks to protect our name brands. Our trademark/service mark ACCORDION PILL is registered in Israel in Classes 5, 40 and 42. We are in the process of registering the ACCORDION PILL trademark/ service mark in the United States, where the application has been recently published. The trademark/service mark ACCORDION PILL is also registered in the UK.

Trade Secrets and Confidential Information

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. Trade secrets and know-how can be difficult to protect. We rely on, among other things, confidentiality and invention assignment agreements to protect our proprietary know-how and other intellectual property that may not be patentable, or that we believe is best protected by means that do not require public disclosure. For example, we require our employees to execute confidentiality agreements in connection with their employment relationships with us, and to disclose and assign to us inventions conceived in connection with their services to us. However, there can be no assurance that these agreements will be enforceable or that they will provide us with adequate protection. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems.

We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For a more comprehensive summary of the risks related to our intellectual property, see "Item 1A. Risk Factors — Risks Related to Our Intellectual Property."

Insurance

We maintain directors' and officers' liability insurance with maximum coverage of $40.0 million in the aggregate for the benefit of our office holders and directors. Such directors' and officers' liability insurance contains certain standard exclusions.

We also maintain insurance for our premises for a maximum of NIS 40.0 million, including coverage of equipment and lease improvements against risk of loss (fire, natural hazard and allied perils, excluding damage from theft - hereinafter "named perils") and business interruption insurance coverage caused by named perils out of which up to NIS 44.0 million for fixed cost and up to NIS 120.0 million for expenses related to the ACCORDANCE study, our Phase III clinical trial for AP-CD/LD. In addition, we maintain the following insurance: employer liability with coverage of NIS 20.0 million; third-party liability with coverage of NIS 20.0 million; and all risk coverage for machinery breakdown of our casting machine of approximately NIS 5.0 million.

We also procure additional insurance for each specific clinical trial which covers a certain number of trial participants and which varies based on the particular clinical trial. Certain of such policies are based on the Declaration of Helsinki, which is a set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association, and certain protocols of the Israeli Ministry of Health.

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

Research Grants

Grants under the Israeli Innovation Law

Under the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Law for the Encouragement of Research and Development in Industry 5744-1984), and the regulations, guidelines, rules, procedures and benefit tracks thereunder, or the Innovation Law, research and development programs that meet specified criteria and are approved by a committee of the IIA are eligible for grants. The grants awarded are typically up to 50% of the project's expenditures, as determined by the IIA committee and subject to the benefit track under which the grant was awarded. A company that receives a grant from the IIA, or a Participating Company, is typically required to pay royalties to the IIA on income generated from products incorporating know-how developed using such grants (including income derived from services associated with such products), until 100% of the U.S. dollars-linked grant plus annual LIBOR interest is repaid. The rate of royalties to be paid may vary between different benefits tracks, as shall be determined by the IIA. Under the regular benefits tracks the rate of royalties varies between 3% to 5% of the income generated from the IIA-supported products. The obligation to pay royalties is contingent on actual income generated from such products and services. In the absence of such income, no payment of such royalties is required.

The terms of the grants under the Innovation Law also (generally) require that the products developed as part of the programs under which the grants were given be manufactured in Israel and that the know-how developed thereunder may not be transferred outside of Israel, unless a prior written approval is received from the IIA (such approval is not required for the transfer of a portion of the manufacturing capacity which does not exceed, in the aggregate, 10% of the portion declared to be manufactured outside of Israel in the applications for funding, in which case only notification is required) and additional payments are required to be made to the IIA. It should be noted, that this does not restrict the export of products that incorporate the funded know-how. See "Item 1A. Risk Factors — Risks Related to Our Operations in Israel" for additional information.

The IIA approved our request to transfer 100% of the manufacturing rights of AP-CD/LD that was developed under one of the IIA funded programs to LTS. As a result, we will be required to pay the IIA royalties from revenue generated from the AP-CD/LD product candidate at an increased rate and up to an increased cap amount. The IIA noted that the approval granted was exceptional and that the IIA will not approve manufacturing additional product candidates out of Israel.

From January 1, 2009 through December 31, 2016, we received from IIA approximately NIS 50.2 million. However, in March 2018, we repaid a portion of the grant amounts received in 2016 in the amount of approximately NIS 8.1 million (approximately $2.3 million), including interest and linkage differences, following a review and assessment by the IIA on the 2016 program. For more information see note 6c in our consolidated financial statements for the year ended December 31, 2018.

Environmental Matters

We are subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal of hazardous materials and wastes and the cleanup of contaminated sites. In addition, all of our laboratory personnel participate in instruction on the proper handling of chemicals, including hazardous substances before commencing employment, and during the course of their employment with us. In addition, all information with respect to any chemical substance that we use is filed and stored as a Material Safety Data Sheet, as required by applicable environmental regulations. Based on information currently available to us, we do not expect environmental costs and contingencies to have a material adverse effect on us. The operation of our facilities, however, entails risks in these areas. Significant expenditures could be required in the future if we are required to comply with new or more stringent environmental or health and safety laws, regulations or requirements.

We hold a business license from the Jerusalem Municipality with respect to manufacturing pharmaceutical products at 12 Hartom Street, Har Hotzvim in Jerusalem. The license is currently valid until December 31, 2023. The business license was granted after an inspection of our raw materials inventory, which we are permitted to maintain in our facilities and warehouses located at 12 Hartom Street. We also hold a toxic substance permit from July 26, 2018, which is valid until July 30, 2021.

On December 15, 2015, following our discussions with the Ministry of Environmental Protection to relax certain restrictions included in our business license, including, among others, to remove certain conditions the compliance with which is not feasible in the premises in which our facility is located, our business license was updated with additional terms which match our current activity.

We believe that our business, operations and facilities are being operated in compliance in all material respects with applicable environmental and health and safety laws and regulations.

Employees

As of December 31, 2018, we had 83 employees, 70 of whom are full-time employees, five of whom were employed in management, 10 of whom were employed in finance and administration, 48 of whom were employed in research and development and operations, nine of whom were employed in clinical trials and regulatory affairs and 11 of whom were employed in quality assurance. As of December 31, 2018, all of these employees are located in Israel or the United States, where our U.S. subsidiary employs five employees.

Israeli labor laws principally govern the length of the workday, minimum wages for employees, procedures for hiring and dismissing employees, determination of severance pay, annual leave, sick days, advance notice of termination of employment, equal opportunity and anti-discrimination laws and other conditions of employment. Subject to certain exceptions, Israeli law generally requires severance pay upon the retirement, death or dismissal of an employee, and requires us and our employees to make payments to the National Insurance Institute, which is similar to the U.S. Social Security Administration. Our employees have defined benefit pension plans that comply with applicable Israeli legal requirements, which also include the mandatory pension payments required by applicable law and allocations for severance pay.

While none of our employees are party to any collective bargaining agreements, certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Associations) are applicable to our employees by extension orders issued by the Israel Ministry of Economy and Industry. These provisions primarily concern the length of the workweek, pension fund benefits for all employees and for employees in the industry section, insurance for work-related accidents, travel expenses reimbursement, holiday leave, convalescent payments and entitlement for vacation days. We generally provide our employees with benefits and working conditions beyond the required minimums. We have never experienced any employment-related work stoppages and believe our relationship with our employees is good.

Available Information

We maintain a corporate website at www.intecpharma.com. Copies of our reports on Forms 10-K, Forms 10-Q and Forms 8-K, may be obtained, free of charge, electronically through our corporate website at www.intecpharma.com as soon as reasonably practicable after we file such material electronically with, or furnish to, the SEC. All of our SEC filings are also available on our website at http://www.intecpharma.com, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. The public may read and copy any materials filed by us with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov. The information on our website is not, and will not be deemed, a part of this Annual Report or incorporated into any other filings we make with the SEC.

Item 1A. Risk Factors.

An investment in our securities involves a high degree of risk. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. You should carefully consider the factors described below, together with all of the other information contained in this Annual Report, including the audited consolidated financial statements and the related notes included in this Annual Report beginning on page F-1, before deciding whether to invest in our ordinary shares. If any of the risks discussed below actually occur, our business, financial condition, operating results and cash flows could be materially adversely affected. The risks described below are not the only risks facing us. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. This could cause the trading price of our ordinary shares to decline, and you may lose all or part of your investment.

Risks Related to Our Financial Position and Capital Requirements

We are a clinical stage biopharmaceutical company with a history of operating losses, are not currently profitable, do not expect to become profitable in the near future and may never become profitable.

We are a clinical stage biopharmaceutical company that was incorporated in 2000. Since our incorporation, we have primarily focused our efforts on research and development and clinical trials. Our two most advanced therapeutic candidates are in clinical stages. We are not profitable and have incurred losses since inception, principally as a result of research and development, clinical trials and general administrative expenses in support of our operations. We have not generated any revenue, expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to incur significant operating and capital expenditures and anticipate that our expenses and losses will increase substantially in the foreseeable future as we:

- initiate and manage preclinical development and clinical trials for our current and any new product candidates;
- prepare new drug applications, or NDAs, for our product candidates, assuming that the clinical trial data support an NDA;
- seek regulatory approvals for our current product candidates, or future product candidates, if any;
- implement internal systems and infrastructure;
- seek to in-license additional technologies for development, if any;
- hire additional management and other personnel; and
- move towards commercialization of our product candidates and future product candidates, if any.

We may out-license our ability to generate revenue from one or more of our product candidates, depending on a number of factors, including our ability to:

- obtain favorable results from and progress the clinical development of our product candidates;

- develop and obtain regulatory approvals in the countries and for the uses we intend to pursue for our product candidates;
- subject to successful completion of registration, clinical trials and perhaps additional clinical trials of any product candidate, apply for and obtain marketing approval in the countries we intend to pursue for such product candidate; and
- contract for the manufacture of commercial quantities of our product candidates at acceptable cost levels, subject to the receipt of marketing approval.

For the years ended December 31, 2017 and 2018, we had net losses of $28.9 million and $43.5 million, respectively, and we expect such losses to continue for the foreseeable future. As a result, we will ultimately need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. If our product candidates fail in clinical trials or do not gain regulatory clearance or approval, or if our product candidates do not achieve market acceptance, we may never become profitable. Our failure to achieve or maintain profitability, or substantial delays in achieving profitability, could negatively impact the value of our ordinary shares and our ability to raise additional financing. A substantial decline in the value of our ordinary shares would also affect the price at which we could sell shares to secure future funding, which could dilute the ownership interest of current shareholders.

Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Accordingly, it is difficult to evaluate our business prospects. Moreover, our prospects must be considered in light of the risks and uncertainties encountered by an early-stage company in highly regulated and competitive markets, such as the biopharmaceutical market, where regulatory approval and market acceptance of our products are uncertain. There can be no assurance that our efforts will ultimately be successful or result in revenues or profits. As a result, our 2018 annual consolidated financial statements note that there is a substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm has expressed substantial doubt regarding our ability to continue as a going concern.

Our independent registered public accounting firm has issued its report on our consolidated financial statements for the year ended December 31, 2018 and included an explanatory paragraph stating that the Company has suffered recurring losses from operations and negative cash outflows from operating activities. We estimate that our current cash resources will allow us to complete our Phase III clinical trial for AP-CD/LD. However, we estimate that further fund raising will be required in order to complete the research and development of all of our product candidates including the manufacturing activities of the AP-CD/LD. As a result, there is substantial doubt about our ability to continue as a going concern within one year after the date our accompanying consolidated financial statements are issued. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. We have no current source of revenue to sustain our present activities, and we do not expect to generate revenue until, and unless, the FDA, or other regulatory authorities approve, and we successfully commercialize, our product candidates. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations, such as submissions of applications for grants from private funds, license agreements with third parties and raising capital from the public and/or private investors and/or institutional investors. There can be no assurance that we will succeed in obtaining the necessary financing to continue our operations. The perception that we might be unable to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees. If we cannot successfully continue as a going concern, our shareholders may lose their entire investment in our ordinary shares.

We will need substantial, additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

We will need to raise substantial, additional capital to complete the research and development of all of our product candidates including the manufacturing activities of the AP-CD/LD. In addition, we may choose to expand our current research and development focus, or other clinical operations. As of December 31, 2018, we had cash and cash equivalents of $39.3 million and marketable securities of $1.3 million. Our future capital requirements may be substantial and will depend on many factors including:

- adhering to patient recruitment in our ongoing and planned clinical trials;
- our clinical trial results;
- developing the Accordion Pill for the treatment of other conditions or indications beyond those currently being explored;
- the cost of filing and prosecuting patent applications and the cost of defending our patents;
- the cost of prosecuting infringement actions against third parties;
- the cost, timing and outcomes of seeking marketing approval of our product candidates;

- the costs associated with commercializing our products if we receive marketing approval, and choose to commercialize our product candidates ourselves, including the cost and timing of establishing external, and potentially in the future, internal, sales and marketing capabilities to market and sell our product candidates;
- subject to receipt of marketing approval, revenue received from sales of approved products, if any, in the future;
- the costs associated with any product liability or other lawsuits related to our future product candidates or products, if any;
- the costs associated with post-market compliance with regulatory requirements, and of addressing any allegations of non-compliance by regulatory authorities in countries where we plan to market and sell our products;
- the demand for our products;
- the costs associated with developing and/or in-licensing other research and development programs;
- the expenses needed to attract and retain skilled personnel; and
- the costs associated with being a public company.

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

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

Because of our limited operating history, we may not be able to successfully operate our business or execute our business plan.

We have a limited operating history upon which to evaluate our proposed business and prospects. Our proposed business operations will be subject to numerous risks, uncertainties, expenses and difficulties associated with early-stage enterprises. Such risks include, but are not limited to, the following:

- the absence of a lengthy operating history;
- insufficient capital to fully realize our operating plan;
- our ability to obtain FDA approvals in a timely manner, if ever, or that the approved label indications are sufficiently broad to make sale of the products commercially feasible;
- expected continual losses for the foreseeable future;
- operating in an environment that is highly regulated by a number of agencies;
- social and political unrest;
- operating in multiple currencies;
- our ability to anticipate and adapt to a developing market(s);
- acceptance of our Accordion Pill by the medical community and consumers;
- limited marketing experience;
- a competitive environment characterized by well-established and well-capitalized competitors;
- the ability to identify, attract and retain qualified personnel; and
- reliance on key personnel.

Because we are subject to these risks, evaluating our business may be difficult, our business strategy may be unsuccessful and we may be unable to address such risks in a cost-effective manner, if at all. If we are unable to successfully address these risks our business could be harmed.

Risks Related to Our Business Strategy and Operations

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

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

- the timing of regulatory approvals in the countries, and for the uses, we intend to pursue with respect to the commercialization of our product candidates;
- the competitive environment;
- the establishment and demonstration in, and acceptance by, the medical community of the safety and clinical efficacy of our products and their potential advantages over other therapeutic products;
- our ability to enter into strategic agreements with a commercial-scale manufacturer and with pharmaceutical and biotechnology companies with strong marketing and sales capabilities;
- the adequacy and success of distribution, sales and marketing efforts;
- the establishment of external, and potentially, internal, sales and marketing capabilities to effectively market and sell our product candidates in the United States and other countries; and
- the pricing and reimbursement policies of government and third-party payors, such as insurance companies, health maintenance organizations and other plan administrators.

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

If we are unable to establish sales, marketing and distribution capabilities or enter into successful relationships with third parties to perform these services, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of products. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish a sales and marketing infrastructure or to out-license the product.

In the future, we may consider building a focused sales and marketing infrastructure to market AP-CD/LD and potentially other product candidates in the United States, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force could be expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

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

If we are unable to establish our own sales, marketing and distribution capabilities or enter into successful arrangements with third parties to perform these services, our product revenues and our profitability, may be materially adversely affected.

In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates inside or outside of the United States or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

The members of our management team are important to the efficient and effective operation of our business, and we may need to add and retain additional leading experts. Failure to retain our management team and add additional leading experts could have a material adverse effect on our business, financial condition or results of operations.

Our executive officers and our management team are important to the efficient and effective operation of our business. Our failure to retain our management personnel, who have developed much of the technology we utilize today, or any other key management personnel, could have a material adverse effect on our future operations. Our success is also dependent on our ability to attract, retain and motivate highly-trained technical and management personnel, among others, to continue the development and commercialization of our current and future products.

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

We expect to face significant competition. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may never be profitable.

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

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

Our competitors are likely to include companies with marketed products and/or an advanced research and development pipeline. The competitive landscape of improving Levodopa for the treatment of Parkinson's disease symptoms includes Novartis AG, Orion Corporation, AbbVie, Amneal Pharmaceuticals, Inc., and more. The competitive landscape in the gastric retention system field includes Teva Pharmaceutical Industries, Assertio Therapeutics, Inc., Merrion Pharmaceuticals, Avadel Pharmaceuticals, Sun Pharma and more. Management is not aware of any companies that are developing or planning to develop a drug delivery system similar to our Accordion Pill platform technology.

There is a substantial risk of product liability claims in our business. We currently do not maintain product liability insurance and a product liability claim against us could adversely affect our business.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits, which may result in substantial losses.

Any of our product candidates could cause adverse events, including injury, disease or adverse side effects. These adverse events may or may not be observed in clinical trials, but may nonetheless occur in the future. If any of these adverse events occur, they may render our product candidates ineffective or harmful in some patients, and our sales would suffer, materially adversely affecting our business, financial condition and results of operations.

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

We face continuous technological change, and developments by competitors may render our products or technologies obsolete or non-competitive. If our new or existing product candidates are rendered obsolete or non-competitive, our marketing and sales will suffer and we may never be profitable.

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

- attract parties for acquisitions, joint ventures or other collaborations;
- license proprietary technology that is competitive with the technology we are developing;
- attract funding; and
- attract and hire scientific talent and other qualified personnel.

Our competitors may succeed in developing and commercializing products earlier and obtaining regulatory approvals from the FDA more rapidly than we do. Our competitors may also develop products or technologies that are superior to those we are developing, and render our product candidates or technologies obsolete or non-competitive. If we cannot successfully compete with new or existing products, our marketing and sales could suffer and we may never be profitable.

We may encounter difficulties in managing our growth. Failure to manage our growth effectively could have a material adverse effect on our business, results of operations and financial condition.

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

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

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

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

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

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

A security breach or disruption or failure in a computer or communications systems could adversely affect us.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, fire, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and interrupt our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, loss of trade secrets or inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, access to our clinical data, or disruption of the manufacturing process, we could incur liability and the further development of our Accordion Pill could be delayed. We may also be vulnerable to cyber-attacks by hackers or other malfeasance. This type of breach of our cybersecurity may compromise our confidential information and/or our financial information and adversely affect our business or result in legal proceedings. Further, these cybersecurity breaches may inflict reputational harm upon us that may result in decreased market value and erode public trust.

Global economic, capital market and political conditions could affect our ability to raise capital and could disrupt or delay the performance of our third-party contractors and suppliers.

Our ability to raise capital may be adversely affected by changes in global economic conditions and geopolitical risks, including credit market conditions, levels of consumer and business confidence, exchange rates, levels of government spending and deficits, trade policies, political conditions, actual or anticipated default on sovereign debt and other challenges that could affect the global economy. These economic conditions affect businesses such as ours in a number of ways. Tightening of credit in financial markets could adversely affect our ability to obtain financing. Similarly, such tightening of credit may adversely affect our supplier base and increase the potential for one or more of our suppliers to experience financial distress or bankruptcy. Our global business is also adversely affected by decreases in the general level of economic activity, such as decreases in business and consumer spending.

Risks Related to the Clinical Development, Manufacturing and Regulatory Approval of Our Product Candidates

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

The progress and results of any future preclinical testing or future clinical trials are uncertain, and the failure of our product candidates and additional product candidates which we may license, acquire or develop in the future to receive regulatory approvals could have a material adverse effect on our business, operating results and financial condition to the extent we are unable to commercialize any such products. None of our product candidates have received regulatory approval for commercial sale. In addition, we face the risks of failure inherent in developing therapeutic products. Some of our product candidates are not expected to be commercially available for several years, if at all.

Our product candidates are subject to extensive regulation and are at various stages of regulatory development and may never obtain regulatory approval.

Our product candidates must satisfy certain standards of safety and efficacy for a specific indication before they can be approved for commercial use by the FDA or foreign regulatory authorities. The FDA and foreign regulatory authorities have full discretion over this approval process. We will need to conduct significant additional research, including testing in animals and in humans, before we can file applications for product approval. Typically, in the pharmaceutical industry, there is a high rate of attrition for product candidates in preclinical testing and clinical trials. Also, even though we believe that some of our product candidates may be eligible for FDA review under Section 505(b)(2) of the FDCA, the FDA may not agree with that assessment, and may require us to submit the application under Section 505(b)(1) which usually requires more comprehensive clinical data than applications submitted under Section 505(b)(2). Even under Section 505(b)(2), satisfying FDA's requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. For example, a number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. In addition, delays or rejections may be encountered based upon additional government regulation, including any changes in legislation or FDA policy, during the process of product development, clinical trials and regulatory reviews. After clinical trials are completed, the FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies.

In order to receive FDA approval or approval from foreign regulatory authorities to market a product candidate or to distribute our products, we must demonstrate through preclinical testing and through human clinical trials that the product candidate is safe and effective for its intended uses (e.g., treatment of a specific condition in a specific way subject to contradictions and other limitations). We anticipate that some foreign regulatory agencies will have different testing and approval requirements from those of the FDA. Even if we comply with all FDA requests, the FDA may ultimately reject or decline to approve one or more of our new drug applications, or it may grant approval for a narrowly intended use that is not commercially feasible. We might not obtain regulatory approval for our product candidates in a timely manner, if at all. Failure to obtain FDA approval of any of our product candidates in a timely manner or at all could severely undermine our business by delaying or halting commercialization of our products, imposing costly procedures, diminishing competitive advantages and reducing the number of salable products and, therefore, corresponding product revenues.

We have collected limited clinical data about the safety and efficacy of AP-CD/LD in an open-label Phase II clinical trial that was not conducted under a U.S. issued IND and we may be unable to replicate these results in large-scale and double-blind controlled clinical trials.

Although the clinical trials performed to date using AP-CD/LD have shown promising results, these results were generated from open-label studies not performed under a U.S.-issued IND and were conducted at a limited number of clinical sites on a limited number of patients. An "open-label" trial is one where both the patient and investigator know whether the patient is receiving the test article or either an existing approved drug or placebo. Open-label trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label studies are aware that they are receiving treatment. Open-label trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

Given that these were open label studies, not conducted under an IND, the FDA may decide not to consider the data that we collected from these open-label studies, even though we are obligated to submit these data to the FDA. The FDA will accept a well-designed, well-conducted, non-IND foreign study as support for an application for marketing approval if the study was conducted in accordance with Good Clinical Practice, or GCP, and if the FDA is able to validate the data from the study through an onsite inspection, if necessary. GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of study subjects are protected, and that the clinical trial data are credible. GCP includes review and approval by an independent ethics committee, or IEC, such as an institutional review board, or IRB, before initiating a study. It also includes continuing review of an ongoing study by an IEC, and obtaining the freely given informed consent of the subject (or a subject's legally authorized representative, if a subject is unable to provide informed consent) before initiating a study.

Our Phase II clinical trial for AP-CD/LD was conducted at several medical centers in Israel. Patients in Israel are genetically similar to European patients and U.S. patients of European descent, but there may be unidentified genetic differences that may result in variable therapeutic response in certain subpopulations in these countries or in patients in other countries. Furthermore, although our initial safety profile has been favorable, safety could be dependent on operator skills. It is possible that we may experience a higher rate of adverse events in the future with wider application of our Accordion Pill technology in real-world practice outside of clinical trials.

If the FDA does not conclude that a given product candidate using our Accordion Pill technology satisfies the requirements for approval under the Section 505(b)(2) regulatory approval pathway, or if the requirements for approval of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval for our product candidates implementing our Accordion Pill technology through the Section 505(b)(2) regulatory pathway. Pursuant to Section 505(b)(2) of the FDCA, a NDA under Section 505(b)(2) is permitted to reference safety and effectiveness data submitted by the sponsor of a previously approved drug as part of its NDA, or rely on FDA's prior conclusions regarding the safety and effectiveness of that previously approved drug, or rely in part on data in the public domain. Reliance on data collected by others may expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. 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 product approval. If this were to occur, the time and financial resources required to obtain FDA approval, and complications and risks associated with regulatory approval of our product candidates, would likely substantially increase. Moreover, our inability to pursue the Section 505(b)(2) regulatory pathway may result in new competitive products reaching the market more quickly than our product, which would likely materially adversely impact our competitive position and prospects. Even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this will ultimately lead to accelerated product development or earlier approval. A 505(b)(2) applicant may rely on the FDA's finding of safety and effectiveness for a previously approved drug only to the extent that the proposed product in the Section 505(b)(2) application shares characteristics (e.g., active ingredient, dosage form, route of administration, strength, indication, conditions of use) in common with the previously approved drug. To the extent that the previously approved drug and the drug proposed in the Section 505(b)(2) application differ (e.g., a product with a different dosage form or route of administration), the Section 505(b)(2) application must include sufficient data to support those differences.

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 may be referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDA for up to 30 months or longer depending on the outcome of any litigation. Further, 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 a new product. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. Amendments to the FDCA attempt to limit the delay that can be caused by a citizen petition to 150 days, although court action by a dissatisfied petitioner is a possibility and this could, in theory, adversely affect the approval process.

Moreover, even if product candidates implementing our Accordion Pill technology are approved under Section 505(b)(2), 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.

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

Even if regulatory authorities approve any of our product candidates, they may not be commercially successful. Our product candidates may not be commercially successful because government agencies or other third-party payors may not provide reimbursement for the costs of the product or the reimbursement may be too low to be commercially successful. In addition, physicians and others may not use or recommend our products candidates, even following regulatory approval. A product approval, even if issued, may limit the uses for which such product may be distributed, which could adversely affect the commercial viability of the product. Moreover, third parties may develop superior products or have proprietary rights that preclude us from marketing our products. We also expect that our product candidates, if approved, will generally be more expensive than the non-Accordion Pill version of the same medication available to patients. Physician and patient acceptance of, and demand for, any product candidates for which we obtain regulatory approval or license will depend largely on many factors, including, but not limited to, the extent, if any, of reimbursement of costs by government agencies and other third-party payors, pricing, competition, the effectiveness of our marketing and distribution efforts, the safety and effectiveness of alternative products, and the prevalence and severity of side effects associated with such products. If physicians, government agencies and other third-party payors do not accept the use or efficacy of our products, we will not be able to generate significant revenue, if any.

We cannot be certain that the results of our current or potential Phase III clinical trials, even if all endpoints are met, will support regulatory approval of any of our product candidates for any indication.

Endpoints for most Phase III clinical trials may vary from drug candidate to drug candidate and from indication to indication; therefore, there are no universally accepted endpoints for Phase III clinical trials. It is possible that even if the results of our current or potential Phase III clinical trial meet the primary endpoints, the FDA will require other data of our product candidates prior to granting marketing approval. Although we held an end of Phase II meeting with the FDA in 2015 for AP-CD/LD and are conducting the ACCORDANCE trial in a manner consistent with the guidance provided by the FDA at that meeting, we have not entered into any Special Protocol Assessment agreement for the sufficiency of the ACCORDANCE trial, if successful, to achieve NDA approval.

Our product candidates and future product candidates will remain subject to ongoing regulatory requirements even if they receive marketing approval, and if we fail to comply with these requirements, we may not obtain such approvals or could lose those approvals that have been obtained, and the sales of any approved commercial products could be suspended.

Even if we receive regulatory approval to market a particular product candidate, any such product will remain subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record keeping. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the uses for which the product may be marketed or the conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, which could negatively impact us or our collaboration partners by reducing revenues or increasing expenses, and cause the approved product candidate not to be commercially viable. In addition, as clinical experience with a drug expands after approval, typically because it is used by a greater number and more diverse group of patients after approval than during clinical trials, side effects and other problems may be observed over time after approval that were not seen or anticipated during pre-approval clinical trials or other studies. Any adverse effects observed after the approval and marketing of a product candidate could result in limitations on the use of or withdrawal of FDA approval of any approved products from the marketplace. Absence of long-term safety data may also limit the approved uses of our products, if any. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks, including, without limitation, the following:

- suspension or imposition of restrictions on the products, manufacturers or manufacturing processes, including costly new manufacturing requirements;

- warning letters;
- civil or criminal penalties, fines and/or injunctions;
- product seizures or detentions;
- import or export bans or restrictions;
- voluntary or mandatory product recalls and related publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications.

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

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

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Regulatory authorities, such as the FDA, may preclude clinical trials from proceeding. Additionally, the clinical trial process is time-consuming, failure can occur at any stage of the trial and we may encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including, but not limited to:

- unforeseen safety issues;
- clinical holds or suspension of a clinical trial by the FDA, us, ethics committees, or the DSMB to determine proper dosing;
- lack of effectiveness or efficacy during clinical trials;
- failure of our contract manufacturers to manufacture our product candidates in accordance with cGMP;
- failure of third party suppliers to perform final manufacturing steps for the drug substance;
- slower than expected rates of patient recruitment and enrollment;
- lack of healthy volunteers and patients to conduct trials;
- inability to monitor patients adequately during or after treatment;
- failure of third party contract research organizations to properly implement or monitor the clinical trial protocols;
- failure of IRBs to approve or renew approvals of our clinical trial protocols;
- inability or unwillingness of medical investigators to follow our clinical trial protocols; and
- lack of sufficient funding to finance the clinical trials.

As noted above, we, regulatory authorities, IRBs or DSMBs may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the regulatory authorities find deficiencies in our regulatory submissions or conduct of these trials. For example, a DSMB has been selected for the Phase III clinical trial of AP-CD/LD and has been reviewing and will continue to periodically review the safety data of the trial. Any suspension of clinical trials will delay possible regulatory approval, if any, and adversely impact our ability to develop products and generate revenue.

We may be forced to abandon development of certain products altogether, which will significantly impair our ability to generate product revenues.

Upon the completion of any clinical trial, if at all, the results of these trials might not support the claims sought by us. Further, success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for its indicated uses. Any such failure may cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination or suspension of, our clinical trials will delay the requisite filings with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. If the clinical trials do not support our drug product claims, the completion of development of such product candidates may be significantly delayed or abandoned, which would significantly impair our ability to generate product revenues and would materially adversely affect our business, financial condition or results of operations.

Positive results in the previous clinical trials of one or more of our product candidates may not be replicated in future clinical trials of such product candidate, which could result in development delays or a failure to obtain marketing approval.

Positive results in the previous clinical trials of one or more of our product candidates may not be predictive of similar results in future clinical trials for such product candidate. Also, interim results during a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the completed preclinical studies and clinical trials for our product candidates may not be predictive of the results we may obtain in later stage trials of such product candidates. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials. Clinical trial results may be inconclusive, or contradicted by other clinical trials, particularly larger clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain FDA or European Medicines Agency, or other applicable regulatory agency, approval for their products.

Our product candidates are manufactured through a compounding, film casting and assembly process, and if we or one of our materials suppliers encounters problems manufacturing our products or raw materials, our business could suffer.

We and our contract manufacturers, if any, are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products. The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with cGMP or similar requirements that the FDA or foreign regulators establish. We and our contract manufacturers must ensure that all of the processes, methods and equipment are compliant with cGMP for drugs on an ongoing basis, as mandated by the FDA and other regulatory authorities, and conduct extensive audits of vendors, contract laboratories and suppliers. The FDA will likely condition grant of any marketing approval, if any, on a satisfactory on-site inspection of our manufacturing facilities.

We currently manufacture our product candidates used in clinical testing and we order certain materials from single-source suppliers. If the supply of any of these single-sourced materials is delayed or ceases, we may not be able to produce the related product in a timely manner or in sufficient quantities, if at all, causing us to be unable to further develop our product candidates or bring them to market or continue to develop our technology, which could materially and adversely affect our business. In addition, a single-source supplier of a key component of one or more of our product candidates could potentially exert significant bargaining power over price, quality, warranty claims or other terms relating to the single-sourced materials. Our materials suppliers may face manufacturing or quality control problems causing product production and shipment delays or a situation where the supplier may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance or raw materials. Drug manufacturers are subject to ongoing periodic unannounced inspections by the FDA, the DEA, and corresponding foreign regulatory agencies to ensure strict compliance with cGMP requirements and other governmental regulations and corresponding foreign standards. Any failure by us or our suppliers to comply with DEA requirements or FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

We intend to rely on a third-party manufacturer to manufacture commercial quantities of AP-CD/LD, if approved, and we may rely on other third-party manufacturers for other product candidates and any failure by a third-party manufacturer or supplier may delay or impair our ability to commercialize our product candidates.

We have manufactured our product candidates for our preclinical studies, Phase I clinical trials, Phase II clinical trials and Phase III clinical trial in our own manufacturing facility. Completion of any current or future Phase III clinical trial and commercialization of our product candidates will require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. Although we believe our facilities are sufficient to manufacture our product candidate needs for Phase III clinical trials, we may be incorrect and we may not have the resources or facilities to manufacture our product candidates for Phase III clinical trials.

With respect to the future commercialization of the AP-CD/LD, we have decided to rely on LTS, a third-party contract manufacturer. LTS will be the sole source of production of AP-CD/LD and the establishment of a manufacturing facility to produce commercial quantities of AP-CD/LD requires substantial investment. Producing products in commercial quantities requires developing and adhering to complex manufacturing processes that are different from the manufacture of products in smaller quantities for clinical trials, including adherence to regulatory standards. Although we believe that we have developed processes and protocols that will enable LTS to manufacture commercial-scale quantities of products at acceptable costs, we cannot provide assurance that such processes and protocols will enable us to manufacture in quantities that may be required for commercialization of AP-CD/LD with yields and at costs that will be commercially attractive. If LTS is unable to establish or maintain commercial manufacture of AP-CD/LD or are unable to do so at costs that we currently anticipate, our business could be adversely affected. Furthermore, if our current and future manufacturing and supply strategies are unsuccessful, we may be unable to conduct and complete any future Phase III clinical trials or commercialize our product candidates in a timely manner, if at all.

We have relied, and we expect to continue to rely, on third-party manufacturers for certain raw materials (excipients, solvents and active pharmaceutical ingredients, or APIs), and for the commercial manufacturing of our AP-CD/LD. Our reliance on third parties for the manufacture of these items increases the risk that we will not have sufficient quantities of these items or will not be able to obtain such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. If the third-party manufacturers on whom we rely fail to supply these items and we need to enter into alternative arrangements with a different supplier, it could delay our product development activities, as we would have to requalify the casting and assembly processes pursuant to FDA requirements. If this failure of supply were to occur after we received approval for and commenced commercialization of AP-CD/LD, we might be unable to meet the demand for this product and our business could be adversely affected. In addition, because we do not have any control over the process or timing of the supply of the APIs used in AP-CD/LD, there is greater risk that we will not have sufficient quantities of these APIs at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Manufacturing our product candidates is subject to extensive governmental regulation. Our failure or the failure of these third parties in any respect (including noncompliance with governmental regulations) could have a material adverse effect on our business, results of operations and financial condition.

Manufacturing our product candidates is subject to extensive governmental regulation. See “Item 1. Business - Government Regulation.” Future FDA, state and foreign inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers. Failure by our third-party manufacturers to pass such inspections and otherwise satisfactorily complete the FDA or foreign regulatory agency approval regimen with respect to our product candidates may result in regulatory actions such as the issuance of Form FDA 483 notices of observations or any foreign counterpart, warning letters or injunctions or the loss of operating licenses. Based on the severity of the regulatory action, our clinical or commercial supply of the items manufactured by third-party manufacturers could be interrupted or limited, which could have a material adverse effect on our business. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA or foreign regulatory agency-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product’s approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA’s or foreign regulatory agency’s policies may change, which could delay or prevent regulatory approval of our products under development. The FDA will likely condition grant of any marketing approval, if any, on a satisfactory on-site inspection of our manufacturing facilities.

If we are unable to use our manufacturing facility for any reason, the manufacture of clinical supplies of our candidates would be delayed, which would harm our business.

We currently manufacture all clinical supply of all our product candidates at our own manufacturing facility. If we were to lose the use of our facility or equipment, our manufacturing facility and manufacturing equipment would be difficult to replace and could require substantial replacement lead time and substantial additional funds. Our facility may be affected by natural disasters, such as floods or fire, or we may lose the use of our facility due to manufacturing issues that arise at our facility, such as contamination or regulatory concerns following a regulatory inspection of our facility. We do not currently have back-up capacity. In the event of a loss of the use of all or a portion of our facility or equipment for the reasons stated above or any other reason, we would be unable to manufacture any of our product candidates until such time as our facility could be repaired, rebuilt or we are able to address other manufacturing issues at our facility. Although we currently maintain property insurance with personal property limits of up to NIS 40.0 million, business interruption insurance coverage of up to NIS 44.0 million for damage to our property and the disruption of our business from fire and other casualties, and up to NIS 120.0 million for expenses related to the ACCORDANCE study, our Phase III clinical trial for AP-CD/LD, such insurance may not cover all occurrences of manufacturing disruption or be sufficient to cover all of our potential losses in the event of occurrences that are covered and may not continue to be available to us on acceptable terms, or at all.

We are subject to extensive and costly government regulation.

The products we are developing and planning to develop in the future are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the CMS, the HHS, including its Office of Inspector General, the Office of Civil Rights, which administers the privacy provisions of HIPAA, the U.S. Department of Justice, the Departments of Defense and Veterans Affairs, to the extent our products are paid for directly or indirectly by those departments, state and local governments, and their respective foreign equivalents. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical products under various regulatory provisions. If any drug products we develop are tested or marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding U.S. regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling our products. Our failure to comply with these regulations could result in, by way of example, significant fines, criminal and civil liability, product seizures, recalls, withdrawals, withdrawals of approvals, and exclusion and debarment from government programs. Any of these actions, including the inability of our proposed products to obtain and maintain regulatory approval, would have a materially adverse effect on our business, financial condition, results of operations and prospects.

In addition to government regulation, rules and policies of professional and other quasi and non-governmental bodies and organizations may impact the prescription of products, as well as the manner of their promotion, marketing, and education. Examples of such bodies are the American Medical Association, the Accreditation Council of Continuing Medical Education, American College of Physicians and the American Academy of Family Physicians.

Elections in the United States could result in significant changes in, and uncertainty with respect to, legislation, regulation and government policy. While it is not possible to predict whether and when any such changes will occur, changes at the federal level could significantly impact our business and the health care industry; we are currently unable to predict whether any such changes would have a net positive or negative impact on our business. To the extent that such changes have a negative impact on us or the health care industry, including as a result of related uncertainty, these changes may materially and adversely impact our business, financial condition, results of operations, cash flows and the trading price of our ordinary shares.

We are subject to additional federal, state and local laws and regulations relating to our business, and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

In the United States, our current and future activities with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers are subject to healthcare regulation and enforcement by the federal government and the states in which we conduct or will conduct our business. The laws that may affect our ability to operate include, but are not limited to, the following:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good, item, facility or service for which payment may be made under government healthcare programs such as the Medicare and Medicaid programs;

- the Anti-Inducement Law, which prohibits persons from offering or paying remuneration to Medicare and Medicaid beneficiaries to induce them to use items or services paid for in whole or in part by the Medicare or Medicaid programs;

- the Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law, prohibits physicians from referring Medicare or Medicaid patients for certain designated items or services where that physician or family member has a financial interest in the entity provided the designated item or service;

- federal false claims laws, including the Federal False Claims Act, that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government healthcare programs that are false or fraudulent;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- state and local law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers; and

- federal, state and local taxation laws applicable to the marketing and sale of our products.

Further, the PPACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity can now be found guilty of fraud or false claims under PPACA without actual knowledge of the statute or specific intent to violate it. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statue constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other government programs, imprisonment, and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

PPACA also contains legislation commonly known as the Physician Payments Sunshine Act, or Sunshine Act, which requires applicable drug and device manufacturers of covered pharmaceutical, biological, device and medical supplies to annually report to CMS information regarding payments and transfers of value made to physicians and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members, and for CMS to annually collect and display information reported by device and pharmaceutical manufacturers. Pursuant to the Sunshine Act, CMS created the federal Open Payments Program, under which data collected for each calendar year is published by CMS in June of the following calendar year. For example, data that was submitted by applicable manufacturers for the 2017 calendar year was published on June 30, 2018. Failure to submit required information may result in civil monetary for all payments, transfers of value or ownership or investment interests that are not reported.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA. Congress and President Trump have expressed their intentions to repeal or repeal and replace the PPACA. President Trump issued an Executive Order and both chambers of Congress passed bills, all with the goal of fulfilling their intensions. However, to date, the Executive Order has had limited effect and the Congressional activities have not resulted in the passage of a law to repeal and replace PPACA. If a law is enacted, many if not all of the provisions of the PPACA may no longer apply to prescription drugs. While we are unable to predict what changes may ultimately be enacted, to the extent that future changes affect how any future products are paid for and reimbursed by government and private payers, our business could be adversely impacted. On December 14, 2018, a federal district court in Texas ruled that the PPACA is unconstitutional as a result of the Tax Cuts and Jobs Act, the federal income tax reform legislation previously passed by Congress and signed by President Trump on December 22, 2017, that eliminated the individual mandate portion of the PPACA. The case, *Texas, et al, v. United States of America, et al.*, (N.D. Texas), is an outlier, and the ruling has been stayed by the ruling judge. We are not able to state with any certainty what will be the impact of this court decision on our business pending further court action and possible appeals.

In addition, there has been a recent trend of increased federal, state and local regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians, and some states limit or prohibit such gifts. Various trade associations, such as the Advanced Medical Technology Association for devices and the Pharmaceutical Research and Manufacturers of America for drugs, have adopted voluntary standards of ethical behavior that limit the amount of and circumstances under which payments made be made to physicians. Additionally, there are state and local laws that require pharmaceutical sales representatives to register or obtain a license with the state or locality and to disclose or report certain information about their interactions with physicians.

The scope and enforcement of these laws is uncertain and subject to change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. We cannot predict the impact on our business of any changes in these laws. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations, and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming.

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

There are extensive U.S. federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These federal laws include: the Anti-Kickback Statute, which prohibits certain business practices and relationships, including the payment or receipt of compensation for the referral of patients whose care will be paid by Medicare or other federal healthcare programs; the physician self-referral prohibition, commonly referred to as the Stark Law; the anti-inducement law, which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program; the civil False Claims Act in 1986, or the False Claims Act, which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment by the federal government, including the Medicare and Medicaid programs; and the Civil Monetary Penalties Law, which authorizes the U.S. Department of Health and Human Services to impose civil penalties administratively for fraudulent or abusive acts. In addition, the Sunshine Act requires device and drug manufacturers to report to the government any payments to physicians for consulting services, research activities, educational programs, travel, food, entertainment and the like.

Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, monetary penalties, imprisonment, integrity obligations and other oversight, denial of Medicare and Medicaid payments or exclusion from the Medicare and Medicaid programs, or both, and debarment. As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to reduce or eliminate waste and to control fraud and abuse in governmental healthcare programs. Private enforcement of healthcare fraud has also increased, due in large part to amendments to the False Claims Act that were designed to encourage private persons, known as relators, to file *qui tam* actions on behalf of the government. The Fraud Enforcement and Recovery Act of 2009 further encouraged whistleblowers to file suit under the *qui tam* provisions of the False Claims Act. A violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on our liquidity and financial condition. An investigation into the use by physicians of any of our products, if ever commercialized, may dissuade physicians from either purchasing or using them, and could have a material adverse effect on our ability to commercialize those products.

In addition, we are subject to analogous foreign laws and regulations, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; foreign 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; foreign 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 foreign laws governing the privacy and security of health information in certain circumstances. Many of these laws differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Our AP-CBD/THC, AP-THC and AP-CBD product candidates (collectively "AP-Cannabinoids") use Cannabidiol and 9-Tetrahydrocannabinol individually or in combination, which are subject to U.S. and international controlled substance laws and regulations; our ability to commercialize the product will depend in part on the ultimate classification of the product under these laws and regulations.

Our AP-Cannabinoids product candidates for treatment of various indications, including low back pain, neuropathic pain and fibromyalgia, uses CBD, and THC. These products are quite distinct from crude herbal "medical marijuana," and we intend to seek FDA approval for these products in accordance with the customary FDA approval process and based on adequate and well-controlled clinical studies. However, the active ingredients in our products are defined as controlled substances under the federal CSA. Under the CSA, the DEA, places each drug that has abuse potential into one of five categories. The five categories, referred to as Schedules I-V, carry different degrees of restriction. Each schedule is associated with a distinct set of controls that affect manufacturers, researchers, healthcare providers, and patients. The controls include registration with the DEA, labeling and packaging, production quotas, security, recordkeeping, and dispensing. Schedule I is the most restrictive, covering drugs that have "no accepted medical use" in the United States and that have high abuse potential.

If and when any of our product candidates receive FDA approval, the DEA will make a scheduling determination and place the product in a schedule other than Schedule I in order for it to be prescribed to patients in the United States. Accordingly, our ability to ultimately commercialize the product will depend in part on the ultimate scheduling classification determination by DEA for our product.

The FDA has stated that it will continue to facilitate the work of companies interested in bringing safe, effective, and quality products to market, including scientifically-based research concerning the medical uses of products derived from marijuana and the FDA has approved synthetic compositions of the active ingredients found in marijuana. However, the use and abuse of controlled substances is currently subject to political and social pressures from certain constituencies related to their usage which could result in additional difficulty with respect to the approval of AP-Cannabinoids as a prescription pharmaceutical. For example, the FDA or DEA may require us to generate more clinical data about the potential for abuse than that which is currently anticipated, which could increase the cost and/or delay the launch of our product. In addition, DEA scheduling may limit our ability to achieve market share in the United States due to restricted access and the disinclination of some physicians to prescribe more restrictive scheduled controlled substances. For example, Schedule II drugs may not be refilled without a new prescription. These factors may limit the commercial viability of AP-Cannabinoids in the United States.

Most countries are parties to the Single Convention on Narcotic Drugs 1961, which governs international trade and domestic control of narcotic substances, including the compounds in our AP-Cannabinoids product candidates. Countries may interpret and implement their treaty obligations in a way that creates a legal obstacle to our obtaining approval to market our AP-Cannabinoids product candidates. Approval to market in these countries could require amendments or modifications to existing laws and regulations that such countries would be unwilling to undertake or may cause material delays in any marketing approval.

Reimbursement may not be available for our products, which could make it difficult for us to sell our products profitably.

Market acceptance and sales of our products will depend on coverage and reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels. We cannot be sure that coverage and reimbursement will be available for our products. We also cannot be sure that the amount of reimbursement available, if any, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully compete through sales of our proposed products.

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. In the United States, MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and certain others. Prior to MMA, Medicare did not cover most outpatient prescription drugs. MMA created a new voluntary Part D, which covers outpatient drugs for Medicare beneficiaries and is administered by private insurance plans that operate partially at-risk under contract with the CMS. These private Part D plans have incentives to keep costs down. MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of certain outpatient drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These and future cost-reduction initiatives could decrease the coverage and price that we receive for our products, if approved, and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under Medicare may result in a similar reduction in payments from private payors.

In March 2010, PPACA became law in the United States. The goal of PPACA is to reduce the cost of healthcare and substantially change the way healthcare is financed by both governmental and private insurers. Among other measures, PPACA imposes increased rebates on manufacturers for certain covered drug products reimbursed by state Medicaid programs. The PPACA remains subject to continuing legislative scrutiny, including efforts by Congress to repeal and amend a number of its provisions, as well as administrative actions delaying the effectiveness of key provisions. In addition, there have been lawsuits filed by various stakeholders pertaining to certain portions of the PPACA that may have the effect of modifying or altering various parts of the law. Efforts to date to amend or repeal the PPACA have generally been unsuccessful. We ultimately cannot predict with any assurance the ultimate effect of the PPACA or changes to the PPACA on our Company, nor can we provide any assurance that its provisions will not have a material adverse effect on our business, financial condition, results of operations, cash flows and the trading price of our ordinary shares. In addition, we cannot predict whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted.

We expect to experience pricing pressures in connection with the sale of our products generally due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative proposals. If we fail to successfully secure and maintain adequate coverage and reimbursement for our future products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

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

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

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

In the United States, the MMA changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In recent years, Congress has considered further reductions in Medicare reimbursement for drugs administered by physicians. CMS has issued and will continue to issue regulations to implement the law which will affect Medicare, Medicaid and other third-party payors. Medicare, which is the single largest third-party payment program and which is administered by CMS, covers prescription drugs in one of two ways. Medicare part B covers outpatient prescription drugs that are administered by physicians and Medicare part D covers other outpatient prescription drugs, but through private insurers. Medicaid, a health insurance program for the poor, is funded jointly by CMS and the states, but is administered by the states; states are authorized to cover outpatient prescription drugs, but that coverage is subject to caps and to substantial rebates. CMS also has the authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. While the MMA and implementing regulations apply primarily to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the PPACA, 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 health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. As amended, the PPACA expanded manufacturers' rebate liability to include covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, increased the minimum rebate due for innovator drugs (both single source drugs and innovator multiple source drugs) from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP or the difference between the AMP and best price, whichever is greater. The total rebate amount for innovator drugs is capped at 100.0% of AMP. The PPACA and subsequent legislation also narrowed the definition of AMP. Furthermore, the PPACA imposes a significant annual, nondeductible fee on companies that manufacture or import certain branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. The PPACA likely will continue to put pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. We ultimately cannot predict with any assurance the ultimate effect of the PPACA or changes to the PPACA on our Company, nor can we provide any assurance that its provisions will not have a material adverse effect on our business, financial condition, results of operations, cash flows and the trading price of our ordinary shares. In addition, we cannot predict whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, then President Obama signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of an amount greater than $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Bipartisan Budget Act of 2015, signed into law on November 2, 2015, increased the rebates that generic drug manufacturers are obligated to pay under the Medicaid program by applying an inflation-based rebate formula to generic drugs that previously only applied to brand name drugs. If we ever obtain regulatory approval and commercialization of any of our product candidates, these new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates may be.

In the fourth quarter of 2018, the Trump Administration announced initiatives that it asserted are intended to result in purportedly lower drug prices. The first initiative, announced on October 15, 2018, involved the plan for a new federal regulation that would require pharmaceutical manufacturers to disclose the list prices of their respective prescription drugs in their television advertisements for their products if the list price is greater than $35. With respect to the second initiative, on October 25, 2018, the CMS gave Advance Notice of Proposed Rulemaking to propose the implementation of an "International Pricing Index" model for Medicare Part B drugs and biologicals (single source drugs, biologicals, and biosimilars). Public comments were due on Dec. 31, 2018 with a proposed rule theoretically being offered as early as spring 2019 with target implementation of a 5 year pilot program beginning in spring 2020. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. While these initiatives have not been put into effect, we are not in a position to know at this time whether they will ever become law or what impact the enactment either of these proposals would have on our business.

Various states, such as California, have also taken steps to consider and enact laws or regulations that are intended to increase the visibility of the pricing of pharmaceutical products with the goal of reducing the prices at which we are able to sell our products. Because these various actual and proposed legislative changes are intended to operate on a state-by-state level rather than a national one, we cannot predict what the full effect of these legislative activities may be on our business in the future.

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

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries comprising the EU, the pricing of pharmaceuticals and certain other therapeutics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Changes in regulatory requirements and guidance or unanticipated events during our clinical trials may occur, which may result in necessary changes to clinical trial protocols, which could result in increased costs to us, delay our development timeline or reduce the likelihood of successful completion of our clinical trials.

Changes in regulatory requirements and guidance or unanticipated events during our clinical trials may occur, as a result of which we may need to amend clinical trial protocols. Amendments may require us to resubmit our clinical trial protocols to IRBs for review and approval, which may adversely affect the cost, timing and successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, any of our clinical trials, the commercial prospects for our affected product candidates would be harmed and our ability to generate product revenue would be delayed, possibly materially.

We may be subject to extensive environmental, health and safety, and other laws and regulations in multiple jurisdictions.

Our business involves the controlled use, directly or indirectly through our service providers, of hazardous materials, various biological compounds and chemicals; therefore, we, our agents and our service providers may be subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal of hazardous, radioactive and biological materials and wastes and the cleanup of contaminated sites. The risk of accidental contamination or injury from these materials cannot be eliminated. If an accident, spill or release of any regulated chemicals or substances occurs, we could be held liable for resulting damages, including for investigation, remediation and monitoring of the contamination, including natural resource damages, the costs of which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials and chemicals. Although we maintain workers' compensation insurance to cover the costs and expenses that may be incurred because of injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. Additional or more stringent federal, state, local or foreign laws and regulations affecting our operations may be adopted in the future. We may incur substantial capital costs and operating expenses and may be required to obtain consents to comply with any of these or certain other laws or regulations and the terms and conditions of any permits or licenses required pursuant to such laws and regulations, including costs to install new or updated pollution control equipment, modify our operations or perform other corrective actions at our respective facilities or the facilities of our service providers. For instance, we have undergone inspections and obtained approvals from various governmental agencies. We hold a business license with respect to testing, developing, storing and manufacturing pharmaceutical products at our current location from the municipality of Jerusalem, which is accompanied by additional terms and conditions approved by the Israeli Ministry of Environmental Protection, or the Ministry of Environmental Protection. The business license is currently valid until March 31, 2019 and we are in the process of renewing it. We also hold a toxic substances permit from the Ministry of Environmental Protection (the Hazardous Material Division) and a Certificate of GMP Compliance of a Manufacturer from the Israeli Ministry of Health – Pharmaceutical Administration. Failure to renew any of the foregoing licenses and permits may harm our on-going and future operations. In addition, fines and penalties may be imposed for noncompliance with environmental, health and safety and other laws and regulations or for the failure to have, or comply with the terms and conditions of our business license or, required environmental or other permits or consents.

Risks Related to Our Intellectual Property

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or these agreements are terminated or we otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We license our core intellectual property from Yissum, an affiliate of Hebrew University and may need to obtain additional licenses from others to advance our research and development activities or allow the commercialization of the Accordion Pill. We initially entered into an exclusive license agreement with Yissum in 2000 and, in 2004 and 2005, we amended the license, which we refer to, as amended, as the License Agreement. According to the License Agreement, we hold an exclusive license for developing, manufacturing and/or world marketing of products that are directly or indirectly based on the patent owned by Yissum and/or other related intellectual property (including any information, research results and related know-how). Yissum is not permitted to transfer such intellectual property to third parties without our prior written consent. Yissum may obtain future financing from other entities for its research, provided that such entities will not be granted rights in its results (including other intellectual property rights) in a way prejudicing the rights granted to us in accordance with the License Agreement. We are entitled to grant perpetual sublicenses of this intellectual property to third parties, and such third parties will not be required to assume any undertaking towards Yissum. We are obligated to research and develop products that are based on the intellectual property of Yissum and to pay Yissum from the date of first sale an amount equal to 3% of our net sales of products based on the intellectual property and 15% from all other payments or benefits received from any such sublicense. In addition, also in consideration of the exclusive license granted to us pursuant to the License Agreement, we issued 5,618 ordinary shares to Yissum. As of the date of this Annual Report, no payments were paid and/or are due under the License Agreement. The License Agreement will be in effect until the latest of: (1) the expiration of the last registered patent within the relevant territory in November 2020; and (2) 15 years from the date of the first commercial sale. We also contracted with Yissum for laboratory services. In January 2008, we signed an addendum to the License Agreement to conduct an additional joint development and study regarding a technology, different from the Accordion Pill, for GR, of a drug. This addendum provides that the intellectual property rights produced as a result of the joint development and study will be jointly owned and we are entitled to receive a license for Yissum's share in these rights in return for payment of royalties. One patent application has been filed by Yissum and us as a result of the development related to that joint project, but this patent application was abandoned.

The License Agreement imposes certain payment, reporting, confidentiality and other obligations on us. In the event that we were to breach any of our obligations under the License Agreement and fail to cure such breach, Yissum would have the right to terminate the License Agreement upon 30 days' notice. In addition, Yissum has the right to terminate the License Agreement upon our bankruptcy or receivership.

In spite of our efforts, Yissum or any future licensor might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. Most of our current product candidates are partly based on the intellectual property licensed under the License Agreement, and therefore if the License Agreement with Yissum was terminated, we may be required to cease our development and commercialization of the Accordion Pill. Any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If we fail to adequately protect, enforce or secure rights to the patents which were licensed to us or any patents we own or may own in the future, the value of our intellectual property rights would diminish and our business and competitive position would suffer.

Our success, competitive position and future revenues, if any, depend in part on our ability to obtain and successfully leverage intellectual property covering our products and product candidates, know-how, methods, processes and other technologies, to protect our trade secrets, to prevent others from using our intellectual property and to operate without infringing the intellectual property rights of third parties.

The risks and uncertainties that we face with respect to our intellectual property rights include, but are not limited to, the following:

- the degree and range of protection any patents will afford us against competitors;
- if and when patents will be issued;
- whether or not others will obtain patents claiming aspects similar to those covered by our own or licensed patents and patent applications;
- we may be subject to interference proceedings;
- we may be subject to opposition or post-grant proceedings in foreign countries;
- any patents that are issued may not provide sufficient protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- other companies may challenge patents licensed or issued to us or our customers;
- other companies may independently develop similar or alternative technologies, or duplicate our technologies;
- other companies may design around technologies we have licensed or developed;
- enforcement of patents is complex, uncertain and expensive; and
- we may need to initiate litigation or administrative proceedings that may be costly whether we win or lose.

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

We cannot be certain that patents will be issued as a result of any pending applications, and we cannot be certain that any of our issued patents or patents licensed from Yissum (or any other third party in the future), will give us adequate protection from competing products. For example, issued patents, including the patents licensed by us, may be circumvented or challenged, declared invalid or unenforceable, or narrowed in scope.

In addition, since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make our inventions or to file patent applications covering those inventions.

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

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

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which could have a material adverse effect on our business.

Costly litigation may be necessary to protect our intellectual property rights, and we may be subject to claims alleging the breach of license or other agreements that we have entered into with third parties or the violation of the intellectual property rights of others.

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

We have entered into license and collaboration agreements with other parties, including other pharmaceutical companies, and intend to continue to do so in the future. We and our counterparties to these agreements have granted and may grant each other, and have or may claim against each other, certain rights with respect to the other party's intellectual property and the intellectual property that we have or may jointly develop, including rights of co-ownership and rights of first refusal in the event that we or our counterparties seek to subsequently license or sell such intellectual property. For instance, a former partner under a terminated collaboration agreement previously indicated to us after the termination of such agreement that it believed it had a right of first offer with respect to a future license by us of certain intellectual property that existed in 2008 and is contained in AP-CD/LD. We do not believe that this party has any such right. However, the cost to us of any litigation or other proceeding relating to our license and collaboration agreements, our licensed patents or patent applications or other intellectual property, even if resolved in our favor, could be substantial, divert management's resources and attention and delay or impair our ability to license or sell such intellectual property. Our ability to enforce our intellectual property protection could be limited by our financial resources, and may be subject to lengthy delays. A third party may claim that we are using inventions claimed by their intellectual property and may go to court to stop us from engaging in our normal operations and activities, such as research, development and the sale of any future products. Such lawsuits are expensive and would consume time and other resources. There is a risk that the court will decide that we are infringing the third party's intellectual property and will order us to stop the activities claimed by the intellectual property, redesign our products or processes to avoid infringement or obtain licenses (which may not be available on commercially reasonable terms or at all). In addition, there is a risk that a court will order us to pay the other party damages for having infringed their patents. 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.

Moreover, there is no guarantee that any prevailing patent or other intellectual property owner would offer us a license so that we could continue to engage in activities claimed by the patent or other intellectual property, or that such a license, if made available to us, could be acquired on commercially acceptable terms. In addition, third parties may, in the future assert other intellectual property infringement claims against us with respect to our product candidates, technologies or other matters. Any claims of infringement or other breach of license or collaboration agreement asserted against us, whether or not successful, may have a material adverse effect on us.

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. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter partes reexamination proceedings before the USPTO, and corresponding foreign patent offices. 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 pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that the Accordion Pill or 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, formulations, methods of manufacture or methods for treatment related to the use or manufacture of the Accordion Pill or our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that the Accordion Pill or 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 the patents protecting the Accordion Pill or our product candidates, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all, or it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize the Accordion Pill or 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 products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. For example, the patent family, IN-1, which we exclusively license from Yissum (i.e., Gastroretentive Controlled Release Pharmaceutical Dosage Forms), is expected to expire in 2020. This patent family relates to the foldable pharmaceutical gastroretentive drug delivery system for the controlled release of an active agent in the GI tract, which can be folded into a single capsule.

If we are not able to obtain patent term extension or non-patent exclusivity in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for the Accordion Pill or any product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval, one of the U.S. patents covering our product candidates or the use thereof may be eligible for up to five years of patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration sooner, and our revenue could be reduced, possibly materially.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering any of our product candidates even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we do not have the right to control prosecution, including filing with the USPTO, a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering the Accordion Pill or our 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. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover the Accordion Pill or our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware of during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact 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 become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

A significant portion of our intellectual property has been developed by our employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967, or the Patent Law, inventions conceived by an employee in the course and as a result of or arising from his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee, or the Committee, a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his inventions. Case law clarifies that the right to receive consideration for "service inventions" can be waived by the employee and that in certain circumstances, such waiver does not necessarily have to be explicit. The Committee will examine, on a case-by-case basis, the general contractual framework between the parties, using interpretation rules of the general Israeli contract laws. Further, the Committee has not yet determined one specific formula for calculating this remuneration (but rather uses the criteria specified in the Patent Law). Although we generally enter into assignment-of-invention agreements with our employees pursuant to which such individuals assign to us all rights to any inventions created in the scope of their employment or engagement with us, we may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current and/or former employees, or be forced to litigate such claims, which could negatively affect our business. Further, litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors 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, intellectual property that is important to our product candidates. 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. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

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

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to obtain these types of agreements from our contractors, consultants, advisors and research collaborators, to the extent that employees and consultants utilize or independently develop intellectual property in connection with any of our projects, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, disputes may arise as to the intellectual property rights associated with our products. If a dispute arises, a court may determine that the right belongs to a third party. We also rely on trade secrets and proprietary know-how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

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

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States 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. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export 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 products and our 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, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or 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 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 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.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Risks Related to Ownership of Our Ordinary Shares

The market price of our ordinary shares is volatile and you may sustain a complete loss of your investment.

The market price of our ordinary shares may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- inability to obtain the approvals necessary to commence further clinical trials;
- results of clinical and preclinical studies;

- announcements of regulatory approval or the failure to obtain it, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements of technological innovations, new products or product enhancements by us or others;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws, regulations or decisions applicable to our product candidates or patents;
- any adverse changes to our relationship with manufacturers or suppliers;
- announcements concerning our competitors or the pharmaceutical or biotechnology industries in general;
- achievement of expected product sales and profitability or our failure to meet expectations;
- our commencement of or results of, or involvement in, litigation, including, but not limited to, any product liability actions or intellectual property infringement actions;
- any major changes in our board of directors, management or other key personnel;
- legislation in the United States, Europe and other foreign countries relating to the sale or pricing of pharmaceuticals;
- announcements by us of significant strategic partnerships, out-licensing, in-licensing, joint ventures, acquisitions or capital commitments;
- expiration or terminations of licenses, research contracts or other collaboration agreements;
- public concern as to the safety of therapeutics we, our licensees or others develop;
- success of research and development projects;
- developments concerning intellectual property rights or regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our ordinary shares are covered by analysts;
- future issuances of ordinary shares or other securities;
- general market conditions, including the volatility of market prices for shares of biotechnology companies generally, and other factors, including factors unrelated to our operating performance; and
- the other factors described in this "Risk Factors" section.

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

Further, the stock market in general, the Nasdaq Capital Market and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies like ours. Broad market and industry factors may negatively affect the market price of our ordinary shares regardless of our actual operating performance. In addition, a systemic decline in the financial markets and related factors beyond our control may cause our share price to decline rapidly and unexpectedly. Price volatility of our ordinary shares might be worse if the trading volume of our ordinary shares is low. In the past, following periods of market volatility, shareholders have often instituted securities class action litigation. If we were involved in securities litigation, it could have a substantial cost and divert resources and attention of management from our business, even if we are successful. Future sales of our ordinary shares could also reduce the market price of such shares.

Moreover, the liquidity of our ordinary shares will be limited, not only in terms of the number of ordinary shares that can be bought and sold at a given price, but by potential delays in the timing of executing transactions in our ordinary shares and a reduction in security analyst and media's coverage of our Company, if any. These factors may result in lower prices for our ordinary shares than might otherwise be obtained and could also result in a larger spread between the bid and ask prices for our ordinary shares. In addition, without a large float, our ordinary shares will be less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our ordinary shares may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate its investment in our ordinary shares. Trading of a relatively small volume of our ordinary shares may have a greater impact on the trading price of our ordinary shares than would be the case if our public float were larger. We cannot predict the prices at which our ordinary shares will trade in the future.

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 ordinary shares, our share price and trading volume could be negatively impacted.

The trading market for our ordinary shares could 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 ordinary shares, or provide more favorable relative recommendations about our competitors, our share price 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 negatively impact our share price or trading volume.

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

We have not paid any cash dividends on our ordinary shares since inception. We do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. Moreover, the Israeli Companies Law, 5759-1999, or the Companies Law, imposes certain restrictions on our ability to declare and pay dividends. As a result, investors in our ordinary shares will not be able to benefit from owning our ordinary shares unless the market price of our ordinary shares becomes greater than the price paid for the shares by such investors and they are able to sell such shares. We cannot assure you that you will ever be able to resell our ordinary shares at a price in excess of the price paid for the shares.

The public trading market for our ordinary shares is volatile and may result in higher spreads in share prices, which may limit the ability of our investors to sell their ordinary shares at a profit, if at all.

Our ordinary shares currently trade on the Nasdaq Capital Market. Our results of operations and the value of our investments are affected by volatility in the securities markets. These difficulties and the volatility of the securities markets in general, and specifically during economic slowdowns, have affected and may continue to affect our ability to realize our investments or to raise financing, which in turn may result in us having to record impairment charges.

It may be difficult for you to sell your ordinary shares at or above the purchase price therefor or at all.

Although our ordinary shares now trade on the Nasdaq Capital Market, an active trading market for our ordinary shares may not be sustained. The market price of our ordinary shares is highly volatile and could be subject to wide fluctuations in price as a result of various factors, some of which are beyond our control. It may be difficult for you to sell your ordinary shares without depressing the market price for the ordinary shares or at all. As a result of these and other factors, you may not be able to sell your ordinary shares at current market price or at all. Further, an inactive market may also impair our ability to raise capital by selling our ordinary shares and may impair our ability to enter into strategic partnerships or acquire companies or products by using our ordinary shares as consideration.

The tax benefits that are available to us require us to continue to meet various conditions and may be terminated or reduced in the future, which could increase our costs and taxes.

We have obtained a tax ruling from the Israeli Tax Authority according to which our activity has been qualified as an "industrial activity," as defined in the Law for the Encouragement of Capital Investments, 1959, generally referred to as the Investment Law, and is eligible for tax benefits as a "Benefited Enterprise," which will apply to the turnover attributed to such enterprise, for a period of up to ten years from the first year in which we generated taxable income. The tax benefits under the Benefited Enterprise status are scheduled to expire at the end of 2023.

In order to remain eligible for the tax benefits of a Benefited Enterprise, we must continue to meet certain conditions stipulated in the Investment Law and its regulations, as amended. In addition, in order to remain eligible for the tax benefits available to the Benefited Enterprise, we must also comply with the conditions set forth in the tax ruling. These conditions include, among other things, that the production, directly or through subcontractors, of all our products should be performed within certain regions of Israel. If we do not meet these requirements, the tax benefits would be reduced or canceled.

There is no assurance that our future taxable income will qualify as Benefited Enterprise income or that the benefits described above will be available to us in the future.

Future changes to tax laws could have a material adverse effect on us and reduce net returns to our shareholders.

Our tax treatment is subject to changes in tax laws, regulations and treaties, or the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, as well as tax policy initiatives and reforms related to the Organization for Economic Co-Operation and Development's, or OECD, Base Erosion and Profit Shifting, or BEPS Project, the European Commission's state aid investigations and other initiatives.

Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or, in the specific context of withholding tax, dividends paid. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

In addition, on December 22, 2017, U.S. federal income tax legislation was signed into law (H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018"), informally titled the Tax Cuts and Jobs Act, that significantly revised the U.S. Internal Revenue Code of 1986, as amended, or the Code. The Tax Cuts and Jobs Act, among other things, contains significant changes to U.S. corporate income taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for business interest expense to 30% of adjusted earnings (except with respect to certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repealing of many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Cuts and Jobs Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act. The impact of this tax reform on holders of our ordinary shares is also uncertain and could be adverse. We urge you to consult with your legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our ordinary shares.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the U.S. Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable nexus, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

We expect to be characterized as a passive foreign investment company for the taxable years ending December 31, 2018, and December 31, 2019, and, as such, our U.S. shareholders may suffer adverse tax consequences.

Generally, if for any taxable year 75% or more of our gross income is passive income, or at least 50% of our assets are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For the taxable year ending December 31, 2018, we believe that we were a PFIC. We also expect to be classified as a PFIC for 2019. Furthermore, because PFIC status is determined annually and is based on our income, assets and activities for the entire taxable year, it is not possible to determine with certainty whether we will be characterized as a PFIC for the 2019 taxable year until after the close of the year, and there can be no assurance that we will not be classified as a PFIC in any future year. If we were to be characterized as a PFIC for U.S. federal income tax purposes in any taxable year during which a U.S. Holder owns ordinary shares, such U.S. Holder could face adverse U.S. federal income tax consequences, including having gains realized on the sale of our ordinary shares classified as ordinary income, rather than as capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. Holders, and having interest charges apply to distributions by us and the proceeds of share sales. Certain elections exist that may alleviate some adverse consequences of PFIC status and would result in an alternative treatment (such as "qualified electing fund" and "mark-to-market" treatment) of our ordinary shares. Upon request, we expect to provide the information necessary for U.S. Holders to make "qualified electing fund elections" if we are classified as a PFIC. Each investor is urged to consult its tax advisor with respect to the application of the PFIC rules.

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of our ordinary shares that, for U.S. federal income tax purposes, is or is treated as any of the following: (a) an individual who is a citizen or resident of the United States; (b) a corporation, or entity treated as a corporation for U.S. federal income tax purposes, created or organized under the laws of the United States, any state thereof, or the District of Columbia; (c) an estate, the income of which is subject to U.S. federal income tax regardless of its source; or (d) a trust that (1) is subject to the supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

U.S. persons who own 10% or more of our ordinary shares may be subject to adverse U.S. tax consequences under the U.S. controlled foreign corporation rules.

If we are or become a controlled foreign corporation, or "CFC," "10% U.S. Shareholders" (as defined below) may be taxed on their pro rata share of certain of our earnings, even if those earnings are not distributed by us. A non-U.S. corporation is a "CFC" if more than 50% of its shares (by vote or value) are owned by "10% U.S. Shareholders." A U.S. person is a "10% U.S. Shareholder" if such person owns (directly, indirectly and/or constructively) 10% or more of the total combined voting power of all classes of shares entitled to vote of such corporation or 10% or more of the total value of shares of all classes of stock of such corporation.

In general, if a U.S. person sells or exchanges stock in a foreign corporation and such person is a "10% U.S. Shareholder" at any time during the 5-year period ending on the date of the sale or exchange when such foreign corporation was a CFC, any gain from such sale or exchange may be treated as a dividend to the extent of the corporation's earnings and profits attributable to such shares that were accumulated during the period that the shareholder held the shares while the corporation was a CFC (with certain adjustments).

The CFC rules are complex. The foregoing is merely a summary of certain potential application of these rules. No assurances can be given that we are not or will not become a CFC, and certain changes to the CFC constructive ownership rules introduced by the Tax Cuts and Jobs Act could, under certain circumstances, cause us to be classified as a CFC. Each investor is urged to consult its tax advisor with respect to the possible application of the CFC rules.

Your percentage ownership in us may be diluted by future issuances of share capital, which could reduce your influence over matters on which shareholders vote.

Our board of directors has the authority, in most cases without action or vote of our shareholders, to issue all or any part of our authorized but unissued shares, including ordinary shares issuable upon the exercise of outstanding warrants and options. Issuances of additional shares would reduce your influence over matters on which our shareholders vote.

The sale of a substantial number of our ordinary shares may cause the market price of our ordinary shares to decline.

Sales of a substantial number of ordinary shares in the public market, or the perception that these sales could occur, could cause the market price of our ordinary shares to decline. We had 33,232,988 ordinary shares outstanding as of December 31, 2018 and as of the date of this Annual Report. All of our ordinary shares outstanding as of December 31, 2018 are freely tradable, without restriction, in the public market in the United States. Any sales of our ordinary shares or any perception in the market that such sales may occur could cause the trading price of our ordinary shares to decline.

In addition, as of February 22, 2019 up to 4,785,263 ordinary shares that are subject to outstanding options under the 2005 Share Option Plan, or the 2005 Plan, and outstanding options and reserved options for future issuance under our 2015 Incentive Compensation Plan, or the 2015 Plan, will be eligible for sale in the public market. We have filed registration statements on Form S-8 under the Securities Act to register such ordinary shares.

If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares could decline.

Because our ordinary shares may be, or become, a "penny stock," it may be more difficult for investors to sell their ordinary shares, and the market price of our ordinary shares may be adversely affected.

Our ordinary shares may be, or become, a "penny stock" if, among other things, the share price is below $5.00 per share, they are not listed on a national securities exchange or they have not met certain net tangible asset or average revenue requirements. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. This document provides information about penny stocks and the nature and level of risks involved in investing in the penny-stock market. A broker must also give a purchaser, orally or in writing, bid and offer quotations and information regarding broker and salesperson compensation, make a written determination that the penny stock is a suitable investment for the purchaser, and obtain the purchaser's written agreement to the purchase. Broker-dealers must also provide customers that hold penny stock in their accounts with such broker-dealer a monthly statement containing price and market information relating to the penny stock. If a penny stock is sold to an investor in violation of the penny stock rules, the investor may be able to cancel its purchase and get its money back.

If applicable, the penny stock rules may make it difficult for investors to sell their ordinary shares. Because of the rules and restrictions applicable to a penny stock, there is less trading in penny stocks and the market price of our ordinary shares may be adversely affected. Also, many brokers choose not to participate in penny stock transactions. Accordingly, investors may not always be able to resell their ordinary shares publicly at times and prices that they feel are appropriate and the market price of our ordinary shares may be adversely affected.

We must meet the Nasdaq Capital Market's continued listing requirements and comply with the other Nasdaq rules, or we may risk delisting. Delisting could negatively affect the price of our ordinary shares, which could make it more difficult for us to sell securities in a financing and for you to sell your ordinary shares.

We are required to meet the continued listing requirements of the Nasdaq Capital Market and comply with the other Nasdaq rules, including those regarding director independence and independent committee requirements, minimum shareholders' equity, minimum share price and certain other corporate governance requirements. If we do not meet these continued listing requirements, our ordinary shares could be delisted. Delisting of our ordinary shares from the Nasdaq Capital Market would cause us to pursue eligibility for trading on other markets or exchanges, or on the pink sheets. In such case, our shareholders' ability to trade, or obtain quotations of the market value of, our ordinary shares would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our securities. There can be no assurance that our ordinary shares, if delisted from the Nasdaq Capital Market in the future, would be listed on a national securities exchange or quoted on a national quotation service, the OTCQB or OTC Pink. Delisting from the Nasdaq Capital Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market liquidity of our ordinary shares, reduce security analysts' coverage of us and diminish investor, supplier and employee confidence. In addition, as a consequence of any such delisting, our share price could be negatively affected and our shareholders would likely find it more difficult to sell, or to obtain accurate quotations as to the prices of, our ordinary shares.

We incur significant costs as a result of the listing of our ordinary shares for trading on the Nasdaq Capital Market and thereby being a public company in the United States, and our management is required to devote substantial additional time to new compliance initiatives as well as to compliance with ongoing U.S. reporting requirements.

As a public company in the U.S., we incur significant accounting, legal and other expenses in order to comply with requirements of the SEC, and the Nasdaq Capital Market, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act. These rules and regulations have increased our legal and financial compliance costs, introduced new costs such as investor relations, stock exchange listing fees and shareholder reporting, and made some activities more time consuming and costly. Any future changes in the laws and regulations affecting public companies in the United States, including Section 404 and other provisions of the Sarbanes-Oxley Act, the rules and regulations adopted by the SEC and the Nasdaq Capital Market, for so long as they apply to us, will result in increased costs to us as we respond to such changes.

Failure to 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 our ordinary shares.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. We are required to document and test our internal control procedures in order to satisfy the requirements of Section 404, which requires annual management assessments of the effectiveness of our internal controls over financial reporting. If we fail to maintain the adequacy of our internal controls, 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 controls over financial reporting in accordance with Section 404. Disclosing deficiencies or weaknesses in our internal controls, 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 our ordinary shares. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed.

As of January 1, 2019, we are required to report as a U.S. domestic issuer and the benefits of a "foreign private issuer" are no longer available to us, which will likely result in additional costs and expenses for us.

As of June 30, 2018, the last business day of our second quarter, we determined that we no longer qualify as a foreign private issuer and as a result from January 1, 2019, we commenced reporting as a U.S. domestic issuer. As a result:

- we are required to report on forms that are applicable to U.S. companies, such as Forms 10-K, 10-Q and 8-K, rather than the forms formerly used by us, such as Forms 20-F and 6-K;
- we are required to prepare our consolidated financial statements in accordance with U.S. GAAP rather than IFRS;
- we are required to include substantially more information in proxy statements than previously provided;
- we can no longer make use of the shelf registration statement on Form F-3 that was declared effective on June 19, 2017, and will need to file a new shelf registration statement on the relevant form applicable to domestic issuers should we wish to engage in certain capital raising activities;
- if we engage in capital raising activities, there is a higher likelihood that investors may require us to file resale registration statements with the SEC as a condition to any such financing; and
- we may be required to modify certain of our policies to comply with accepted governance practices associated with U.S. domestic issuers.

We expect that complying with these additional requirements would increase our legal and audit fees which in turn, could have a material adverse effect on our business, financial condition and results of operations. In addition, as a result of being considered a "domestic issuer" for reporting and disclosure requirements:

- we are no longer exempt from certain of the provisions of U.S. securities laws such as (i) Regulation FD, which restricts the selective disclosure of material information, (ii) exemptions for filing beneficial ownership reports under Section 16(a) of the Exchange Act for executive officers, directors and 10% shareholders (Forms 3, 4, and 5), and (iii) the Section 16(b) short swing profit rules;
- we are no longer permitted to disclose compensation information for our executive officers on an aggregate rather than an individual basis, although such exemption may still be available to us as long as we remain an "emerging growth company"; and
- we have lost the ability to rely upon exemptions from Nasdaq corporate governance requirements that are available to foreign private issuers.

While we currently qualify as an "emerging growth company" under the JOBS Act, we will cease to be an emerging growth company on or before the end of 2020, and, to the extent we do not qualify as a smaller reporting company, at such time our costs and the demands placed upon our management will increase.

As an "emerging growth company" under the JOBS Act, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements. Most of such requirements relate to disclosures that we would otherwise be required to make, having ceased to be a foreign private issuer. While we currently qualify as an "emerging growth company" under the JOBS Act, we will cease to be an emerging growth company on or before the end of 2020, and, to the extent we do not qualify as a smaller reporting company, at such time our costs and the demands placed upon our management will increase unless we qualify as a smaller reporting company. For so long as we remain an emerging growth company, we will not be required to:

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

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common shares held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure, are exempt from the auditor attestation requirements of Section 404, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

We have elected to take advantage of certain of the reduced reporting obligations. We cannot predict whether investors will find our ordinary shares less attractive if we rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our stock price may be reduced or more volatile.

Risks Related to Our Operations in Israel

Potential political, economic and military instability in the State of Israel, where some of our senior management, our head executive office, research and development, and manufacturing facilities are located, may adversely affect our results of operations.

Our head executive office, our research and development facilities, our current manufacturing facility, as well as some of our clinical sites are located in Israel. Some 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 and operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries, as well as terrorist acts committed within Israel by hostile elements. 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. During November 2012 and from July through August 2014, Israel was engaged in an armed conflict with a militia group and political party who controls the Gaza Strip, and during the summer of 2006, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party. In December 2008 and January 2009 there was an escalation in violence among Israel, Hamas, the Palestinian Authority and other groups, as well as extensive hostilities along Israel's border with the Gaza Strip, which resulted in missiles being fired from the Gaza Strip into Southern Israel. Similar hostilities accompanied by missiles being fired from the Gaza Strip into Southern Israel, as well at areas more centrally located near Tel Aviv and at areas surrounding Jerusalem, occurred during November 2012 and July through August 2014. These conflicts involved missile strikes against civilian targets in various parts of Israel, including areas in which our employees and some of our consultants are located, and negatively affected business conditions in Israel.

Since February 2011, Egypt has experienced political turbulence and an increase in terrorist activity in the Sinai Peninsula following the resignation of Hosni Mubarak as president. This included protests throughout Egypt, and the appointment of a military regime in his stead, followed by the elections to parliament which brought groups affiliated with the Muslim Brotherhood (which had been previously outlawed by Egypt), and the subsequent overthrow of this elected government by a military regime. Such political turbulence and violence may damage peaceful and diplomatic relations between Israel and Egypt, and could affect the region as a whole. Similar civil unrest and political turbulence has occurred in other countries in the region, including Syria which shares a common border with Israel, and is affecting the political stability of those countries. Since April 2011, internal conflict in Syria has escalated, and evidence indicates that chemical weapons have been used in the region. Intervention may be contemplated by outside parties in order to prevent further chemical weapon use. This instability and any intervention may lead to deterioration of the political and economic relationships that exist between the State of Israel and some of these countries, and may have the potential for additional conflicts in the region. In addition, Iran has threatened to attack Israel and may be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, and various rebel militia groups in Syria. These situations may potentially escalate in the future to more violent events which may affect Israel and us. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. 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 commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained or that it will sufficiently cover our 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 and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business. A campaign of boycotts, divestment and sanctions has been undertaken against Israel, which could also adversely impact our business.

Our operations may be disrupted as a result of the obligation of Israeli citizens to perform military service.

Many Israeli citizens are obligated to perform up to 36 days, and in some cases more, of annual military reserve duty each year until they reach the age of 40 (or older, for reservists who are military officers or who have certain occupations) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists. It is possible that there will be military reserve duty call-ups in the future. Our operations could be disrupted by such call-ups, which may include the call-up of members of our management. Such disruption could materially adversely affect our business, financial condition and results of operations.

Investors may have difficulties enforcing a U.S. judgment, including judgments based upon the civil liability provisions of the U.S. federal securities laws against us, or our executive officers and directors or asserting U.S. securities laws claims in Israel.

Not all of our directors or officers are residents of the United States. Most of our assets and those of our non-U.S. directors and officers are located outside the United States. Service of process upon us or our non-U.S. resident directors and officers and enforcement of judgments obtained in the United States against us or our non-U.S. directors and executive officers may be difficult to obtain within the United States. We have been informed by our legal counsel in Israel that it may be difficult to assert claims under U.S. securities laws in original actions instituted in Israel or obtain a judgment based on the civil liability provisions of U.S. federal securities laws. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws against us or our non-U.S. officers and directors because Israel may not be the most appropriate forum 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 U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, 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 addressing the matters described above. Israeli courts might not enforce judgments rendered outside Israel, which may make it difficult to collect on judgments rendered against us or our non-U.S. officers and directors.

Moreover, among other reasons, including but not limited to, fraud or absence of due process, or the existence of a judgment which is at variance with another judgment that was given in the same matter if a suit in the same matter between the same parties was pending before a court or tribunal in Israel, an Israeli court will not enforce a foreign judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases) or if its enforcement is likely to prejudice the sovereignty or security of the State of Israel.

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

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

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

We are incorporated under Israeli law. The rights and responsibilities of holders of our ordinary shares are governed by our articles of association and the Companies Law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders in typical U.S. corporations. In particular, pursuant to the Companies Law each shareholder of an Israeli company has to act in good faith in exercising his or her rights and fulfilling his or her obligations toward the Company and other shareholders and to refrain from abusing his or her power in the Company, including, among other things, in voting at the general meeting of shareholders and class meetings, on amendments to a company's articles of association, increases in a company's authorized share capital, mergers, and transactions requiring shareholders' approval under the Companies Law. In addition, a controlling shareholder of an Israeli company or a shareholder who knows that it possesses the power to determine the outcome of a shareholder vote or who has the power to appoint or prevent the appointment of a director or officer in the Company, or has other powers toward the Company has a duty of fairness toward the Company. However, Israeli law does not define the substance of this duty of fairness. There is little case law available to assist in understanding the implications of these provisions that govern shareholder behavior.

Provisions of Israeli law and our articles of association may delay, prevent or make undesirable an acquisition of all or a significant portion of our shares or assets.

Certain provisions of Israeli law and our articles of association could have the effect of delaying or preventing a change in control and may make it more difficult for a third party to acquire us or for our shareholders to elect different individuals to our board of directors, even if doing so would be beneficial to our shareholders, and may limit the price that investors may be willing to pay in the future for our ordinary shares. For example, Israeli corporate law regulates mergers and requires that a tender offer be effected when more than a specified percentage of shares in a company are purchased. Further, Israeli tax considerations may make potential transactions undesirable to us or to some of our shareholders whose country of residence does not have a tax treaty with Israel granting tax relief to such shareholders from Israeli tax. With respect to certain mergers, Israeli tax law may impose certain restrictions on future transactions, including with respect to dispositions of shares received as consideration, for a period of two years from the date of the merger.

Furthermore, under the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Law for the Encouragement of Research and Development in Industry 5744-1984), and the regulations guidelines, rules, procedures and benefit tracks thereunder, or the Innovation Law, to which we are subject due to our receipt of grants from the Israel Innovation Authority, or IIA (formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry, or the OCS), a recipient of IIA grants such as us must report to IIA regarding any change of control or any change in the holding of its means of control of our Company which transforms any non-Israeli citizen or resident into an "interested party", as defined in the Israeli Securities Law 5728-1968, or the Israeli Securities Law, and in the latter event, the non-Israeli citizen or resident shall execute an undertaking in favor of IIA, in a form prescribed by IIA.

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

Under the Innovation Law, research and development programs that meet specified criteria and are approved by a committee of the IIA are eligible for grants. The grants awarded are typically up to 50% of the project's expenditures, as determined by the IIA committee and subject to the benefit track under which the grant was awarded. A company that receives a grant from the IIA, or a Participating Company, is typically required to pay royalties to IIA on income generated from products incorporating know-how developed using such grants (including income derived from services associated with such products), until 100% of the U.S. dollar-linked grant plus annual LIBOR interest is repaid. The rate of royalties to be paid may vary between different benefits tracks, as shall be determined by IIA. In general, the rate of royalties varies between 3% to 5% of the income generated from the IIA supported products.

The obligation to pay royalties is contingent on actual income generated from such products and services. In the absence of such income, no payment of royalties is required. It should be noted that the restrictions under the Innovation Law will continue to apply even after the repayment of such royalties in full by the Participating Company including restrictions on the sale, transfer or assignment outside of Israel of know-how developed as part of the programs under which the grants were given.

The terms of the grants under the Innovation Law also (generally) require that the products developed as part of the programs under which the grants were given be manufactured in Israel and that the know-how developed thereunder may not be transferred outside of Israel, unless prior written approval is received from the IIA (such approval is not required for the transfer of a portion of the manufacturing capacity which does not exceed, in the aggregate, 10% of the portion declared to be manufactured outside of Israel in the applications for funding (in which case only notification is required), and additional payments are required to be made to IIA, as described below. It should be noted that this does not restrict the export of products that incorporate the funded know-how.

Ordinarily, as a condition to obtaining approval to manufacture outside Israel, we may be required to pay royalties at an increased rate and up to an increased cap amount of three times the total amount of the IIA grants, plus interest accrued thereon, depending on the manufacturing volume to be performed outside Israel. The IIA approved our request to transfer 100% of the manufacturing rights of our AP-CD/LD product candidate that was developed under one of the IIA funded programs to a non-Israeli manufacturer. As a result, we will be required to pay the IIA royalties from revenue generated from the AP-CD/LD product candidate at an increased rate, and up to an increased cap amount. The IIA noted that the approval granted was exceptional and that the IIA will not approve manufacturing of additional product candidates out of Israel.

The Innovation Law restricts the ability to transfer know-how funded by IIA outside of Israel. Transfer of IIA-funded know-how outside of Israel requires prior approval and is subject to payment of a redemption fee to the IIA calculated according to a formula provided under the Innovation Law. A transfer for the purpose of the Innovation Law is generally interpreted very broadly and includes, inter alia, any actual sale of the IIA-funded know-how, any license to develop the IIA-funded know-how or the products resulting from such IIA-funded know-how or any other transaction, which, in essence, constitutes a transfer of the IIA-funded know-how. Generally, a mere license solely to market products resulting from the IIA-funded know-how would not be deemed a transfer for the purpose of the Innovation Law.

The IIA approval to transfer know-how created, in whole or in part, in connection with an IIA-funded project to a third party outside Israel where the transferring company remains an operating Israeli entity is subject to payment of a redemption fee to IIA calculated according to a formula provided under the Innovation Law that is based, in general, on the ratio between the aggregate IIA grants received by the company (including the accrued interest) and the company's aggregate investments in the project that was funded by these IIA grants, multiplied by the transaction consideration (taking into account any depreciation in accordance with a formula set forth in the in the Innovation Law) less any royalties already paid to the IIA. 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 aggregate IIA grants received by the company (including the accrued interest) and the company's aggregate research and development expenses, multiplied by the transaction consideration (taking into account any depreciation in accordance with a formula set forth in the Innovation Law) less any royalties already paid to the IIA. The Innovation Law establishes a maximum payment amount of the redemption fee paid to the IIA under the above mentioned formulas and differentiates between two situations: (i) in the event that the company sells its IIA-funded know-how, in whole or in part, or is sold as part of certain merger and acquisition transactions, and subsequently ceases to conduct business in Israel, the maximum redemption fee under the above mentioned formulas shall be no more than six times the amount received (plus accrued interest) for the applicable know-how being transferred; and (ii) in the event that following the transactions described above (i.e., asset sale of IIA-funded know-how or transfer as part of certain merger and acquisition transactions), the company continues to conduct its research activity in Israel (for at least three years following such transfer, keeps on staff at least 75% of the number of research and development employees it had for the six months before the know-how was transferred and keeps the same scope of employment of such research and development staff), then the company is eligible for a reduced cap of the redemption fee of no more than three times the amounts received (plus accrued interest) for the applicable know-how being transferred. The obligation to pay royalties mentioned above will no longer apply following the payment of the redemption fee, as described above.

Subject to prior approval of the IIA, the Company may transfer the IIA-funded know-how to another Israeli company. If the IIA-funded know-how is transferred to another Israeli entity, the transfer would still require IIA approval but will not be subject to the payment of the redemption fee (although there will be an obligation to pay royalties to the IIA from the income of such sale transaction as part of the royalty payment obligation). In such case, the acquiring company would have to assume all of the selling company's restrictions and obligations towards the IIA (including the restrictions on the transfer of know-how and manufacturing capacity outside of Israel) as a condition to IIA approval.

Our research and development efforts have been financed, partially, through grants that we have received from the IIA. We therefore must comply with the requirements of the Innovation Law and related regulations. As of December 31, 2018, we received approximately NIS 50.2 million of such grants. However, in March 2018, we repaid a portion of the grant amounts received in 2016 in the amount of approximately NIS 8.1 million (approximately $2.3 million), including interest and linkage differences, following a review and assessment by the IIA on the 2016 program. For more information see note 6c in our consolidated financial statements for the year ended December 31, 2018. The Innovation Law restricts the ability to transfer know-how funded by the IIA outside of Israel. Transfer of IIA-funded know-how outside of Israel requires the prior approval of the IIA and, under certain circumstances, is subject to significant payments to IIA (calculated according to a formula set forth under the Innovation Law), as further described above. Therefore, the discretionary approval of an IIA committee will be required for any transfer to third parties outside of Israel of rights related to our Accordion Pill, which has been developed with IIA-funding. The restrictions under the Innovation Law may impair our ability to enter into agreements which involve IIA-funded products or know-how without the approval of IIA. We cannot be certain that any approval of IIA will be obtained on terms that are acceptable to us, or at all. We may not receive the required approvals should we wish to transfer IIA-funded know-how, manufacturing and/or development outside of Israel in the future. Furthermore, in the event that we undertake a transaction involving the transfer to a non-Israeli entity of know-how developed with IIA-funding pursuant to a merger or similar transaction, the consideration available to our shareholders may be reduced by the amounts we are required to pay to IIA. Any approval, if given, will generally be subject to additional financial obligations. Failure to comply with the requirements under the Innovation Law may subject us to mandatory repayment of grants received by us (together with interest and penalties), as well as expose us to criminal proceedings. In addition, IIA may from time to time conduct royalties audits and such audits may lead to additional royalties being payable on additional products. Such grants may be terminated or reduced in the future, which would increase our costs. IIA approval is not required for the marketing of products resulting from the IIA-funded research or development in the ordinary course of business.

Item 1B. Unresolved Staff Comments.

We do not have any unresolved comments issued by the SEC staff.

Item 2. Properties

Our principal executive offices are located in Har Hotzvim at 12 Hartom Street, Jerusalem, Israel 9777512. The space is in a commercial office building and houses our office space of approximately 900 square meters, manufacturing facility for our clinical trials of approximately 1,070 square meters, which includes production, packaging, warehousing and logistics areas, and our laboratory facilities of approximately 200 square meters.

The manufacturing and laboratory facilities are fully equipped for manufacturing and testing of the required quantities for Phase III clinical trials, including, mixers, casting equipment, laminating equipment, capsulating equipment and analytical equipment such as High Pressure/Performance Liquid Chromatography and dissolution testers. These facilities are cGMP compliant and approved by Israeli and European regulatory authorities and qualified for Phase III manufacturing.

We lease this space, which presently consists of a total area of approximately 2,170 square meters, from an unaffiliated third party, pursuant to a lease agreement which, as amended, expires June 30, 2021. We also lease four standard size offices, three offices in Modi'in, Israel and an office in New York City for our U.S. subsidiary, Intec Pharma Inc. Pursuant to the leases our annual rental costs for 2018 were approximately $688,000 (excluding VAT). Our expected rental costs for 2019 are approximately $700,000 (excluding VAT).

Although we will continue to produce product candidates ourselves for use in clinical trials, with respect to the future commercialization of the AP-CD/LD, we have decided to rely on third-party manufacturers and in 2018, we entered into a series of agreements with LTS for the manufacture of AP-CD/LD. See "*Item 1. Business— Manufacturing*."

Item 3. Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. There are currently no pending material legal proceedings, and we are currently not aware of any legal proceedings or claims against us or our property that we believe will have any significant effect on our business, financial position or operating results. None of our officers or directors is a party against us in any legal proceeding.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our ordinary shares have been listed on the Nasdaq Capital Market under the symbol "NTEC" since August 2015. Prior to that date, there was no public trading market for our ordinary shares in the United States.

Holders

As of February 22, 2019, we had two record holders of our ordinary shares. This number does not include the number of persons whose shares are in nominee or in "street name" accounts through brokers.

Dividend Policy

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

Under the Companies Law, we may declare and pay dividends only if, upon the determination of our board of directors, there is no reasonable concern that the distribution will prevent us from being able to meet the terms of our existing and foreseeable obligations as they become due. Under the Companies Law, the distribution amount is further limited to the greater of retained earnings or earnings generated over the two most recent years legally available for distribution according to our then last reviewed or audited consolidated financial statements, provided that the date of the consolidated financial statements is not more than six months prior to the date of distribution. In the event that we do not have retained earnings or earnings generated over the two most recent years legally available for distribution, we may seek the approval of the court in order to distribute a dividend. The court may approve our request if it is convinced that there is no reasonable concern that the payment of a dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to "Item 11. Executive Compensation", of this Annual Report.

Recent Sales of Unregistered Securities

None.

Item 6. Selected Financial Data.

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion along with our consolidated financial statements and the related notes included in this Annual Report. The following discussion contains forward-looking statements that are subject to risks, uncertainties and assumptions, including those discussed under "Risk Factors." Our actual results, performance and achievements may differ materially from those expressed in, or implied by, these forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements." We have prepared our consolidated financial statements in accordance with U.S. GAAP.

Overview

We are a clinical stage biopharmaceutical company focused on developing drugs based on our proprietary Accordion Pill platform technology, which we refer to as the Accordion Pill. Our Accordion Pill is an oral drug delivery system that is designed to improve the efficacy and safety of existing drugs and drugs in development by utilizing an efficient GR and specific release mechanism. Our product pipeline currently includes several product candidates in various clinical trial stages. Our leading product candidate, AP-CD/LD, is being developed for the indication of treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients. We have successfully completed a Phase II clinical trial for AP-CD/LD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients and have agreed with the FDA on the remaining clinical development program for AP-CD/LD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, including the main principles of the single required pivotal Phase III clinical trial in advanced Parkinson's disease patients.

We are currently conducting a pivotal Phase III clinical for AP-CD/LD for the treatment of advanced Parkinson's disease known as the ACCORDANCE study. In April 2016, we enrolled the first patient in the ACCORDANCE study and in October 2018, we completed enrollment. We currently expect to release top-line results in mid-2019. In our correspondence with the FDA, the FDA previously agreed that an acceptable regulatory pathway for AP-CD/LD would be to submit a new drug application, or NDA, pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA which is a streamlined approval pathway that may accelerate the time to commercialize and decrease the costs of FDA approval for AP–CD/LD, as compared to those typically associated with an NCE.

In February 2019, we announced that AP-CD/LD met the primary endpoint in a pharmacokinetic, or PK, study comparing the AP-CD/LD 50/500mg dosed three times daily, the most common dose used in our on-going ACCORDANCE study, to 1.5 tablets of CD/LD immediate release (Sinemet™) 25/100 dosed five times per day in Parkinson's disease patients.

We have invested in the commercial scale manufacture of AP-CD/LD, for which we are in partnership with LTS Lohmann Therapie-Systeme AG, or LTS. In December 2018, the large commercial scale production line was delivered to LTS in Andernach, Germany. We are in the process of installing and connecting all the ancillary equipment and expect to begin the validation, bioequivalency and stability studies needed for approval of our commercial production processes in the coming months. After preliminary discussions with the FDA in anticipation of filing for marketing approval of AP-CD/LD, we remain confident we are on track to submit a NDA for approval of AP-CD/LD in mid- to late-2020, assuming positive topline data in the Accordance Study in mid-2019.

In addition, we have initiated a clinical development program for our Accordion Pill platform with the two primary cannabinoids contained in cannabis sativa, which we refer to as AP-Cannabinoids. We are formulating and testing CBD and THC for the treatment of various pain indications. AP-Cannabinoids are designed to extend the absorption phase of CBD and THC, with the goal of more consistent levels for an improved therapeutic effect, which may address several major drawbacks of current methods of treatment, such as short duration of effect, delayed onset, variability of exposure, variability of the administered dose and adverse events that correlate with peak levels. In March 2017, we initiated a Phase I single-center, single-dose, randomized, three-way crossover clinical trial in Israel to compare the safety, tolerability and PK of AP-THC/CBD with Sativex®, an oral buccal spray containing CBD and THC that is commercially available outside of the United States. Initial results demonstrate that the Accordion Pill platform is well suited to safely deliver CBD and THC with significant improvements in exposure compared with Sativex®. In December 2018, we initiated a PK study of AP-THC. We have completed the dosing of the AP-THC PK study and the data is in the process of being analyzed by a third party contract research organization per protocol. However, upon raw data review, the delivery of THC does not appear to meet our full program expectations. We await the full dataset and the statistical analysis to determine our next steps.

In December 2018, we reported that we successfully developed an Accordion Pill for a Novartis proprietary compound that met the required in vitro specifications set forth in a feasibility agreement with Novartis. We have mutually agreed to proceed with the program and plan to enter the clinic with a first-in-human PK study in the first half of 2019. We believe continued success with this program further validates the platform, confirms our technical abilities to build custom APs and paves the way for additional collaborative agreements.

For further information regarding our business and operations, see "Item 1. Business."

Transition to U.S. GAAP

As of June 30, 2018, we no longer met the requirements to qualify as a foreign private issuer under the Exchange Act. As a result, we began reporting as a domestic issuer as of January 1, 2019 and we are now required under current SEC rules to prepare our financial statements in accordance with U.S. GAAP, rather than IFRS. The transition from consolidated financial statements under IFRS to U.S. GAAP had a non-material impact on our consolidated financial statements.

History of Losses

Since our inception, we have generated significant losses in connection with our research and development, including the clinical development of AP-CD/LD. As of December 31, 2018, we had an accumulated deficit of $141.8 million. We expect that additional losses will be accumulated in the near future as a result of our research and development activities. Such research and development activities will require further resources if we are to be successful. As a result, we will continue to incur operating losses, and we will need to obtain additional funds to further develop our research and development programs and our product candidates.

Because of, among other things, our research and development activities, as well as the fact that we have not generated revenues since our inception, for the year ended December 31, 2018, our net loss was approximately $43.5 million.

We have funded our operations primarily through the sale of equity securities (both in private placements and in public offerings on the Nasdaq Capital Market and the Tel Aviv Stock Exchange as described above), funding received from the IIA and other funds, and reimbursements received pursuant to collaborations with multinational pharmaceutical companies in connection with certain research and development activities. Since our inception, we have raised approximately $195.6 million in various investment rounds, private placements, an initial public offering in Israel in February 2010, various rights issuances, an initial public offering on the Nasdaq Capital Market in August 2015 and follow-on public offerings on the Nasdaq Capital Market in August 2017 and April 2018. We received approximately $34 million and $95 million from our initial U.S. public offering and U.S. follow-on public offerings on the Nasdaq Capital Market, respectively. As of December 31, 2018, we had approximately $40.6 million of cash, cash equivalents and marketable securities.

Operating Expenses

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

Research and Development Expenses

Our research and development expenses during the year ended December 31, 2017 and 2018 relate primarily to the development of AP–CD/LD. We record expenses for each product candidate on a direct cost basis only, rather than on a project basis. Direct costs, which include contract research organization expenses, clinical trials and pre-clinical trials, expenses related to the establishment of the commercial scale production capabilities for AP-CD/LD, consulting expenses, APIs, and other similar expenses are recorded to the product candidate for which such expenses are incurred. However, salaries and related personnel expenses, indirect materials and costs for facilities and equipment are considered overhead, are shared among all of our product candidates, and are not recorded on a product-by-product basis. Our direct costs related to product candidates other than AP–CD/LD for 2017 and 2018 were insignificant. We expect our research and development expense to remain our primary expense in the near future as we continue to develop our products. Increases or decreases in research and development expenditures are primarily attributable to the number and/or duration of the clinical studies that we conduct.

We expect that a large percentage of our research and development expense in the future will be incurred in support of our current and future clinical development projects. Due to the inherently unpredictable nature of clinical development processes, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to conduct additional clinical trials for our product candidates.

While we are currently focused on advancing our product development, our future research and development expenses will depend on the clinical success of our product candidates, as well as ongoing assessments of the candidates' commercial potential. As we obtain results from clinical studies, we may elect to discontinue or delay clinical studies for one or more of our product candidates in certain indications in order to focus our resources on more promising product candidates. Completion of clinical studies may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate.

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

Under applicable accounting rules, we deduct from research and development expenses grants and other participation in research and development expenses as incurred.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and expenses related to employee benefits, including share-based compensation, for our general and administrative employees, which includes employees in executive and operational roles, including finance and human resources, as well as consulting, legal and professional services related to our general and administrative operations.

Financial Expense and Income

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

Income Tax

During 2018, the standard corporate tax rate in Israel was 23%, and during 2017 it was 24%. During 2018, the U.S. statutory tax rate was 21%, and during 2017, it was 35%.

We have not yet generated taxable income in Israel. We have historically incurred operating losses resulting in carry forward tax losses totaling approximately $107.6 million as of December 31, 2018. We anticipate that we will continue to generate tax losses for the foreseeable future and that we will be able to carry forward these tax losses indefinitely to future taxable years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses. We have provided a full valuation allowance with respect to the deferred tax assets related to these carry forward losses.

During 2018 and 2017, we incurred tax expenses of $103,000 and $29,000, respectively, in our U.S. subsidiary.

Results of Operations

The table below provides our results of operations for the periods indicated.

	Year ended December 31	
	2018	2017
	(dollars in thousands)	
Research and development expenses, net	$ (35,402)	$ (24,295)
General and administrative expenses	(7,926)	(5,144)
Operating loss	(43,328)	(29,439)
Financial income (expenses), net	(112)	559
Loss before income tax	(43,440)	(28,880)
Income tax	(103)	(29)
Net loss	$ (43,543)	$ (28,909)

Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

Research and Development Expenses, Net

Our research and development expenses, net, for the year ended December 31, 2018 amounted to approximately $35.4 million, an increase of $11.1 million, or approximately 46%, compared to approximately $24.3 million for the year ended December 31, 2017. The increase was primarily due to an increase in expenses related to the progression of our ACCORDANCE study and OLE study, expenses related to the establishment of the commercial scale production capabilities for AP-CD/LD at LTS, share based compensation and payroll and related expenses, mostly due to an increase in headcount. This increase was offset by a decrease in expenses related to the repayment to the IIA, which were recorded in 2017.

General and Administrative Expenses

Our general and administrative expenses for the year ended December 31, 2018 amounted to approximately $7.9 million, an increase of $2.8 million, or approximately 55%, compared to approximately $5.1 million for the year ended December 31, 2017. The increase was primarily related to the increase in share-based compensation and payroll and related expenses primarily related to the hiring of executives in the United States since the fourth quarter of 2017, professional services and expenses related to investor relations activities.

Operating Loss

Because of the foregoing, for the year ended December 31, 2018 our operating loss was approximately $43.3 million, an increase of $13.9 million, or approximately 47%, compared to our operating loss for the year ended December 31, 2017 of approximately $29.4 million. The increase was mainly due to an increase in research and development expenses and general and administrative expenses, as detailed above.

Financial Income (expenses), Net

For the year ended December 31, 2018, we had financial expenses from foreign currency exchange expenses in the amount of approximately $747,000, change in fair value of marketable securities in NIS currency, in the amount of approximately $194,000 (including foreign currency exchange expenses in the amount of approximately $120,000) and bank fees, offset by financial income from interest on cash and cash equivalents in the amount of approximately $852,000. For the year ended December 31, 2017, we had financial income from interest on cash equivalents and bank deposits in the amount of approximately $286,000, change in fair value of marketable securities in NIS currency, in the amount of approximately $220,000 (including foreign currency exchange income in the amount of approximately $192,000) and foreign currency exchange income in the amount of approximately $70,000 offset by bank fees.

Income tax

During 2018 and 2017, we have not generated taxable income in Israel. However, in 2018 and 2017 we incurred tax expenses in our U.S. subsidiary in the amount of $103,000 and $29,000, respectively. The increase was primarily due to an increase in the subsidiary's operations that was incorporated in September 2017.

Net Loss

Because of the foregoing, for the year ended December 31, 2018 our loss and comprehensive loss was approximately $43.5 million, an increase of $14.6 million, or approximately 51%, compared to our loss and comprehensive loss for the year ended December 31, 2017 of approximately $28.9 million. The increase was mainly due to an increase in research and development expenses and general and administrative expenses, as detailed above.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through public and private offerings (in Israel and in the U.S.) of our equity securities, grants from the IIA and other grants from organizations such as the Michael J. Fox Foundation, and payments received under the feasibility and related agreements we have entered into with multinational pharmaceutical companies, pursuant to which we are entitled to full coverage of our development costs with regard to the projects specified in those agreements.

As of December 31, 2018, we had cash and cash equivalents and marketable securities of approximately $40.6 million. As of December 31, 2017, we had cash and cash equivalents and marketable securities of approximately $55.2 million.

Net cash used in operating activities was approximately $39.1 million for the year ended December 31, 2018 compared with net cash used in operating activities of approximately $22.1 million for the year ended December 31, 2017. This increase resulted from an increase in our net loss of approximately $14.6 million and changes in operating asset and liability items of approximately $5.8 million, which were offset by an increase in expenses not involving cash flows of approximately $3.4 million.

We had negative cash flow from investing activities of approximately $9.3 million for the year ended December 31, 2018 compared to negative cash flow from investing activities of approximately $4.7 million for the year ended December 31, 2017. This increase resulted primarily from investment in other assets related to Production Equipment in the amount of approximately $4.9 million. For more information, see note 6(f) in our consolidated financial statements for the year ended December 31, 2018. This was offset by a decrease in purchase of property and equipment in the amount of approximately $334,000.

Net cash provided by financing activities was approximately $35.1 for the year ended December 31, 2018 compared with net cash provided in financing activities of approximately $63.7 million for the year ended December 31, 2017. The principal source of the cash provided by financing activities during 2018 was the funds received from our April 2018 underwritten public offering of ordinary shares that resulted in net proceeds of approximately $35.0 million. The principal source of the cash provided by financing activities during 2017, was the funds received from our March 2017 private placement of ordinary shares that resulted in net proceeds of approximately $9.5 million and an underwritten public offering of ordinary shares in August 2017 that resulted in net proceeds of approximately $53.6 million.

Current Outlook

We estimate that our current cash resources will allow us to complete our Phase III clinical trial for AP-CD/LD. We believe however, that further fund raising will be required in order to complete the research and development of all of our product candidates, including the manufacturing activities of the AP-CD/LD. As a result, there is substantial doubt about our ability to continue as a going concern within one year after the date our accompanying consolidated financial statements are issued. We expect to satisfy our future cash needs through submissions of applications for grants from private funds, license agreements with third parties and capital raising from the public, private investors and institutional investors, such as through the public offering of ordinary shares that we completed in April 2018. We may also engage with a partner in order to share the costs associated with the development and manufacturing of our product candidates. For more information, see note 1(2) in our consolidated financial statements for the year ended December 31, 2018.

Developing drugs, conducting clinical trials, obtaining commercial manufacturing capabilities and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. We will require significant additional financing in the future to fund our operations, including if and when we progress into additional clinical trials of our product candidates, obtain regulatory approval for one or more of our product candidates, obtain commercial manufacturing capabilities and commercialize one or more of our product candidates. Our future capital requirements will depend on many factors, including, but not limited to:

- the progress and costs of our clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues and contributions we receive under future licensing, collaboration, development and commercialization arrangements with respect to our product candidates;
- the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval for one or more of our product candidates;
- the ability of us, or our collaborators, to achieve development milestones, marketing approval and other events or developments under our potential future licensing agreements;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;

- the costs of contracting with third parties to provide sales and marketing capabilities for us or establishing such capabilities ourselves;
- the costs of acquiring or undertaking development and commercialization efforts for any future products, product candidates or technology;
- the magnitude of our general and administrative expenses; and
- any cost that we may incur under future in- and out-licensing arrangements relating to one or more of our product candidates.

Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through capital raising or by out-licensing applications of one or more of our product candidates. 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, one or more of our product candidates and make necessary change to our operations to reduce the level of our expenditures in line with available resources.

Contractual Obligations

Our significant contractual obligations as of December 31, 2018 included the following:

	Total	Less than 1 Year	1 – 3 Years	3 – 5 Years	More than 5 Years
Operating Lease Obligations in thousands of $ (payments due by June 30, 2021)	$ 1,825	$ 772	$ 1,053	—	—

(1) Operating lease obligations consist of lease of our facilities and lease of vehicles.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have had or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

Trend Information

We are a development stage company and it is not possible for us to predict with any degree of accuracy the outcome of our research and development efforts. As such, it is not possible for us to predict with any degree of accuracy any significant trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on our net loss, liquidity or capital resources, or that would cause financial information to not necessarily be indicative of future operating results or financial condition. However, to the extent possible, certain trends, uncertainties, demands, commitments and events are in this "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

Critical Accounting Policies

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates that affect the reported amounts of our assets, liabilities and expenses. Significant accounting policies employed by us, including the use of estimates, are presented in the notes to the consolidated financial statements included elsewhere in this Annual Report. We periodically evaluate our estimates, which are based on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Critical accounting policies are those that are most important to the portrayal of our financial condition and results of operations and require our subjective or complex judgments, resulting in the need to make estimates about the effect of matters that are inherently uncertain. If actual performance should differ from historical experience or if the underlying assumptions were to change, our financial condition and results of operations may be materially impacted.

Share-based payments

The fair value of equity-based payment transactions is recognized as an expense over the requisite service period and computed using the Black-Scholes model. We recognize compensation costs for awards conditioned only on continued service and which have a graded vesting schedule using the straight-line method based on the multiple-option award approach. Performance based awards are expensed over the vesting period when the achievement of performance criteria is probable. When options are granted as consideration for services provided by consultants and other non-employees, the grant is accounted for based on the fair value of the consideration received or the fair value of the options issued, whichever is more reliably measurable. The fair value of the options granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

Jumpstart Our Business Startups Act of 2012

We are an emerging growth company within the meaning of the rules under the Securities Act, and we will utilize certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies. Such exemptions include, but are not limited to, (i) not being required to comply with the auditor attestation requirements of Section 404, (ii) being exempt from adoption of new or revised financial accounting standards until they would apply to private companies, (iii) being exempt from compliance with any new requirements adopted by the PCAOB requiring mandatory audit firm rotation or a supplement to the auditor's report in which the auditor would be required to provide additional information about our audit and our consolidated financial statements and (iv) reduced disclosure obligations regarding executive compensation. We could remain an "emerging growth company" for up to five years from the date of our first sale of common equity securities pursuant to an effective registration statement under the Securities Act, or until the earliest of (a) the last day of the first fiscal year in which our annual gross revenue exceeds $1.07 billion (as such amount is indexed for inflation every five years by the SEC to reflect the change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics) or more, (b) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our ordinary shares that is held by non-affiliates exceeds $700.0 million as of the last business day of our most recently completed second fiscal quarter, or (c) the date on which we have issued more than $1.0 billion in nonconvertible debt during the preceding three year period.

The JOBS Act also permits us, as an "emerging growth company," to take advantage of an extended transition period to comply with certain new or revised accounting standards if such standards apply to companies that are not issuers. We chose to "opt out" of this provision and, as a result, we comply with new or revised accounting standards when they are required to be adopted by issuers. This decision to opt out of the extended transition period under the JOBS Act was irrevocable.

Government Policies and Factors

We believe certain governmental policies and factors could materially affect, directly or indirectly, our operations or your investment. Please see "Item 1A. Risk Factors — Risks Related to Our Business Strategy and Operations" and "Item 1A. Risk Factors — Clinical Development, Manufacturing and Regulatory Approval of Our Product Candidates".

Recently Issued Accounting Pronouncements

Certain recently issued accounting pronouncements are discussed in Note 2, Summary of Significant Accounting Policies, to the consolidated financial statements included in "Item 8. Financial Statements and Supplementary Data" of this Annual Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

INTEC PHARMA LTD.
CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the board of directors and shareholders of Intec Pharma Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Intec Pharma Ltd. and its subsidiary (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, changes in shareholders' equity and cash flows for each of the two years in the period ended December 31, 2018**,** including 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 financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About 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 1(2) to the consolidated financial statements, the Company has suffered recurring losses from operations and cash outflows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1(2). The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 of these consolidated financial statements 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Kesselman & Kesselman
Certified Public Accountants (lsr.)
A member firm of PricewaterhouseCoopers International Limited
Tel-Aviv, Israel
February 26, 2019

We have served as the Company's auditor since 2006.

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel,
P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il

INTEC PHARMA LTD.
CONSOLIDATED BALANCE SHEETS

	December 31	
	2018	2017
	U.S. dollars in thousands	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 39,246	$ 53,393
Investment in marketable securities (Note 3)	1,333	1,825
Prepaid expenses and other receivables (Note 8a)	2,986	1,125
TOTAL CURRENT ASSETS	43,565	56,343
NON-CURRENT ASSETS:		
Other assets (Note 6f)	5,431	-
Property and equipment, net (Note 4)	12,233	8,206
Deferred tax assets (Note 9)	281	-
TOTAL NON-CURRENT ASSETS	17,945	8,206
TOTAL ASSETS	$ 61,510	$ 64,549
Liabilities and shareholders' equity		
CURRENT LIABILITIES -		
Accounts payable and accruals:		
Trade	$ 2,849	$ 1,854
Other (Note 8b)	4,807	3,893
TOTAL CURRENT LIABILITIES	7,656	5,747
LONG-TERM LIABILITIES -		
Other liabilities (Note 9)	309	-
TOTAL LIABILITIES	7,965	5,747
COMMITMENTS AND CONTINGENT LIABILITIES (Note 6)		
SHAREHOLDERS' EQUITY:		
Ordinary shares, with no par value - authorized: 100,000,000 and 50,000,000 Ordinary Shares as of December 31, 2018 and December 31, 2017, respectively; issued and outstanding: 33,232,988 and 26,075,770 Ordinary Shares as of December 31, 2018 and December 31, 2017, respectively	727	727
Additional paid-in capital	194,642	156,356
Accumulated deficit	(141,824)	(98,281)
TOTAL SHAREHOLDERS' EQUITY	53,545	58,802
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 61,510	$ 64,549

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

INTEC PHARMA LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31	
	2018	2017
	U.S. dollars in thousands	
OPERATING EXPENSES:		
RESEARCH AND DEVELOPMENT EXPENSES, net	$ (35,402)	$ (24,295)
GENERAL AND ADMINISTRATIVE EXPENSES	(7,926)	(5,144)
OPERATING LOSS	(43,328)	(29,439)
FINANCIAL INCOME (EXPENSES), net (Note 8c)	(112)	559
LOSS BEFORE INCOME TAX	(43,440)	(28,880)
INCOME TAX (Note 9)	(103)	(29)
NET LOSS	$ (43,543)	$ (28,909)
LOSS PER SHARE BASIC AND DILUTED	$ (1.40)	$ (1.64)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE IN THOUSANDS	31,193	17,660

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

INTEC PHARMA LTD.

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

	Ordinary Shares		Additional paid-in capital	Accumulated Deficit	Total
	Number of shares	Amounts	Amounts		
	U.S. dollars in thousands				
BALANCE AT JANUARY 1, 2017	11,448,191	$ 727	$ 91,446	(69,372)	$ 22,801
CHANGES DURING 2017:					
Issuance of ordinary shares, net of issuance costs (Note 7b)	14,514,138	-	63,131	-	63,131
Exercise of warrants (Note 7c)	102,058	-	531	-	531
Exercise of options by employees (Note 7d)	11,383	-	45	-	45
Share-based compensation (Note 7d)	-	-	1,203	-	1,203
Net loss	-	-	-	(28,909)	(28,909)
BALANCE AT DECEMBER 31, 2017	26,075,770	$ 727	$ 156,356	$ (98,281)	$ 58,802
CHANGES DURING 2018:					
Issuance of ordinary shares, net of issuance costs (Note 7b)	7,150,000	-	35,029	-	35,029
Exercise of options by employees (Note 7d)	7,218	-	30	-	30
Share-based compensation (Note 7d)	-	-	3,227	-	3,227
Net loss	-	-	-	(43,543)	(43,543)
BALANCE AT DECEMBER 31, 2018	33,232,988	$ 727	$ 194,642	$ (141,824)	53,545

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

INTEC PHARMA LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31	
	2018	2017
	U.S. dollars in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (43,543)	$ (28,909)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	859	829
Exchange differences on cash and cash equivalents	829	(127)
Losses (gains) on marketable securities	194	(220)
Loss from sale of property and equipment	-	2
Share-based compensation	3,227	1,203
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses and other receivables	(1,861)	1,259
Increase in deferred tax assets	(281)	-
Increase in accounts payable and accruals	1,191	3,831
Increase in other liabilities	309	-
Net cash used in operating activities	(39,076)	(22,132)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(4,667)	(5,001)
Investment in other assets	(4,932)	-
Proceeds from disposal of marketable securities, net	298	247
Proceeds from sale of property and equipment	-	7
Net cash used in investing activities	(9,301)	(4,747)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of ordinary shares, net of issuance costs	35,029	63,131
Proceeds from exercise of warrants	-	531
Proceeds from exercise of options by employees	30	45
Net cash provided by financing activities	35,059	63,707
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(13,318)	36,828
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR	53,393	16,438
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(829)	127
CASH AND CASH EQUIVALENTS AT END OF THE YEAR	$ 39,246	$ 53,393
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING ACTIVITIES:		
Liability with respect to property and equipment (see note 6e)	170	-
Liability with respect to other assets (see note 6f)	499	-
SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION:		
Taxes paid	96	-
Interest received	734	244

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

NOTE 1 - NATURE OF OPERATIONS:

General Information:

1) Intec Pharma Ltd. ("Intec") is engaged in the development of proprietary technology which enables the gastric retention of certain drugs. The technology is intended to significantly improve the efficiency of the drugs and substantially reduce their side-effects or the effective doses.

   Intec is a limited liability public company incorporated in Israel.

   Intec's ordinary shares are traded on the NASDAQ Capital Market ("NASDAQ"). Intec's ordinary shares were delisted from the Tel-Aviv Stock Exchange in August 2018.

   In September 2017, Intec incorporated a wholly-owned subsidiary in the United States of America in the State of Delaware – Intec Pharma Inc. (the "Subsidiary"). The Subsidiary was incorporated mainly to provide Intec executive and management services, including business development, medical affairs and investor relationship activities outside of Israel.

2) Intec together with its Subsidiary (the "Company") engage in research and development activities and as a group have not yet generated revenues from their operations. Accordingly, there is no assurance that the Company's operations will generate positive cash flows. As of December 31, 2018, the cumulative losses of the Company were approximately $141.8 million. Management expects that the Company will continue to incur losses from its operations, which will result in negative cash flows from operating activities. The Company's management estimates that its current cash resources will allow the Company to complete its Phase III clinical trial for AP-CD/LD. However, management estimates that further fund raising will be required in order for the Company to complete the research and development of all of its product candidates including the manufacturing activities of the AP-CD/LD. As a result, there is substantial doubt about the Company's ability to continue as a going concern within one year after the issuance date of these financial statements.

   The Company plans to fund its future operations through submissions of applications for grants from private funds, license agreements with third parties and raising capital from the public and/or private investors and/or institutional investors. There is no assurance, however, that the Company will be successful in obtaining the level of financing needed for its operations and the research and development of its product candidates. If the Company is unsuccessful in securing sufficient financing, it may need to make the necessary changes to its operations to reduce the level of expenditures in line with available resources.

   These financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

3) On April 13, 2018, the Company completed an underwritten public offering of its ordinary shares. The Company raised, together with the exercise of part of the underwriting over-allotment option, a total of approximately $35.0 million, net of underwriting discounts, commissions and other offering expenses. For details see note 7b(4).

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES:

a. Basis of presentation

The Company's financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ('U.S. GAAP').

Prior to 2018, the Company prepared its financial statements in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"), as permitted in the United States ("U.S.") based on the Company's status as a foreign private issuer as defined by the U.S. Securities and Exchange Commission (the "SEC"). During 2018, the Company determined that it is no longer qualified as a foreign private issuer under the SEC rules. As a result, as of January 1, 2019, the Company is required to comply with all of the disclosure and reporting requirements applicable to U.S. domestic issuers.

b. Principles of consolidation

The consolidated financial statements include the accounts of Intec and its Subsidiary. Intercompany balances and transactions have been eliminated upon consolidation.

c. Use of estimates in the preparation of financial statements

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results may differ from those estimates. As applicable to these financial statements, the most significant estimates and assumptions relate to the fair value of share-based compensation.

d. Functional and presentation currency

The U.S. dollar ("dollar") is the currency of the primary economic environment in which the operations of Intec and the Subsidiary are conducted. Almost all of the Company's operational expenses are in dollars and the Company's financings have been provided in dollars. Accordingly, the functional currency of the Company is the dollar.

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in non-dollar currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For non-dollar transactions and other items in the statements of operations (indicated below), the following exchange rates are used: (i) for transactions — exchange rates at transaction dates or average rates; and (ii) for other items (derived from non-monetary balance sheet items such as depreciation) — historical exchange rates. Currency transaction gains and losses are presented in financial income or expenses, as appropriate.

e. Cash and cash equivalents

The Company considers as cash equivalents all short-term, highly liquid investments, which include short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

f. Marketable securities

The Company's marketable securities include bonds issued by the State of Israel and corporate bonds with a minimum of A rating by global rating agencies. These assets are recoded at fair value with changes recorded in the statement of operations as "financial income**,** net", as the Company choose to apply the fair value option.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

g. Property and equipment

1) Property and equipment are stated at cost, net of accumulated depreciation.

2) The Company's property and equipment are depreciated by the straight-line method on the basis of their estimated useful lives.

Annual rates of depreciation are as follows:

	%
Computers and peripheral equipment	33
Production and laboratory equipment	10-14
Office furniture and equipment	7-10

Leasehold improvements are depreciated by the straight-line method over the shorter of the expected lease term and the estimated useful life of the improvements.

h. Impairment of long-lived assets

The Company tests long-lived assets, comprised of property and equipment and other assets, for impairment whenever events or circumstances present an indication of impairment. If the sum of expected future cash flows (undiscounted and without interest charges) of the assets is less than the carrying amount of such assets, an impairment loss would be recognized. The assets would be written down to their estimated fair values, calculated based on the present value of expected future cash flows (discounted cash flows), or some other fair value measure.

As of December 31, 2018, and 2017, the Company did not recognize an impairment loss for its long-lived assets.

i. Share-based compensation

The Company accounts for employees' and directors' share-based payment awards classified as equity awards using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period.

The Company elected to recognize compensation costs for awards conditioned only on continued service that have a graded vesting schedule using the accelerated method based on the multiple-option award approach. Performance based awards are expensed over the vesting period when the achievement of performance criteria is probable.

When options are granted as consideration for services provided by consultants and other non-employees, the grant is accounted for based on the fair value of the consideration received or the fair value of the options issued, whichever is more reliably measurable. The fair value of the options granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

The Company has elected to recognize forfeitures as they occur.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

j. Research and development expenses, net

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, share-based compensation expenses, payroll taxes and other employee benefits, subcontractors and materials used for research and development activities, including clinical trials, manufacturing costs and professional services. All costs associated with research and developments are expensed as incurred.

Grants received from Israel Innovation Authority, formerly known as the Office of the Chief Scientist of Israel's Ministry of Industry, Trade and Labor (the "IIA"), were recognized when the grant becomes receivable, provided there was reasonable assurance that the Company will comply with the conditions attached to the grant and there was reasonable assurance the grant will be received. The grant is deducted from the research and development expenses as the applicable costs are incurred, see note 6c.

Research and development expenses, net for the years ended December 31, 2018 and 2017, include participation in research and development expenses in the amount of approximately $829 thousand and approximately $88 thousand, respectively.

Clinical trial expenses are charged to research and development expense as incurred. The Company accrue for expenses resulting from obligations under contracts with clinical research organizations (CROs). The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided. The Company's objective is to reflect the appropriate trial expense in the consolidated financial statements by matching the appropriate expenses with the period in which services and efforts are expended. In the event advance payments are made to a CRO, the payments are recorded as other assets, which will be recognized as expenses as services are rendered.

k. Income taxes

1) Deferred taxes

Income taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future.

2) Uncertainty in income taxes

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the available evidence indicates that it is more likely than not that the position will be sustained based on technical merits. If this threshold is met, the second step is to measure the tax position as the largest amount that has more than a 50% likelihood of being realized upon ultimate settlement.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

l. Loss per share

Loss per share, basic and diluted, is computed on the basis of the net loss for the year divided by the weighted average number of ordinary shares outstanding during the year. Diluted loss per share is based upon the weighted average number of ordinary shares and of ordinary shares equivalents outstanding when dilutive. Ordinary share equivalents include outstanding stock options and warrants which are included under the treasury stock method when dilutive.

The following share options and warrants were excluded from the calculation of diluted loss per ordinary share because their effect would have been anti-dilutive for the years presented (share data):

	December 31,	
	2018	**2017**
Outstanding stock options	3,441,670	2,229,870
Warrants	-	198,812

m. Fair value measurement

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

The marketable securities which are measures at fair value are categorized as Level 1.

The carrying amount of the cash and cash equivalents, other receivable and accrued expenses and other liabilities approximates their fair value.

n. Concentration of credit risks

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash and cash equivalents, marketable securities and certain receivables. The Company deposits cash and cash equivalents with highly rated financial institutions (Israeli banks). In addition, all marketable securities carry a high rating or are government insured. The Company has not experienced any material credit losses in these accounts and does not believe it is exposed to significant credit risk on these instruments.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

o. Newly issued accounting pronouncements

1) In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This ASU will require the recognition of lease assets and liabilities for operating leases with terms of more than 12 months. Presentation of leases within the consolidated statements of operations and cash flows will be substantially consistent with current accounting guidance. The ASU, which is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods, will have a material impact on our consolidated balance sheets. We plan to adopt the ASU effective January 1, 2019 using the modified retrospective transition method and will not restate comparative periods. The modified retrospective transition method requires the cumulative effect, if any, of initially applying the guidance to be recognized as an adjustment to our accumulated deficit as of that adoption date. We plan to elect the package of practical expedients permitted under the transition guidance within the ASU, which allows us to carry forward prior conclusions about lease identification, classification and initial direct costs for leases entered into prior to adoption of Topic 842. Additionally, we plan to not separate lease and non-lease components for all of our leases. For leases with a term of 12 months or less, we plan to elect the short-term lease exemption, which allows us to not recognize right-of-use assets or lease liabilities for qualifying leases existing at transition and new leases we may enter into in the future. While we continue to assess all impacts of adoption, we currently expect to recognize additional lease liabilities of $2.2 million representing the present value of the remaining lease payments at January 1, 2019 and corresponding right-of-use assets of the same amount. See note 6d, Commitments and Contingencies, for information about our lease commitments.

2) In June 2018, the FASB issued ASU 2018-07, "Compensation-Stock Compensation" ("Topic 718" or "ASU 2018-07") to improve the usefulness of information provided to users of financial statements while reducing cost and complexity in financial reporting and provide guidance aligning the measurement and classification for share-based payments to nonemployees with the guidance for share-based payments to employees. Under the guidance, the measurement of equity-classified nonemployee awards will be fixed at the grant date. This standard is effective for fiscal years beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The standard is effective for accounting periods beginning on or after January 1, 2019. The Company believes that the adoption of ASU 2018-07 is not expected to have a material impact on its consolidated financial statements.

NOTE 3 - MARKETABLE SECURITIES:

The Company's marketable securities include bonds issued by the State of Israel and corporate bonds with a minimum of A rating by global rating agencies. These assets are recoded as fair value with changes recorded in the statement of operations as "financial income, net", as the Company choose to apply the fair value option.

As of December 31, 2018, and 2017, the amount of the marketable securities is approximately $1.3 million and $1.8 million, respectively.

The loss, net from changes in marketable securities amounted to approximately $194 thousand in 2018 and the gain, net from changes in marketable securities amounted to approximately $220 thousand in 2017.

NOTE 4 - PROPERTY AND EQUIPMENT, NET:

	December 31	
	2018	2017
	U.S. dollars in thousands	
Cost:		
Computers and communications equipment	$ 237	$ 181
Production and laboratory equipment	7,280	7,121
Office furniture and equipment	203	167
Leasehold improvements	2,029	1,839
Advances payments for property and equipment, see note 6e	8,826	4,381
	18,575	13,689
Less:		
Accumulated depreciation	(6,342)	(5,483)
Property and equipment, net	$ 12,233	$ 8,206

Depreciation expense totaled approximately $859 thousand, and approximately $829 thousand for the years ended December 31, 2018 and 2017, respectively.

NOTE 5 - EMPLOYEE SEVERANCE BENEFITS

The Company is required by Israeli law to make severance payments to Israeli employees upon dismissal or upon termination of employment in certain other circumstances.

The Company operates a number of post-employment defined contribution plans. A defined contribution plan is a program that benefits an employee after termination of employment, under which the Company regularly makes fixed payments to a separate and independent entity so that the Company has no legal or constructive obligation to pay additional contributions if the fund does not hold sufficient assets to pay all employees the benefits relating to employee service in the current and prior periods. The fund assets are not included in the Company's financial position.

The Company operates pension and severance compensation plans subject to Section 14 of the Israeli Severance Pay Law. The plans are funded through payments to insurance companies or pension funds administered by trustees. In accordance with its terms, the plans meet the definition of a defined contribution plan, as defined above.

The Company expects contribution plan expenses in 2019 to amount to approximately $650 thousand.

NOTE 6 - COMMITMENTS AND CONTINGENT LIABILITIES:

a. Joint venture and exclusive license agreement

In June 2000, the Company engaged in a joint venture and exclusive license agreement with Yissum Research and Development Company, owned by the Hebrew University of Jerusalem ("Yissum"). Under the license agreement, the Company has been granted a perpetual and exclusive license to develop, manufacture and market products globally, which are based directly or indirectly on a patent owned by Yissum and based on the intellectual property that has been created as a result of the research that has been conducted by Yissum and financed by the Company under the license agreement.

The Company is entitled to grant sub-licenses to third parties and said sub-licenses may be perpetual, and any sublicensee thereunder will not be required to assume any undertaking towards Yissum.

NOTE 6 - COMMITMENTS AND CONTINGENT LIABILITIES (continued):

Under the license agreement, the Company committed to act for the future development of products that are based on Yissum's patent and on the initial research activity that was undertaken under the license agreement (the "Products"). Several pending patents have resulted from the development work done by the Company, on its behalf or on behalf of the Company and Yissum jointly. Further, the Company assumed in the license agreement all costs of submitting and managing patent applications, as well as maintaining pending and granted patents.

In accordance with an amendment to the license agreement dated July 13, 2005 (which reduced royalty rates), and in exchange for the license, the Company agreed to pay 3% royalties on its overall net income (as defined in the license agreement) from the sale of the Products, to Yissum from the time of the first commercial sale. Furthermore, the Company agreed to pay 15% royalties on sub-licenses on any payment or benefit whatsoever that the Company may receive from sub-licenses.

As of the date of issuance of the financial statements, the Company has not yet begun to sell its product candidates and has not yet granted sub-licenses to any party, and, accordingly, no obligation has yet to arise to pay royalties in accordance with the license agreement.

The parties are entitled to cancel the license agreement in the following cases: (a) the appointment of a liquidator or a receiver or the submission of an application for liquidation in relation to the other party, which is not cancelled within 180 days; (b) attachment proceedings, debt collecting agency proceedings and similar proceedings in connection with a significant portion of the other party's assets; (c) the liquidation or bankruptcy of the other party; (d) a significant breach that is not cured within 30 days from the time notice is given. If the license agreement is cancelled except in the case of its cancellation as a result of a breach by Yissum, the rights that were granted under the license will return to Yissum.

In accordance with the license agreement, the agreement will remain in force until the later of the expiry of the last patent that partially underlies the Products on a global basis or 15 years from the time of the first commercial sale under the license agreement.

b. Cooperation agreements

As part of its operations, the Company entered into feasibility agreements with multinational companies for the development of products that combine the Company's proprietary Accordion Pill platform technology with certain drugs for the treatment of various indications. These agreements sometimes include a mutual possibility of entering into negotiations for the acquisition of a future license for the commercial use of the products that are being developed by the multinational companies under the feasibility agreements. In addition, the multinational companies agreed to reimburse the Company for its expenses, based on milestones that are detailed in the feasibility agreements. This funding is recognized in the statements of operations as a deduction from research and development expenses, as they are incurred.

In January 2018, the Company entered into a feasibility and option agreement with Novartis Pharmaceuticals to explore using the Accordion Pill platform for a proprietary Novartis compound. Under the agreement and the research plan, the Company's activities will be funded by Novartis subject to the achievement of agreed milestones.

NOTE 6 - COMMITMENTS AND CONTINGENT LIABILITIES (continued):

c. Grants from the IIA

The Company has received grants from the IIA for research and development funding and therefore is subject to the provisions of the Israeli Law for the Encouragement of Research, Development and Technological Innovation in the Industry and the regulations and guidelines thereunder (the "Innovation Law", formerly known as the Law for the Encouragement of Research and Development in Industry). Under the Innovation Law the rate of royalties varies between 3% to 5% computed based on the revenues from the products that their development was also funded by grants from the IIA. Such commitment is up to the amount of grants received (dollar linked), plus interest at annual rate based on LIBOR. Pursuant to the Innovation Law there are restrictions regarding intellectual property and manufacturing outside of Israel, unless approval is received, and additional payments are made to the IIA.

At the time the Company received the grants, successful development of the program was not assured and, accordingly, no liability has been recognized in the financial statements. In 2017, the Company recorded a liability in the amount of $2.3 million following a review and assessment by the IIA on the 2016 program. In March 2018, this amount was repaid to the IIA.

In February 2018, the Company received an approval from the IIA to manufacture its AP-CD/LD product outside of Israel. As such, the royalties to the IIA will be paid at an increased rate and up to an increased cap amount of three times the total amount of the IIA grants, plus interest accrued thereon, depending on the manufacturing volume to be performed outside Israel. As of December 31, 2018, the Company received from the IIA grants in the total amount of approximately NIS 42.3 million (approximately $11.3 million).

The Company did not apply for any grants from the IIA for the years ended December 31, 2018 and 2017.

d. Lease Agreements

1) The Company is a tenant under a lease agreement in respect of offices and operational spaces in Jerusalem until June 30, 2021. The lease agreement includes an option to extend the lease term until June 30, 2022 (the "extension option"). In January 2018, the Company amended the lease agreement and added additional operational spaces that will allow the Company to expand its research and development activities. Rent payments are denominated in NIS and linked to the Israeli CPI. To secure the Company's obligations to the lease agreement in Jerusalem, the Company has granted a bank guarantee to the lessor, which amounted to approximately $135 thousand as of December 31, 2018.

   The Company also leases office space in Modi'in and New York City.

2) The Company has entered into operating lease agreements for vehicles used by its employees. The lease periods are generally for three years and the payments are linked to the Israeli CPI. To secure the terms of the lease agreements, the Company has made certain prepayments to the leasing company, representing approximately three months of lease payments.

   Operating lease expenses for the years ended December 31, 2018 and 2017, are as follows:

	2018	2017
	U.S. dollars in thousands	
Rental expenses	$ 688	$ 520
Vehicles lease expenses	$ 214	$ 166

NOTE 6 - COMMITMENTS AND CONTINGENT LIABILITIES (continued):

3) Future contractual obligations under the abovementioned operating lease agreements (not including the extension option) are as follows:

Year	Amount U.S. dollars in thousands
2019	$ 772
2020	721
2021	332
Total	$ 1,825

e. Automated Production Line

In April 2017, the Company engaged with an international manufacturer for ordering a large-scale automated production line for manufacturing Accordion Pills (the "Production Line"). The order covers engineering, manufacture and assembly of the Production Line. The total cost of the Production Line including additional components amounted to approximately €8.0 million. As of December 31, 2018, the Company transferred payments of approximately €7.4 million (approximately $8.6 million), of which approximately €3.6 million (approximately $4.2 million) was paid during 2018 and recognized a liability in amount of approximately €148 thousand (approximately $170 thousand). As of December 31, 2018, the Production Line has been delivered to the commercial site at Lohmann Therapie-Systeme AG ("LTS"), which is located in Germany, and as of the date of the issuance of the consolidated financial statements the Production Line is in installation phase. For more details regarding the Manufacturing Services with LTS see note f below.

f. Establishment of the Commercial Scale Production Capabilities for AP-CD/LD

In March 2018, the Company entered into a Term Sheet for Manufacturing Services with LTS for the manufacture of AP-CD/LD, which was subsequently superseded in December 2018 by a Process Development Agreement (the "Agreement"). Under the Agreement, the Company will bear the costs incurred by LTS to acquire the production equipment for AP-CD/LD ("Equipment") in the amount of approximately €7.0 million, however such amount will later be reimbursed to the Company by LTS in the form of a reduction in the purchase price of the AP-CD/LD product. As of December 31, 2018, the Company transferred payments of approximately €4.3 million (approximately $4.9 million) in costs of the Equipment and recognized a liability in an additional amount of €436 thousand (approximately $499 thousand). As of that date, the Company has recognized the Equipment as non-current other assets.

The Agreement contains several termination rights which are expected to be included in a definitive manufacturing and supply agreement. According to the Agreement, upon the Company's decision to not continue with the project or commercialization of the AP-CD/LD, LTS has the right to (a) purchase the Equipment from the Company in which case it is required to pay to the Company the share of the cost of the Equipment paid by the Company less up to €2.0 million for upgrading facility costs invested by LTS or (b) transfer such Equipment to the Company in which case the Company will pay LTS up to €2.0 million for upgrading facility costs invested by LTS. In addition, the Company may under certain circumstances be required to pay to LTS up to €1.0 million for certain upgrading costs of LTS' facility upon the earlier of the announcement of AP-CD/LD Phase III results or October 31, 2019. As of December 31, 2018, the Company recognized a liability that was recorded against research and development expenses, net in the amount of approximately €1.65 million (approximately $1.9 million), for LTS' facility upgrading costs which will be paid to LTS only if the Company decides to not continue with the project or commercialization of AP-CD/LD.

NOTE 7 - SHARE CAPITAL:

a. Rights of the Company's ordinary shares

Each ordinary share is entitled to one vote. The holders of ordinary shares are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. Since its inception, the Company has not declared any dividends.

b. Changes in share capital:

1) In August 2015, the Company completed an initial public offering, pursuant to which the Company issued 5,025,000 ordinary shares at a price of $6.00 per ordinary share. In September 2015, the underwriters partially exercised their over-allotment option and purchased 638,750 additional ordinary shares. The total net proceeds were approximately $30.6 million, after deducting underwriting discounts, commissions and other offering expenses in the amount of $3.4 million.

2) In March 2017, the Company entered into subscription agreements for a private placement with several institutional and private investors, in which the Company issued 2,289,638 ordinary shares at a price of $4.4 per ordinary share. The total net proceeds of approximately $9.5 million, after deducting issuance expenses in the amount of $0.5 million.

3) In August 2017, the Company completed an underwritten public offering, pursuant to which the Company issued 12,224,500 ordinary shares including a full exercise by the underwriters of their over-allotment option, at a price of $4.70 per ordinary share. The total net proceeds were approximately $53.6 million, after deducting underwriting discounts, commissions and other offering expenses in the amount of $3.9 million.

4) In April 2018, the Company completed an underwritten public offering, pursuant to which the Company issued 6,750,000 ordinary shares at a price of $5.25 per ordinary share. In May 2018, the underwriters partially exercised their over-allotment option and purchased 400,000 additional ordinary shares. The total net proceeds were approximately $35.0 million, after deducting underwriting discounts, commissions and other offering expenses in the amount of $2.5 million.

c. Investment agreement

As part of an investment agreement signed in August 2013, the Company issued to several investors warrants exercisable into 198,812 ordinary shares. These warrants were exercisable over a period of four years from the date of their issuance. Under the terms of these warrants, the investors had the right to exercise them into shares through a cashless net-settlement basis. In September 2017, all 198,812 warrants were exercised. 86,579 warrants were exercised into 86,579 ordinary shares in cash at an exercise price of NIS 21.7 for a total consideration of approximately NIS 1.9 million (approximately $531 thousand) and 112,233 warrants were exercised into 15,479 ordinary shares on a cashless basis.

NOTE 7 - SHARE CAPITAL (continued):

d. Share-based compensation:

In September 2005, the Company's board of directors approved a share option plan for grants to directors, employees and consultants. The 2005 plan expired in September 2015.

In January 2016, the Company's board of directors approved a new option plan (the "2015 Plan"). Originally, the maximum number of ordinary shares reserved for issuance under the 2015 Plan was 700,000 ordinary shares for grants to directors, employees and consultants. In July 2016 an increase of 700,000 ordinary shares was approved by the board of directors.

In December 2017 and June 2018, an increase of 2,100,000 and 1,000,000 ordinary shares, respectively, was approved by the Company's shareholders at a general meeting of shareholders.

As of December 31, 2018, 1,343,593 shares remain available for grant under the Plan.

The 2015 Plan is designed to enable the Company to grant options to purchase ordinary shares under various and different tax regimes including, without limitation: pursuant and subject to Section 102 of the Israeli Tax Ordinance and pursuant and subject to Section 3(i) of the Israeli Tax Ordinance.

The awards may be exercised after vesting and in accordance with vesting schedules which will be determined by the Company's board of directors for each grant. The maximum term of the awards is 10 years. The fair value of each option granted under the 2015 Plan is estimated using the Black-Scholes option pricing method. Expected volatility is based on the Company's historical volatility. The risk-free interest rate was determined on the basis of the yield rates to maturity of unlinked government bonds bearing a fixed interest rate, whose maturity dates correspond to the expected exercise dates of the options. The Company's management uses the contractual term or its expectations, as applicable, of each option as its expected life. The expected term of the options granted represents the period of time that granted options are expected to remain outstanding. During the years ended December 31, 2018 and 2017, the Company granted options to employees and directors as follows:

	Year ended December 31, 2018			
	Number of options granted	Exercise price range	Vesting period	Expiration
Employees	1,175,000	$ 4.44-$6.67	3 years	7 years
Directors	120,000	$ 4.44	3 years	7 years

	Year ended December 31, 2017			
	Number of options granted	Exercise price range	Vesting period range	Expiration
Employees	230,500	$ 5.46	3-4 years	7 years
	165,000	$ 7.44	18-21 months	7 years
	580,000	$ 6.70-$8.56	3 years	10 years
Directors	120,000	$ 5.32	3 years	10 years
	65,000	$ 5.32	9 months	10 years

The weighted average fair value of options granted during the years was generally estimated by using the Black-Scholes option-pricing model as follows:

	Year ended December 31	
	2018	2017
Weighted average fair value	$ 2.37	$ 2.10

NOTE 7 - SHARE CAPITAL (continued):

The underlying data used for computing the fair value of the options are as follows:

	Year ended December 31	
	2018	2017
Value of ordinary share	$ 4.20-$6.45	$ 5.15-$8.95
Dividend yield	0%	0%
Expected volatility	45.87%-46.47%	37.09%-46.65%
Risk-free interest rate	2.25%-2.73%	1.41%-2.16%
Expected term	5 years	1.5 years- 10 years

The following table summarizes the number of options outstanding with exercise price in NIS for the years ended December 31, 2018 and 2017, and related information:

	Employees and directors		Consultants	
	Number of options	NIS (1)	Number of options	NIS (1)
Outstanding at January 1, 2017	418,484	38.13	8,035	0.5
Exercised	(377)	0.5	-	-
Forfeited	(2,538)	32.47	-	-
Expired	(66,417)	79.88	-	-
Outstanding at December 31, 2017	349,152	30.27	8,035	0.5
Forfeited	(400)	34.24	-	-
Expired	(53,300)	45.48	-	-
Outstanding at December 31, 2018	295,452	27.52	8,035	0.5

The following table summarizes the number of options outstanding with exercise price in USD for the years ended December 31, 2018 and 2017, and related information:

	Employees and directors	
	Number of options	USD(2)
Outstanding at January 1, 2017	794,333	4.23
Granted	1,160,500	6.66
Exercised	(11,006)	4.14
Forfeited	(70,832)	4.10
Expired	(312)	4.14
Outstanding at December 31, 2017	1,872,683	5.74
Granted	1,295,000	6.01
Exercised	(7,218)	4.14
Forfeited	(22,282)	6.64
Outstanding at December 31, 2018	3,138,183	5.85

(1) Weighted average price in NIS per share.
(2) Weighted average price in USD per share.

NOTE 7 - SHARE CAPITAL (continued):

The following table summarizes information concerning outstanding and exercisable options with exercise price in NIS as of December 31, 2018:

December 31, 2018				
Options outstanding			Options exercisable	
Exercise price per share (NIS)	Number of options outstanding at the end of year	Weighted average remaining contractual life	Number of options exercisable at the end of year	Weighted average remaining contractual life
0.5	136,445	0.69	8,051	0.61
32.47-39.55	45,000	1.90	45,000	1.90
48.91	39,420	1.50	39,420	1.50
52.35-60.42	82,622	0.68	33,622	0.73
	303,487		126,093	

The following table summarizes information concerning outstanding and exercisable options with exercise price in USD as of December 31, 2018:

December 31, 2018				
Options outstanding			Options exercisable	
Exercise price per share (USD)	Number of options outstanding at the end of year	Weighted average remaining contractual life	Number of options exercisable at the end of year	Weighted average remaining contractual life
3.46	68,250	0.69	42,657	0.69
3.53	224,478	7.38	149,652	7.38
4.14-4.47	526,455	7.04	142,033	7.32
5.19-5.46	543,500	6.59	190,468	7.06
6.0-6.7	1,410,500	6.76	201,667	7.36
7.44	165,000	0.70	86,385	0.70
8.56	200,000	8.91	66,667	8.91
	3,138,183		879,529	

The aggregate intrinsic value of the total outstanding and exercisable options as of December 31, 2018, is $6.5 million and $1.9 million respectively.

The following table illustrates the effect of share-based compensation on the statements of operations:

	Year ended December 31	
	2018	2017
	U.S. dollars in thousands	
Research and development expenses, net	$ 1,732	$ 362
General and administrative expenses	1,495	841
	$ 3,227	$ 1,203

NOTE 8 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

Balance sheets:

	December 31	
	2018	2017
	U.S. dollars in thousands	
a. Prepaid expenses and other receivable:		
Prepaid expenses	$ 227	$ 208
Advances to suppliers	728	439
Institutions	1,683	436
Interest receivable	118	42
Other receivables	230	-
	$ 2,986	$ 1,125
b. Accounts payable and accruals - other:		
Accrual for repayment of grants to IIA, see note 6c	$ -	$ 2,300
Expenses payable	3,400	724
Salary and related expenses, including social security and other taxes	1,078	588
Accrual for vacation days and recreation pay for employees	309	248
Other	20	33
	$ 4,807	$ 3,893

Statements of operations:

	Year ended December 31	
	2018	2017
	U.S. dollars in thousands	
c. Financial income (expenses), net:		
Financial income:		
Interest on cash and cash equivalents	$ 852	$ 286
Gains from changes in fair value of marketable securities	-	220
Gain on changes in exchange rates	-	70
	$ 852	$ 576
Financial expenses -		
Loss from changes in exchange rates	$ (747)	$ -
Losses from changes in fair value of marketable securities	(194)	-
Bank fees	(23)	(17)
	$ (964)	$ (17)
Financial income (expenses), net	$ (112)	$ 559

NOTE 9 - TAXES ON INCOME:

a. Tax rates

1) Income from Israel is taxed at a regular rate. Capital gains are taxed at the standard corporate tax rate.

In December 2016, the Economic Efficiency Law (Legislative Amendments for Implementing the Economic Policy for the 2017 and 2018 Budget Year), 2016 was published, introducing a gradual reduction in corporate tax rate from 25% to 23%. However, the law also included a temporary provision setting the corporate tax rate in 2017 at 24%. As a result, the corporate tax rate in 2017 was 24% and in 2018 and thereafter reduced to 23%. For tax benefits in Israel see note b below.

2) Income of the subsidiary is taxed according to the federal tax laws in the US and the relevant state laws. The relevant U.S. statutory tax rates for 2018 and 2017 were 21% and 35%, respectively. The relevant state tax rate for 2018 and 2017 was approximately 7%.

The U.S. Tax Cuts and Jobs Act ("Tax Act") was enacted on December 22, 2017 and introduced significant changes to U.S. income tax law. Effective in 2018, the Tax Act reduced the U.S. federal statutory tax rate from 35% to 21% and created new taxes on certain foreign-sourced earnings and certain related-party payments, which are referred to as the global intangible low-taxed income tax and the base erosion tax, respectively.

b. Tax benefits under the Law for the Encouragement of Capital Investments, 1959 in Israel (the "ECI Law")

Under the ECI Law, Intec may be entitled to tax benefits, by virtue of its status as a "Benefited Enterprise", which was awarded to Intec in October 2007.

Intec received the status of a "plant under establishment" in Development Area A in a tax-exempt track, subject to compliance with the applicable requirements by the Law.

As of December 31, 2018, Intec has not yet generated operating income that will allow it to benefit from the tax benefits under the ECI Law.

The tax benefits under the ECI Law will apply for a period of up to ten years from the first year in which taxable income will be generated and are scheduled to expire at the end of 2023.

c. Tax assessments

Intec has tax assessments that are considered to be final through tax year 2013.

d. Losses for tax purposes carried forward to future years

As of December 31, 2018, Intec had approximately $107.6 million of net carry forward tax losses which are available to reduce future taxable income with no limited period of use.

e. Subsidiary tax liability

During 2018 and 2017, the Subsidiary incurred a tax expense in the amount of $103 thousand and $29 thousand, respectively.

NOTE 9 - TAXES ON INCOME (continued)**:**

f. Deferred income taxes:

	December 31	
	2018	2017
	U.S. dollars in thousands	
In respect of:		
Net operating loss carry forward	$ 24,739	$ 17,982
Research and Development expenses	6,705	4,057
Issuance costs	734	674
Other	787	61
Less—valuation allowance	(32,684)	(22,774)
Net deferred tax assets	$ 281	$ -

The change in valuation allowance for the years ended December 31, 2018 and 2017 were as follows:

	December 31	
	2018	2017
	U.S. dollars in thousands	
Balance at the beginning of the year	$ 22,774	$ 15,344
Changes during the year	9,910	7,430
Balance at the end of the year	$ 32,684	$ 22,774

g. Loss before income tax

The components of loss before income tax are as follows:

	December 31	
	2018	2017
	U.S. dollars in thousands	
Income (loss) before income tax:		
Intec	$ (43,943)	$ (28,928)
Subsidiary	503	48
	$ (43,440)	$ (28,880)

h. Current taxes on income

The difference between the statutory tax rate of the Company and the effective rate results virtually all from the changes in valuation allowance in respect of carryforward tax losses and research and development expenses due to the uncertainty of the realization of such tax benefits.

NOTE 9 - TAXES ON INCOME (continued)**:**

i. ASC No. 740, Income Taxes, requires significant judgment in determining what constitutes an individual tax position as well as assessing the outcome of each tax position. Changes in judgment as to recognition or measurement of tax positions can materially affect the estimate of the effective tax rate and consequently, affect the operating results of the Company.

The following table summarizes the activity of the Company unrecognized tax benefits:

	December 31 2018
	U.S. dollars in thousands
Balance at the beginning of the year	$ -
Increase in uncertain tax positions for the current year	309
Balance at the end of the year	$ 309

The Company does not expect unrecognized tax expenses to change significantly over the next 12 months.

NOTE 10 - EVENTS SUBSEQUENT TO DECEMBER 31, 2018

On January 22, 2019, the board of directors approved a grant of options to purchase an aggregate of 940,000 ordinary shares to the Company's executive officers and employees. Each option shall be exercisable at an exercise price of $7.63 per share. The options will vest over a three-year period, with one-third of the options vesting at the end of the first anniversary of the date of grant, and the remaining options vesting in eight equal quarterly installments following the first anniversary of the grant date. The options will expire seven years after the date of grant. The value of the benefit in respect of the said options, as calculated on the grant date, is approximately $3.4 million.

In addition, the board of directors approved a grant of options to purchase 125,000 ordinary shares to the Company's Chief Executive Officer which shall be granted following the approval of the Company's shareholders at a general meeting of shareholders. Each option shall be exercisable at an exercise price per share equal to the average closing sale price of the Company's ordinary shares on the NASDAQ Capital Market over the 30 trading day period prior to the date of the general meeting of shareholders, or the fair market value of one of our ordinary shares on the date prior to the general meeting, whichever amount is greater. These options will vest over a three-year period, with one third of the options vesting at the end of the first anniversary of the date of grant, and the remaining options vesting in eight equal quarterly installments following the first anniversary of the grant date. The options will expire seven years after the date of grant.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2018. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of December 31, 2018 these disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, the company's executive and financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes and includes those policies and procedures that (a) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company; (b) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (c) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's 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 misstatements. 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 assessed the effectiveness of our internal control over financial reporting, as of December 31, 2018. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). Based on our assessment, management believes that as of December 31, 2018, our internal control over financial reporting is effective based on these criteria.

As an emerging growth company, our auditors were not required to attest to, or report on the effectiveness of our internal control over financial reporting, and therefore such attestation is not included in this Annual Report on Form 10-K, in accordance with section 103 of the JOBS Act which amended section 404(b) of the Sarbanes-Oxley Act with regard to emerging growth companies.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the year ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following table sets forth information relating to our executive officers and directors as of February 22, 2019.

Name	Age	Position
Executive Officers		
Jeffrey A. Meckler	52	Chief Executive Officer, Vice Chairman of the Board of Directors
Dr. Nadav Navon	50	Chief Operating Officer
Walt A. Linscott, Esq.	58	Chief Business Officer
Nir Sassi	43	Chief Financial Officer
Dr. R. Michael Gendreau	63	Chief Medical Officer
Non-Executive Directors		
Dr. John W. Kozarich (3)	69	Chairman of the Board of Directors
Gil Bianco (1)	67	Director
Hila Karah (2)(3)	50	Director
Issac Silberman (1)(2)	67	Director
Anthony J. Maddaluna (2)(3)	66	Director
William B. Hayes (1)	53	Director
Dr. Roger J. Pomerantz (2)	61	Director

(1) Member of audit committee

(2) Member of compensation committee

(3) Member of nominating and corporate governance committee

Biographical information with respect to our executive officers and directors is provided below.

Our Executive Officers

Mr. Jeffrey A. Meckler has served as our Vice Chairman of the board of directors since April 2017 and as our Chief Executive Officer since July 2017. Mr. Meckler has served on numerous public and private corporate boards and since October 2014 has served as a director of Retrophin, Inc. (Nasdaq: RTRX). Mr. Meckler recently served as Chief Executive Officer and a director of CoCrystal Pharma, Inc., a pharmaceutical company, from April 2015 to July 2016. He has also served as a director of QLT, Inc. (Nasdaq: QLTI), a biotechnology company, from June 2012 to November 2016, as well as the Managing Director of The Andra Group, a life sciences consulting firm since 2009. Mr. Meckler also served as Chief Executive Officer of Trieber Therapeutics from January 2017 to July 2017. Earlier in his career, Mr. Meckler held a series of positions at Pfizer Inc. in manufacturing systems, market research, business development, strategic planning and corporate finance, which included playing a significant role in acquisitions and divestitures. Mr. Meckler is the past President and continues to serve on the board of directors of Children of Bellevue, a non-profit organization focused on advocating and developing pediatric programs at Bellevue Hospital Center. Mr. Meckler holds a B.S. in Industrial Management and M.S. in Industrial Administration from Carnegie Mellon University. In addition, Mr. Meckler received his J.D. from Fordham University School of Law. We believe that Mr. Meckler is qualified to serve on our board of directors because of his extensive executive leadership experience in the biopharmaceutical industry, including his service at Pfizer, and his experience serving on public company boards.

Dr. Nadav Navon joined us in March 2006 and has served as our Chief Operating Officer since July 2017. Between March 2015 and July 2017, Dr. Navon served as our Executive Vice President of Research & Development and Operations. Before that, he served as our Vice President of Research & Development and Operations from May 2013 until March 2015. Prior to his service with us, Dr. Navon headed the analytical and quality assurance operations at Sharon Laboratories Ltd., a chemical company that develops and manufactures raw materials for the pharmaceutical, cosmetic and food industries, from 2001 to 2006. Prior to that, Dr. Navon led a number of research and development projects in the Negev's Nuclear Research Center. Dr. Navon has a Ph.D. in inorganic and analytical chemistry, and an MBA and a BSc in chemistry, each from Ben-Gurion University in Be'er Sheva, Israel.

Walt A. Linscott, Esq. joined us in October 2017 and has served as our Chief Business Officer since July 2018. Previously, from October 2017 to July 2018, Mr. Linscott served as our Chief Administrative Officer. Prior to his service with us, Mr. Linscott co-founded a global consulting enterprise in October 2014 providing strategic advice to developing companies and most recently served as the President and Chief Operating Officer of Treiber Therapeutics, Inc. from March 2017 to October 2017. Mr. Linscott also has held senior level executive positions at public and private medical device and pharmaceutical companies including Cocrystal Pharma, Inc., from July 2015 to March 2017, Carestream Health, Inc., from January 2011 to January, 2015 and Solvay Pharmaceuticals, Inc., from 2001 to 2005. In addition to this experience, he was an associate and partner at Thompson Hine LLP from 1990 to 2001, and again as a partner from 2005 to 2010 where he founded the firm's Atlanta, Georgia office, served as Partner in Charge and Chair of the firm's Life Science Practice Group. Mr. Linscott holds a Postgraduate Diploma in Global Business from the University of Oxford and a Postgraduate Diploma in Entrepreneurship from Cambridge University. He earned a bachelor's degree from Syracuse University and a Juris Doctor from the University of Dayton School of Law. Mr. Linscott served on active duty as an Officer in the United States Marine Corps prior to attending law school.

Nir Sassi has served as our Chief Financial Officer since August 2016. Prior to serving as our Chief Financial Officer, Mr. Sassi served as our VP Finance commencing in January 2015 and as our Chief Financial Officer between March 2010 and January 2015. Prior to his service with us, Mr. Sassi served as a Senior Manager at PricewaterhouseCoopers Israel, an accounting firm, from 2002 until 2010, including two years relocation to the PricewaterhouseCoopers New York office. Mr. Sassi is a certified public accountant in Israel and has a bachelor's degree in economics and accounting from Ben Gurion University in Be'er Sheva, Israel.

Dr. R. Michael Gendreau has served as our Chief Medical Officer since February 2018. In 2011, prior to joining Intec, Dr. Gendreau founded Gendreau Consulting, LLC, a consulting firm providing strategic advice and operational leadership on the design and management of clinical programs, strategic planning, and technology assessments for emerging pharmaceutical, diagnostic, and medical device companies. He has served on various scientific advisory boards, executive strategic planning boards, and Data Safety Monitoring Boards. Prior to his consulting career, Dr. Gendreau served from 1996 until 2011 as Chief Medical Officer at Cypress Bioscience, Inc., a clinical-stage biotech company developing therapies for central nervous system disorders. Prior to Cypress Bioscience, Dr. Gendreau was Chief Medical Officer of Microprobe Corporation from 1991 to 1994. Additionally, he has served as Chief Medical Officer/Therapeutic Area Head at other institutions, including Battelle Memorial Institute. Dr. Gendreau received his B.S. in Chemistry from Ohio University, and earned his M.D./Ph.D. from The Ohio State University.

Our Non-Executive Directors

John W. Kozarich has served as our Chairman of the board of directors since July 2016. Dr. Kozarich has nearly 40 years of experience in the biopharmaceutical industry and academia. Dr. Kozarich currently serves as Chairman of Ligand Pharmaceuticals (Nasdaq: LGND) and has served as a member of Ligand's board since 2003. Dr. Kozarich currently serves as Distinguished Scientist and Executive Advisor of ActivX Biosciences, Inc., and previously served as ActivX's Chairman and President from 2004 through March 2017 having joined ActivX in 2002. Prior to his role at ActivX, Dr. Kozarich was Vice President at Merck Research Laboratories where he was responsible for a variety of drug discovery and development programs and external biotech collaborations. Dr. Kozarich previously held full professorships at the University of Maryland and Yale School of Medicine. He was named Director of the Year for 2014 by the Corporate Directors Forum, has been an American Cancer Society Faculty Research Awardee, and received the Distinguished Scientist Award of the San Diego Section of the American Chemical Society. Since April 2015, Dr. Kozarich has served as a director at Retrophin, Inc., a publicly traded biopharmaceutical company (Nasdaq: RTRX). Previously, Dr. Kozarich served as a director of Corium International, Inc. (Nasdaq: CORI) and QLT, Inc. (Nasdaq: QLTI). Dr. Kozarich holds a B.S. in chemistry from Boston College and a Ph.D. in biological chemistry from the Massachusetts Institute of Technology and was an NIH Postdoctoral Fellow at Harvard University. We believe that Dr. Kozarich is qualified to serve on our board of directors because of his extensive experience in the biopharmaceutical industry, including his service at Merck Research Laboratories, his academic experience and his experience serving on public company boards.

Gil Bianco has served on our board of directors since April 2010. From November 2009 to November 2012, Mr. Bianco served as a director of D-Pharm Ltd., an Israeli public biopharmaceutical company, and from May 2007 to May 2010, Mr. Bianco served as a director of BioLineRx Ltd. (Nasdaq: BLRX), a clinical-stage biopharmaceutical development company. From December 2003 to December 2009, Mr. Bianco served as an external director of the Tel Aviv Stock Exchange Ltd. Prior to that, from 2001 to 2003, Mr. Bianco served as chief executive officer of Agis Industries Ltd., a pharmaceutical manufacturer. Mr. Bianco previously served as an external director at Mazor Robotics Ltd. (Nasdaq: MZOR), a medical device company, from November 2007 until its acquisition in 2018. Mr. Bianco is also a director of several private companies in the fields of biotech and medical devices. Mr. Bianco holds a B.A. in economics and accounting from Tel-Aviv University in Tel-Aviv, Israel and is a certified public accountant in Israel. We believe Mr. Bianco is qualified to serve on our board of directors because of his longstanding service with us, his extensive experience serving on public company boards and his accounting background.

Hila Karah has served as a member of our board of directors since December 2009. Ms. Karah is an experienced board director and since 2013 serves as an independent business consultant to private and public companies on strategy, operations, financing, regulatory and corporate governance. From November 2017 to September 2018, Ms. Karah was the executive chairperson of FloraFotonica Ltd., an Israeli Agro Tech startup. From 2006 until 2013, Ms. Karah was the chief investment officer of Eurotrust Ltd., a family office, where she focused primarily on investments in life science, internet and high-tech companies. Prior to joining Eurotrust, Ms. Karah served as a senior analyst at Perceptive Life Sciences Ltd., a New York-based hedge fund. Prior to her position at Perceptive, Ms. Karah was a research analyst at Oracle Partners Ltd., a healthcare-focused hedge fund based in Connecticut. Ms. Karah has served on the board of Cyren Ltd. a cyber security company (Nasdaq, TASE: CYRN) since 2008 and the board of Dario Health Corp., (Nasdaq: DRIO) since 2014. She also serves on the board of several private companies. Ms. Karah has a BA in molecular and cell biology from the University of California, Berkeley, and has studied at the UCSB – UCSF Joint Medical Program. We believe Ms. Karah is qualified to serve on our board of directors because of her longstanding service with us, her investment career in life science companies, her scientific background and experience serving on public company boards.

Issac Silberman has served on our board of directors since April 2010. From 2007 through the end of 2016, Mr. Silberman also served as a special investment advisor at Sullam Holdings L.R. Ltd., a financial services corporation in the Lenny Recanati Group, focusing primarily on investments in high-tech, biotechnology and real estate companies. Mr. Silberman also serves as a director in other private Israeli companies, and has over 20 years of prior experience as an executive officer of various public and private companies. Mr. Silberman holds a B.A. in economics and accounting from Tel Aviv University in Tel Aviv, Israel, and he is a certified public accountant in Israel. We believe Mr. Silberman is qualified to serve on our board of directors because of his longstanding service with us, his extensive experience serving on company boards and his accounting background.

Anthony J. Maddaluna has served on our board of directors since December 2017. Mr. Maddaluna has more than 40 years of experience in the pharmaceutical manufacturing industry, including leadership positions in plants, regions and globally. From January 2011 to December 2016, Mr. Maddaluna held a series of positions at Pfizer Inc., most recently serving as the Executive Vice President and President of Pfizer Global Supply. Prior to that Mr. Maddaluna served as Senior Vice President of Pfizer Global Manufacturing Strategy and Supply Network Transformation from 2008 until 2011, and as Vice President of Pfizer Global Manufacturing Europe Area from 1998 until 2008. Mr. Maddaluna served as a director of Albany Molecular Research Inc. from February 2016 until its acquisition by The Carlyle Group and GTCR in August 2017 and currently serves on the board of managers for the private company. Mr. Maddaluna holds a B.S. in Chemical Engineering from Northeastern University and an M.B.A. from Southern Illinois University. We believe that Mr. Maddaluna is qualified to serve on our board of directors because of his extensive experience in the pharmaceutical manufacturing industry, including his service at Pfizer, and his experience serving on company boards.

William B. Hayes has served on our board of directors since June 2018. Most recently, Mr. Hayes was Executive Vice President, Chief Financial Officer and Treasurer of Laboratory Corporation of America Holdings (LabCorp) (NYSE: LH), a diagnostics laboratory company. Mr. Hayes joined LabCorp in 1996, where he was responsible for day-to-day operations of the revenue cycle function. He rose through a series of promotions and in 2005 was named Executive Vice President, Chief Financial Officer and Treasurer of LabCorp, a role he held until his retirement in 2014. Prior to LabCorp, Mr. Hayes was at KPMG for nine years in their audit department. Mr. Hayes served as a director from March 2016 for Patheon N.V. (NYSE: PTHN), a pharmaceutical manufacturing company, until its acquisition by Thermo Fisher in late 2017. Mr. Hayes holds a Bachelor of Science in accounting from the University of North Carolina at Greensboro and is a Certified Public Accountant. We believe Mr. Hayes is qualified to serve on our board of directors because of his accounting background and experience serving on public company boards.

Roger J. Pomerantz has served on our board of directors since March 2018. Since November 2013, Dr. Pomerantz served as Chairman of Seres Therapeutics (Nasdaq: MCRB) and from June 2014 until January 2019, Dr. Pomerantz served as the President and Chief Executive Officer of Seres. Since July 2014, Dr. Pomerantz has been a Senior Partner at Flagship Pioneering, formerly known as Flagship Ventures, an early-stage venture capital firm. Prior to joining Seres, Dr. Pomerantz was Worldwide Head of Licensing & Acquisitions, Senior Vice President at Merck & Co., Inc., where he oversaw all licensing and acquisitions at Merck Research Laboratories, including external research, out-licensing regional deals, and academic alliances. Previously, he served as Senior Vice President and Global Franchise Head of Infectious Diseases at Merck. Prior to joining Merck, Dr. Pomerantz was Global Head of Infectious Diseases for J&J. He has served on the board of directors of ContraFect Corporation (Nasdaq: CFRX) and Rubius Therapeutics (Nasdaq: RUBY) since 2014. Dr. Pomerantz earned his B.A. in biochemistry at the Johns Hopkins University and his M.D. at the Johns Hopkins School of Medicine. He completed his internal medicine internship and residency training, and his subspecialty clinical and research training in infectious diseases and virology at the Massachusetts General Hospital of Harvard Medical School. His post-doctoral research training in molecular retrovirology was obtained at both Harvard Medical School and the Whitehead Institute of the Massachusetts Institute of Technology (MIT). Dr. Pomerantz also served as the Chief Resident at the Massachusetts General Hospital. Following his medical-scientist training, he was an Endowed, Tenured Professor of Medicine and Molecular Pharmacology and Chairman of the Infectious Diseases Department of Thomas Jefferson University in Philadelphia. Dr. Pomerantz is an internationally recognized expert in HIV molecular pathogenesis and latency. He has developed ten approved infectious disease drugs in important diseases including HIV, HCV, tuberculosis, and Clostridium difficile infection. We believe that Dr. Pomerantz is qualified to serve on our board of directors because of his significant scientific, executive and board leadership experience in drug development and in the pharmaceutical industry.

Family Relationships

There are no family relationships among our executive officers and directors.

Board Composition

Board of Directors

Under the Companies Law and our articles of association, the management of our business is vested in our board of directors. Our board of directors may exercise all powers and may take all actions that are not specifically granted to our shareholders or to management. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our board of directors. Our Chief Executive Officer is appointed by, and serves at the discretion of, our board of directors, subject to his personal contract with the Company. All other executive officers are also appointed by our board of directors, and are subject to the terms of their personal employment agreements (as such may be updated from time to time).

Our board of directors determined that all of our directors other than Mr. Meckler are independent under Nasdaq Capital Market rules.

Under our articles of association, our board of directors must consist of at least four and not more than nine directors, including at least two external directors, to the extent applicable and subject to the Relief Regulations described below under "—External Directors". Our board of directors currently consists of eight members. Our directors are elected at the annual and/or special general meeting of our shareholders by a simple majority. Because our ordinary shares do not have cumulative voting rights in the election of directors, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors. We have held elections for each of our non-external directors at each annual meeting of our shareholders since our initial public offering in Israel.

In addition, our articles of association allow our board of directors to appoint directors to fill vacancies on our board of directors, for a term of office ending on the earlier of the next annual general meeting of our shareholders, or the conclusion of the term of office in accordance with our articles or any applicable law, subject to the maximum number of directors allowed under our articles of association.

In addition, 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 John Kozarich to serve as chairman of the board of directors.

External directors

Under the Companies Law, Israeli public companies are generally required to appoint at least two external directors, who need to meet certain criteria and be appointed according to a specific procedure. However, according to the Israeli Companies Regulations (Relief for Companies whose Securities are Listed for Trading on a Stock Exchange Outside Israel), 2000, or the Relief Regulations, a company whose shares are traded on certain stock exchanges outside Israel (including the Nasdaq Capital Market, such as our company) that does not have a controlling shareholder and that complies with the requirements of the laws of the foreign jurisdiction where the company's shares are listed, as they apply to domestic issuers, with respect to the appointment of independent directors and the composition of the audit committee and compensation committee, may elect to exempt itself from the requirements of Israeli law with respect to among other things (i) the requirement to appoint external directors and that one external director serve on each committee of the board of directors; and (ii) certain limitations on the employment or service of an external director or his or her spouse, children or other relatives, following the cessation of his or her service as an external director, by or for the company, its controlling shareholder or an entity controlled by the controlling shareholder. In May 14, 2018, our board decided to opt out of these requirements.

Under the Relief Regulations, these concessions will continue to be available to us so long as (i) our shares are traded on a U.S. stock exchange, including the Nasdaq Capital Market; (ii) we do not have a "controlling shareholder" (as such term is defined under the Companies Law), and (iii) we comply with the majority board independence requirements and audit committee and compensation committee requirements under U.S. laws applicable to U.S. domestic issuers.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and governance committee. Our board of directors may establish other committees to facilitate the management of our business. We are required to comply with both the Nasdaq listing rules and the Companies Law regarding the composition of our board committees.

The composition and functions of our established committees are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors.

Audit Committee

Our audit committee consists of Brad Hayes, Gil Bianco and Issac Silberman. Mr. Hayes serves as the Chairman of the audit committee.

Under the Nasdaq Capital Market corporate governance rules, we are required to maintain an audit committee consisting of at least three independent directors, each of whom is financially literate and one of whom has accounting or related financial management expertise. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq Capital Market corporate governance rules. Our board of directors has affirmatively determined that Gil Bianco is an audit committee financial expert as defined by the SEC rules and has the requisite financial experience as defined by the Nasdaq Capital Market corporate governance rules.

Each of the members of the audit committee is "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act, which is different from the general test for independence of board and committee members.

Audit Committee Role

Our board of directors has adopted an audit committee charter which became effective upon the listing of our shares on the Nasdaq Capital Market that sets forth the responsibilities of the audit committee consistent with the rules of the SEC and the Listing Rules of the Nasdaq Capital Market, as well as the requirements for such committee under the Companies Law, including the following:

- 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; and
- 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.

Our audit committee provides assistance to our board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our audit committee also oversees the audit efforts of our independent accountants and takes those actions that it deems necessary to satisfy itself that the accountants are independent of management.

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

(i) determining whether there are deficiencies in the business management practices of our Company, including in consultation with our internal auditor or the independent auditor, and making recommendations to our board of directors to improve such practices;
(ii) determining the approval process for transactions that are 'non-negligible' (i.e., transactions with a controlling shareholder that are classified by the audit committee as non-negligible, even though they are not deemed extraordinary transactions), as well as determining which types of transactions would require the approval of the audit committee, optionally based on criteria which may be determined annually in advance by the audit committee;
(iii) 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 "— Approval of Related Party Transactions under Israeli Law");
(iv) where the board of directors approves the working plan of the internal auditor, to examine such working plan before its submission to our board of directors and proposing amendments thereto;
(v) examining our internal controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of its responsibilities;
(vi) 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; and
(vii) establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees.

Internal Auditor

Under the Companies Law, the board of directors of an Israeli public company must appoint an internal auditor in accordance with the recommendation of the audit committee. Each of the following may not be appointed as internal auditor:

- a person (or a relative of a person) who holds more than 5% of the company's outstanding shares or voting rights;
- a person (or a relative of a person) who has the power to appoint a director or the general manager of the company;
- an office holder (including a director) of the company (or a relative thereof); or
- a member of the company's independent accounting firm, or anyone on his or her behalf.

The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures. The audit committee is required to oversee the activities and to assess the performance of the internal auditor as well as to review the internal auditor's work plan. Haim Halfon has been appointed as our internal auditor. Mr. Halfon is a certified internal auditor and a partner of Amit, Halfon (a member firm of the PKF International Limited).

The board of directors shall determine the direct supervisor of the internal auditor. The internal auditor is required to submit his findings to the audit committee, unless specified otherwise by the board of directors.

Compensation Committee

Our compensation committee currently consists of Roger J. Pomerantz, M.D. (Chairman), Hila Karah, Anthony J. Maddaluna and Issac Silberman. Dr. Pomerantz serves as the Chairman of the compensation committee. Each member of our compensation committee is independent under the NASDAQ Stock Market rules.

Under the Companies Law, the board of directors of a public company must appoint a compensation committee and adopt a compensation policy.

Under the Companies Law, the compensation committee is responsible, among other things, for (i) recommending to the board of directors regarding its approval of a compensation policy in accordance with the requirements of the Companies Law; (ii) overseeing the development and implementation of such compensation policy and recommending to the board of directors regarding any amendments or modifications that the compensation committee deems appropriate; (iii) determining whether to approve transactions concerning the terms of engagement and employment of our officers and directors that require compensation committee approval under the Companies Law; and (iv) resolving whether or not to exempt a transaction with a candidate for chief executive officer from shareholder's approval. In addition, any amendment of existing terms of office and employment of office holders (other than directors or controlling shareholders and their relatives, who serve as office holders) requires the sole approval of the compensation committee, if the committee determines that the amendment is not material in relation to its existing terms and if such amendment is in accordance with the approved compensation policy of the company then in effect.

Nominating and Governance Committee

Since we ceased to report as a foreign private issuer as of December 31, 2018, and in accordance with Nasdaq listing rules, we were required to either appoint a nominating and corporate governance committee for the nomination of our directors or have director nominees recommended for appointment by a majority of the board's independent directors in a vote in which only independent directors participate. Our board has opted for the first alternative and during 2018 established a nominating and governance committee of the board and adopted a charter.

Our nominating and governance committee consists of Hila Karah, who also serves as chairperson of the committee, along with Dr. John W. Kozarich and Anthony J. Maddaluna. Each of the members of our nominating and corporate governance committee is independent under the Nasdaq listing rules.

Our nominating and governance committee is responsible for identifying and making recommendations to the board of directors regarding candidates for directorships. In addition, the committee is responsible for developing our corporate governance policies, as appropriate, overseeing our corporate governance guidelines and reporting and making recommendations to the board concerning governance matters. The committee shall exercise such other powers and authority as are set forth in its charter, which is available on our website at *www.intecpharma.com*, as well as such other powers and authority as shall from time to time be assigned thereto by resolution of the board, to the extent permitted by law.

To date, our nominating and governance committee has not adopted a formal policy with respect to a fixed set of specific minimum qualifications for its candidates for membership on the board of directors. Instead, when considering candidates for director, the nominating and corporate governance committee will generally consider all of the relevant qualifications of board of directors candidates, including such factors as the candidate's relevant expertise upon which to be able to offer advice and guidance to management, having sufficient time to devote to the affairs of the company, demonstrated excellence in his or her field, having relevant financial or accounting expertise, having the ability to exercise sound business judgment, having the commitment to rigorously represent the long-term interests of our shareholders and whether the board candidates will be independent for purposes of the Nasdaq listing standards, as well as the current needs of the board of directors and the company.

In addition, while it does not have a formal policy on the board of directors' diversity, our nominating and governance committee will take into account a broad range of diversity considerations when assessing director candidates, including individual backgrounds and skill sets, professional experiences and other factors that contribute to the board of directors having an appropriate range of expertise, talents, experiences and viewpoints. Our nominating and governance committee will consider diversity criteria in view of the needs of the board of directors as a whole when making decisions on director nominations. In the case of incumbent directors whose terms of office are set to expire, our nominating and governance committee will also review, prior to nominating such directors for another term, such directors' overall service to the company during their term. Our nominating and corporate governance committee will conduct any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the board of directors. We have, from time to time, engaged an executive search firm to assist our nominating and corporate governance committee in identifying and recruiting potential candidates for membership on the board of directors.

Material Changes to Director Nomination Procedures

Except with respect to the establishment of a nominating and governance committee and adoption of a nominating and governance committee charter during 2018, there have been no material changes to the procedures by which shareholders may recommend nominees to our board of directors since such procedures were last disclosed.

Approval of Related Party Transactions under Israeli Law

Fiduciary Duties of Directors and Executive Officers

The Companies Law codifies the fiduciary duties that office holders owe to a company. Each person listed in the table under "Item 10. Directors, Executive Officers and Corporate Governance" is an office holder under the Companies Law.

An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. 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 loyalty requires that an office holder act in good faith and in the best interests of the company.

The duty of care includes a duty to use reasonable means to obtain:

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

The duty of loyalty includes a duty to:

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

Disclosure of Personal Interests of an Office Holder and Approval of Certain Transactions

The Companies Law requires that an office holder promptly disclose to the board of directors any personal interest that he or she may be aware of and all related material information or documents concerning any existing or proposed transaction with the company. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. A personal interest includes an interest of any person in an act or transaction of a company, including a personal interest of such person's relative or of a corporate body in which such person or a relative of such person is a 5% or greater shareholder, director or general manager or in which he or she has the right to appoint at least one director or the general manager, but excluding a personal interest stemming from one's ownership of shares in the company. A personal interest furthermore includes the personal interest of a person for whom the office holder holds a voting proxy or the 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. An office holder is not however obligated 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 defined as any of the following:

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

If it is determined that an office holder has a personal interest in a transaction, approval by the board of directors is required for the transaction, unless the company's articles of association provide for a different method of approval. Our articles of association do not provide otherwise. Further, so long as an office holder has disclosed his or her personal interest in a transaction, the board of directors may approve an action by the office holder that would otherwise be deemed a breach of the duty of loyalty. However, a company may not approve a transaction or action that is adverse to the company's interest or that is not performed by the office holder in good faith. An extraordinary transaction in which an office holder has a personal interest requires approval of the company's audit committee followed by the approval of the board of directors. The compensation of, or an undertaking to indemnify or insure, an office holder who is not a director requires approval by the company's compensation committee, followed by the approval of the company's board of directors, and, if such compensation arrangement or an undertaking to indemnify or insure is inconsistent with the company's stated compensation policy, or if the said office holder is the chief executive officer of the company (apart from a number of specific exceptions), then such arrangement is subject to the approval of a majority vote of the shares present and voting at a shareholders meeting, provided that either: (a) such majority includes at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in the approval of such compensation arrangement (excluding abstaining shareholders); or (b) the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in the approval of the compensation arrangement and who vote against the arrangement does not exceed 2% of the company's aggregate voting rights. We refer to this as the Special Approval for Compensation. Arrangements regarding the compensation, indemnification or insurance of a director require the approvals of the compensation committee, board of directors and shareholders by simple majority, and under certain circumstances, a Special Approval for Compensation.

Generally, a person who has a personal interest in a matter which is considered at a meeting of the board of directors or the audit committee may not be present at such a meeting or vote on that matter unless the chairman of the relevant committee or board of directors, as applicable, determines that he or she should be present in order to present the transaction that is subject to approval. Generally, if a majority of the members of the audit committee or the board of directors, as applicable, have 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. In the event a majority of the members of the board of directors have a personal interest in the approval of a transaction, then the approval thereof shall also require the approval of the shareholders.

Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions

Pursuant to the Companies Law, the disclosure requirements regarding personal interests that apply to directors and executive officers also apply to a controlling shareholder of a public company. The approval of the audit committee or the compensation committee, as the case may be, the board of directors and the shareholders of the company, in that order is required for (a) extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, (b) the engagement with a controlling shareholder or his or her relative, directly or indirectly, for the provision of services to the company, (c) the terms of engagement and compensation of a controlling shareholder or his or her relative who is not an office holder or (d) the employment of a controlling shareholder or his or her relative by the company, other than as an office holder (collectively referred as Transaction with a Controlling Shareholder). In addition, such shareholder approval requires one of the following, which we refer to as a Special Majority:

- at least a majority of the shares held by all shareholders who do not have a personal interest in the transaction and who are present and voting at the meeting approving the transaction, excluding abstentions; or
- the shares voted against the transaction by shareholders who have no personal interest in the transaction and who are present and voting at the meeting do not exceed 2% of the voting rights in the company.

To the extent that any such Transaction with a Controlling Shareholder is for a period extending beyond three years, approval is required once every three years, unless, with respect to certain transactions, the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

Arrangements regarding the compensation, indemnification or insurance of a controlling shareholder in his or her capacity as an office holder require the approval of the compensation committee, board of directors and shareholders by a Special Majority and the terms thereof may not be inconsistent with the company's stated compensation policy.

Pursuant to regulations promulgated under the Companies Law, certain transactions with a controlling shareholder, a relative thereof, or with a director, that would otherwise require approval of a company's shareholders may be exempt from shareholder approval upon certain determinations of the audit 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.

Shareholder Duties

Pursuant to the Companies Law, a shareholder has a duty to act in good faith and in a customary manner toward the company and its other shareholders and to refrain from abusing his or her power in the company, including, among other things, in voting at a general meeting and at shareholder class meetings with respect to the following matters:

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

In addition, a shareholder also has a general duty to refrain from discriminating against other shareholders.

In addition, certain shareholders also have a duty of fairness toward the company. These shareholders include any controlling shareholder, any shareholder who knows that he or she has the power to determine the outcome of a shareholder vote at a general meeting or a shareholder class meeting, and any shareholder who has the power to appoint or to prevent the appointment of an office holder of the company or other power towards the company. The Companies Law does not define the substance of the duty of fairness, 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.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the 1934 Exchange Act requires our directors and executive officers, and persons who beneficially own more than 10% of our shares, to file with the SEC initial reports of ownership and reports of changes in ownership of our ordinary shares and other equity securities.

SEC regulations require us to identify officers and directors, and persons who beneficially owned more than 10% of our shares who failed to file a required report or filed a late report during the most recent fiscal year. We reported as a "foreign private issuer" until December 31, 2018. As a result, our officers and directors, and persons who beneficially owned more than 10% of our shares, were exempt from filing reports of ownership and changes in ownership with the SEC under Section 16(a) of the Exchange Act during the year ended December 31, 2018, in accordance with Rule 3a12-3 under the Exchange Act.

As of January 1, 2019, our officers, directors and persons who beneficially owned more than 10% of our shares are required by SEC regulations to file forms pursuant to Section 16(a).

Code of Ethics

We have adopted a Code of Business Conduct and Ethics applicable to all of our directors and employees, including our Chief Executive Officer, Chief Financial Officer, controller or principal accounting officer or other persons performing similar functions, which is a "code of ethics" compliant with Item 406 of SEC Regulation S-K promulgated by the SEC and the Nasdaq Capital Market Listing Rules, which refers to Section 406(c) of the Sarbanes-Oxley Act.

The full text of the Code of Business Conduct and Ethics is posted on our website at *www.intecpharma.com*. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report and is not incorporated by reference herein. We will provide a copy of such code of ethics without charge upon request by mail or by telephone. 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 of Business Conduct and Ethics, 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.

Item 11. Executive Compensation.

Our named executive officers for 2018, which consist of our principal executive officer and the next two most-highly compensated executive officers are:

- Jeffrey Meckler, CEO;
- Walt. A. Linscott, Esq., Chief Business Officer; and
- Dr. Michael Gendreau, Chief Medical Officer.

Summary Compensation Table

The following table sets forth all of the compensation awarded to, earned by or paid to our named executive officers during 2017 and 2018. In addition, the table below reflects the compensation granted to our five most highly compensated office holders (as defined in the Companies Law) during or with respect to the year ended December 31, 2018 and 2017.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards(1) ($)	Non-equity Incentive Plan Compensation	All Other Compensation ($)	Total ($)
Jeffrey Meckler, CEO(2)	2018	500,000	213,750	-	658,229	-	48,000(4)	1,419,979
	2017	143,286(2)	385,000	-	419,143	-	4,000(4)	951,429
Walt A. Linscott, Esq.,	2018	300,000	130,613	-	254,884	-	48,000(5)	733,497
Chief Business Officer	2017	57,954	75,000	-	33,140	-	12,000(5)	178,094
Dr. Michael Gendreau,	2018	350,483(3)	111,008	-	408,265	-	12,081(6)	881,837
Chief Medical Officer (3)	2017	182,325(3)	-	-	-	-	-	182,325
Nadav Navon,	2018	210,329	52,273	-	290,011	-	93,166(7)	645,779
Chief Operating Officer	2017	168,735	70,842	-	156,842	-	63,530(7)	459,949
Nir Sassi,	2018	165,534	42,774	-	181,239	-	85,648(8)	475,195
Chief Financial Officer	2017	145,166	61,065	-	93,079	-	74,469(8)	373,779

(1) Represents the share-based compensation expenses recorded in our consolidated financial statements for the year ended December 31, 2018 and 2017, based on the option's fair value, calculated in accordance with accounting guidance for equity-based compensation. For a discussion of the assumptions used in reaching this valuation, see note 7 to our consolidated audited financial statements included in Item 8. Financial Statements and Supplemental Data.

(2) Mr. Meckler was appointed to act as our Vice Chairman in April 2017 and as our chief executive officer in July 2017. The salary for Mr. Jeffrey Meckler in 2017 includes $112,532 of director fees.

(3) Dr. Gendreau acted as our consultant since July 2017 until January 2018 and was appointed to act as our Chief Medical Officer in February 2018. The salary for Dr. Michael Gendreau in 2018 includes $57,150 of consulting fees and in 2017 is comprised entirely from consulting fees.

(4) For 2018, referenced amount is for employer contribution to 401K plan and for life insurance and other medical premiums. For 2017, referenced amount is for life insurance, and other medical premiums.

(5) For 2018 and 2017, referenced amount is for life insurance and other medical premiums.

(6) Referenced amount is for life insurance and other medical premiums.

(7) For 2018, the bulk of the other compensation consisted of $21,183 of automobile expenses, $31,788 deposits to severance funds, $11,597 of gross-up of related tax, $10,096 of social security payments and deposits of $15,712 to an education fund. For 2017, the bulk of such compensation consisted of $14,660 of automobile expenses, $25,419 of deposits to severance funds, $10,100 of social security payments, and deposits of $12,592 to an education fund.

(8) For 2018, the bulk of the other compensation consisted of $20,147 of automobile expenses, $24,897 deposits to severance funds, $15,580 of gross-up of related tax, $10,096 of social security payments and deposits of $12,360 to an education fund. For 2017, the bulk of the other compensation consisted of $15,029 of automobile expenses, $21,860 deposits to severance funds, $16,085 of gross-up of related tax, $10,100 of social security payments and deposits of $10,829 to an education fund.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning outstanding option awards as of December 31, 2018, for each named executive officer:

	Option Awards				
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date
Jeffrey Meckler, CEO	04/10/17(1)	40,000	80,000	5.32	04/10/2027
	05/01/17(2)	65,000	-	5.32	05/01/2027
	12/11/17(3)	126,667	253,333	6.70	12/11/2027
	06/28/18(4)	-	100,000	4.44	06/28/2025
Walt A. Linscott, Esq., Chief Business Officer	10/23/17(5)	20,000	40,000	8.56	10/23/2027
	12/11/17(6)	46,667	93,333	8.56	12/11/2027
Dr. Michael Gendreau, Chief Medical Officer	02/01/18(7)	-	250,000	6.10	02/01/2025

(1) The options vest over a period of three years from April 10, 2017, 33.3% on each anniversary of such date, ending April 10, 2020.

(2) The options vest over a period of nine months from May 1, 2017, 11.1% every month after such date, ending January 31, 2018.

(3) The options vest over a period of three years from December 11, 2017, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending December 11, 2020.

(4) The options vest over a period of three years from June 28, 2018, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending June 28, 2021.

(5) The options vest over a period of three years from October 23, 2017, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending October 23, 2020.

(6) The options vest over a period of three years from December 11, 2017, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending December 11, 2020.

(7) The options vest over a period of three years from February 1, 2018, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending February 1, 2021.

Employment Agreements of Chairman and Named Executive Officers

Our employees are employed under the terms prescribed in their respective personal contracts, in accordance with the decisions of our management. Under these employment contracts, the employees are entitled to the social benefits prescribed by law and as otherwise provided in their personal contracts. These employment contracts each contain provisions standard for a company in our industry regarding non-competition, confidentiality of information and assignment of inventions. Under current applicable employment laws, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

Services Agreement with Chairman of the Board of Directors, Dr. John W. Kozarich

Dr. Kozarich was elected to serve as our chairman of the board of directors in May 2016, and started his tenure on July 1, 2016. Under Dr. Kozarich's service agreement, he is entitled to an annual fee of $80,000, paid in four quarterly payments, as well as to reimbursement for out-of-pocket expenses incurred in connection with his services as chairman of the board of directors. Dr. Kozarich's service agreement is for a term of three years and can be terminated by either us or Dr. Kozarich upon 90 days' prior written notice, or immediately if Dr. Kozarich no longer acts as our chairman of the board of directors. Dr. Kozarich's agreement also includes customary non-disclosure, non-compete and ownership assignment of intellectual property undertakings.

Employment Agreement with Vice Chairman of the Board of Directors and Chief Executive Officer, Mr. Jeffrey A. Meckler

Mr. Meckler has served as our Vice Chairman of the Board since April 2017 and has served as Chief Executive Officer since July 2017. On December 11, 2017, Mr. Meckler entered into an employment with our wholly owned subsidiary, Intec Pharma, Inc., or Intec US, which superseded a services agreement that was previously entered into on August 29, 2017.

Under Mr. Meckler's employment agreement, he is currently entitled to receive a base salary at the annual rate of $500,000. In addition, Mr. Meckler is entitled to (i) paid holidays as generally provided by the Company to its personnel and (ii) five weeks of paid vacation each calendar year.

Mr. Meckler is also entitled to an annual bonus. For each calendar year beginning on or after January 1, 2018, during which Mr. Meckler's term of employment continues through December 31 of each such year, Mr. Meckler will be entitled to receive an annual bonus of up to 50% of his base salary. The annual bonus will be paid, subject to the achievement by Mr. Meckler of certain goals to be set by our board of directors after consultation with Mr. Meckler and further subject to the terms of our compensation policy then in effect, as approved by our shareholders.

The agreement with Mr. Meckler will terminate upon the earliest to occur of (i) a termination by the Company without cause, subject to 30 days' prior notice, (ii) immediate termination by the Company for cause (subject to a reasonable cure period, if curable), (iii) a termination by Mr. Meckler for good reason, subject to 30 days' prior notice (which will also serve as a cure period) to be provided to the Company within 60 days of the occurrence of the event that constitutes good reason, (iv) a termination by Mr. Meckler without good reason, subject to 90 days' prior notice, (v) Mr. Meckler's death, or (vi) a termination by the Company or Mr. Meckler by reason of Mr. Meckler's disability.

Upon termination by the Company without cause, Mr. Meckler will be entitled to a severance amount payable in six equal monthly installments, which will be equal to (i) 50% of Mr. Meckler's annual base salary as in effect prior to the termination date, (ii) 1/12th of Mr. Meckler's annual bonus for each completed month of such fiscal year provided the termination date is following June 30 of such fiscal year, and (iii) an amount equal to Mr. Meckler's cost of continued health insurance coverage for six months. In addition, any options that have not previously vested will become vested and exercisable immediately prior to such termination.

If Mr. Meckler's employment is terminated by the Company without cause or by Mr. Meckler for good reason during the one year period immediately following a change in control, then Mr. Meckler will be entitled to receive a lump-sum payment equal of up to two times the severance amount.

Mr. Meckler's employment agreement includes additional customary provisions, such as non-solicitation, non-competition, confidentiality, intellectual property assignment, participation in our medical and similar insurance plans and reimbursement of expenses.

Under the services agreement which was effective from May 1, 2017 through December 11, 2017, Mr. Meckler was paid $112,532 in fees and a cash bonus of $250,000.

On January 22, 2019, our board of directors, upon recommendation of the compensation committee, approved the payment of a 2018 cash performance bonus of $213,750 to Mr. Meckler. In addition in view of Mr. Meckler's credentials and capabilities, proven track record and our expectation of his continued contribution, our compensation committee and board of directors have resolved to approve the following adjustments to the compensation terms for Mr. Meckler, subject to his continuing service as CEO to the Company in 2019 and further subject to shareholder approval which is pending:

- an annual base salary of $540,000 effective January 1, 2019, reflecting an annual increase of $40,000.

- a grant of 125,000 options, at a per share exercise price equal to the average closing price of our ordinary shares on Nasdaq Stock Market in the last 30 trading days prior to the date of grant, but not less than the fair market value under Section 409A of the Code. Subject to Mr. Meckler's continued employment by us, the options will vest over three years according to the following schedule: 33% of the options shall vest and become exercisable on the first anniversary of the date of grant, and the remaining portion of the options shall vest and become exercisable on a pro rata basis in eight equal quarterly installments thereafter. The options will have a seven-year term, and will be subject to such other terms and conditions set forth in an option agreement to be entered into between us and Mr. Meckler and the provisions of our 2015 Equity Incentive Plan, or the 2015 Plan. In the event of (i) a change in control or (ii) the entry into a "Material Agreement" (as will be defined by our compensation committee and board of directors) any options that have not previously vested shall become vested and exercisable immediately prior to such event.

Employment Agreement with Chief Business Officer, Walt Addison Linscott, Esq.

Mr. Linscott has served as our Chief Administration Officer from October 2017 until July 2018 and as Chief Business Officer since July 9, 2018. On October 23, 2017, Mr. Linscott and Intec US entered into an employment agreement. Mr. Linscott is currently entitled to receive a base salary at the annual rate of $340,000. In addition, Mr. Linscott is entitled to (i) paid holidays as generally provided by the Company to its personnel and (ii) four weeks of paid vacation each calendar year.

Mr. Linscott is also entitled to an annual bonus. He received a bonus of $75,000 upon entering into the employment agreement. Going forward, for each calendar year beginning on or after January 1, 2018, during which Mr. Linscott's term of employment continues through December 31 of each such year, Mr. Linscott will be entitled to receive an annual bonus of up to 50% of his base salary. The annual bonus will be paid, subject to the achievement by Mr. Linscott of certain goals to be set by our board of directors after consultation with Mr. Linscott and further subject to the terms of our compensation policy then in effect, as approved by our shareholders.

The agreement with Mr. Linscott will terminate upon the earliest to occur of (i) a termination by the Company without cause, subject to 30 days' prior notice, (ii) immediate termination by the Company for cause (subject to a reasonable cure period, if curable), (iii) a termination by Mr. Linscott for good reason, subject to 30 days' prior notice (which will also serve as a cure period) to be provided to the Company within 60 days of the occurrence of the event that constitutes good reason, (iv) a termination by Mr. Linscott without good reason, subject to 90 days' prior notice, (v) Mr. Linscott's death, or (vi) a termination by the Company or Mr. Linscott by reason of Mr. Linscott's disability.

Upon termination by the Company without cause or by Mr. Linscott for good reason, Mr. Linscott will be entitled to a severance of 25% of Mr. Linscott's annual base salary and an amount equal to Mr. Linscott's cost of continued health insurance coverage for three months.

If Mr. Linscott's employment is terminated by the Company without cause or by Mr. Linscott for good reason during the one year period immediately following a change in control, then Mr. Linscott will be entitled to receive a lump-sum payment equal to the severance amount.

Mr. Linscott's employment agreement includes additional customary provisions, such as non-solicitation, non-competition, confidentiality, intellectual property assignment, participation in our medical and similar insurance plans and reimbursement of expenses.

On January 22, 2019, our board of directors, upon recommendation of the compensation committee, approved the payment of a 2018 cash performance bonus of $130,613, the grant of 90,000 options to purchase ordinary shares pursuant to the 2015 Plan, an annual 2019 base salary of $340,000, and an annual discretionary bonus target for 2019 of 50% of annual base salary to Mr. Linscott. The foregoing options have an exercise price of $7.268 per share, a seven-year term and, subject to Mr. Linscott's continued employment with us on the applicable vesting date, vest with respect to one-third of the ordinary shares on the first anniversary of the date of grant and with respect to the balance of the ordinary shares shall vest over two years in eight equal quarterly installments following the first anniversary of the date of grant.

Employment Agreement with Chief Medical Officer, Michael Gendreau, MD.

Dr. Michael Gendreau has served as our Chief Medical Officer since February 1, 2018. Under an employment agreement dated February 1, 2018, entered into between Dr. Gendreau and Intec US, Dr. Gendreau is employed on a part-time basis (80% position) and devotes four days per week. Dr. Gendreau is currently entitled to receive a base salary at the annual rate of $336,000. In addition, Dr. Gendreau is entitled to (i) paid holidays as generally provided by the Company to its personnel and (ii) four weeks of paid vacation each calendar year.

Dr. Gendreau is also entitled to an annual bonus. For each calendar year beginning on or after January 1, 2018, during which Dr. Gendreau's term of employment continues through December 31 of each such year, Dr. Gendreau will be entitled to receive an annual bonus of up to 40% of his base salary. The annual bonus will be paid, subject to the achievement by Dr. Gendreau of certain goals to be set by our board of directors and subject to the terms of our compensation policy then in effect, as approved by our shareholders.

The agreement with Dr. Gendreau will terminate upon the earliest to occur of (i) a termination by the Company without cause, subject to 30 days' prior notice, (ii) immediate termination by the Company for cause (subject to a reasonable cure period, if curable), (iii) a termination by Dr. Gendreau for good reason, subject to 30 days' prior notice (which will also serve as a cure period) to be provided to the Company within 60 days of the occurrence of the event that constitutes good reason, (iv) a termination by Dr. Gendreau without good reason, subject to 90 days' prior notice, (v) Dr. Gendreau's death, or (vi) a termination by the Company or Dr. Gendreau by reason of Dr. Gendreau's disability.

Upon termination by the Company without cause or by Dr. Gendreau for good reason, Dr. Gendreau will be entitled to a severance of 25% of Dr. Gendreau's annual base salary and an amount equal to Dr. Gendreau's cost of continued health insurance coverage for twelve months.

If Dr. Gendreau's employment is terminated by the Company without cause or by Dr. Gendreau for good reason during the one year period immediately following a change in control, then Dr. Gendreau will be entitled to receive a lump-sum payment equal to the severance amount.

Dr. Gendreau's employment agreement includes additional customary provisions, such as non-solicitation, confidentiality, intellectual property assignment, participation in our medical and similar insurance plans and reimbursement of expenses.

On January 22, 2019, our board of directors, upon recommendation of the compensation committee, approved the payment of a 2018 cash performance bonus of $110,008, the grant 110,000 options to purchase ordinary shares pursuant to the 2015 Plan, an annual 2019 base salary of $336,000, and an annual discretionary bonus target for 2019 of 40% of annual base salary to Dr. Gendreau. The foregoing options have an exercise price of $7.268 per share, a seven-year term and, subject to Dr. Gendreau's continued employment with us on the applicable vesting date, vest with respect to one-third of the ordinary shares on the first anniversary of the date of grant and with respect to the balance of the ordinary shares shall vest over two years in eight equal quarterly installments following the first anniversary of the date of grant.

Current Compensation Policy

As approved by our shareholders, and as required by the Companies Law, we have adopted a compensation policy regarding the terms of office and employment of its "office holders" (as defined under the Companies Law, which includes directors, the CEO, other executive officers and any other managers directly subordinate to the CEO), including cash compensation, equity-based awards, releases from liability, indemnification and insurance, severance and other benefits. Each of the named executive officers is an "office holder" within the meaning of the Companies Law. The compensation policy is reviewed from time to time by our compensation committee and our board of directors to ensure its appropriateness, and is required to be brought at least once every three years to our shareholders for reassessment and approval.

Our most recent compensation policy was last approved at our annual general meeting of shareholders that was held in May 2017 and certain amendments to the compensation policy were approved by our shareholders in December 2017 and June 2018. Following a review of the compensation policy by our compensation committee and board of directors, our compensation committee and board have approved, and recommended that our shareholders approve, certain amendments to the compensation policy related to non-employee director cash compensation and officer and director liability insurance which are pending shareholder approval.

The compensation policy must be based on certain considerations, must include certain provisions and needs to reference certain matters as set forth in the Companies Law. The compensation policy must be approved by the board of directors after considering the recommendations of the compensation committee. In addition, the compensation policy needs to be approved by our shareholders by a simple majority, provided that (i) such majority includes a majority of the votes cast by the shareholders who are not controlling shareholders and who do not have a personal interest in the matter, present and voting (abstentions are disregarded) or (ii) the votes cast by shareholders who are not controlling shareholders and who do not have a personal interest in the matter who were present and voted against the compensation policy, constitute 2% or less of the voting power of the company. Such majority determined in accordance with clause (i) or (ii) is hereinafter referred to as the "Compensation Majority."

To the extent a compensation policy is not approved by shareholders at a duly convened shareholders meeting or by the Compensation Majority, the board of directors of a company may override the resolution of the shareholders following a re-discussion of the matter by the board of directors and the compensation committee and for specified reasons, and after determining that despite the rejection by the shareholders, the adoption of the compensation policy is in the best interest of the company. A compensation policy that is for a period of more than three years must be approved in accordance with the above procedure once in every three years.

Notwithstanding the above, the amendment of existing terms of office and employment of office holders (other than directors or controlling shareholders and their relatives, who serve as office holders) requires the sole approval of the compensation committee, if such committee determines that the amendment is not material in relation to its existing terms.

The compensation policy must serve as the basis for decisions concerning the consolidated financial terms of employment or engagement of office holders, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The compensation policy must relate to certain factors, including advancement of the company's objectives, the company's business plan and its long-term strategy, and creation of appropriate incentives for office holders. 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;
- the office holder's roles and responsibilities and prior compensation agreements with him or her;
- the ratio between the cost of the terms of employment of an office holder and the cost of the compensation of the other employees of the company, including those employed through manpower companies, in particular the ratio between such cost and the average and median compensation of the other employees of the company, as well as the impact such disparities may have on the work relationships in the company;
- the possibility of reducing variable compensation, if any, at the discretion of the board of directors; and the possibility of setting a limit on the exercise value of non-cash variable equity-based compensation; and
- as to severance compensation, if any, the period of service of the office holder, 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 an office holder 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 consolidated financial statements;
- the minimum holding or vesting period for variable, equity-based compensation; and
- maximum limits for severance compensation.

Potential Payments Upon Termination or Change in Control

See "Executive Compensation—Employment Agreements of Chairman and Named Executive Officers."

Our compensation policy provides that we may provide certain benefits to our office holders (which includes directors, the CEO, other executive officers and any other managers directly subordinate to the CEO) upon termination or change in control. Under the compensation policy, office holders may be awarded, subject to the approvals required in each case under the Companies Law (i) severance pay in full (other than in the case of termination for cause), (ii) advance notice of termination of up to six months during which the office holder would be eligible to receive bonuses with respect to this period and would also continue to accrue vesting of options awarded, (iii) a bonus upon termination in return for a commitment not to compete with us in an amount equal to two months' salary for each three months' non-compete, up to a maximum of twelve months' salaries, and (iv) a retirement bonus of up to six months' salary for office holders that served for over five years or the CEO and two months' salary for an office holder that served for less than five years but more than three years. In addition, to the foregoing, in the case of a change in control, an office holder may be entitled to the following (i) accelerated vesting of outstanding options, (ii) an extension in the exercise period of options for up to six months from termination, (iii) up to 12 months' base salary and benefits from date of termination, and (iv) a cash bonus of up to three monthly salaries.

Director Compensation

The following table provides certain information concerning the compensation for services rendered in all capacities by each non-employee director serving on our board during the year ended December 31, 2018, other than Mr. Meckler, our Chief Executive Officer, who did not receive additional compensation for his services as director and whose compensation is set forth in the Summary Compensation Table found elsewhere in this Item 11.

Name	Fees earned ($)	Stock awards ($)	Option awards ($) (1)	Non-equity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation ($)	Total ($)
Dr. John W. Kozarich	80,000	-	79,257	-	-	-	159,257
Gil Bianco	49,516	-	18,857	-	-	-	68,373
Hila Karah	52,736	-	19,150	-	-	-	71,886
Issac Silberman	53,530	-	18,857	-	-	-	72,387
Anthony J. Maddaluna	44,922	-	24,329	-	-	-	69,251
Roger J. Pomerantz (2)	32,076	-	18,139	-	-	-	50,215
William B. Hayes (3)	27,500	-	12,054	-	-	-	39,554

(1) Represents the share-based compensation expenses recorded in our consolidated financial statements for the year ended December 31, 2018 and 2017, based on the option's fair value, calculated in accordance with accounting guidance for equity-based compensation. For a discussion of the assumptions used in reaching this valuation see note 7 to our consolidated audited financial statements included in Item 8. Financial Statements and Supplemental Data.

(2) Roger Pomerantz was appointed to our board of directors effective March 22, 2018.

(3) William Hayes was appointed to our board of directors effective June 28, 2018.

Our independent, non-employee directors' receive a yearly retainer of US$45,000 with an additional payment of US$5,000 per membership at a committee of the board (with the exception of the chairman of the audit committee, which is entitled for a payment of US$10,000 in lieu of the US$5,000 payment referenced above). Upon first becoming a member of the board (whether appointed by the board or elected by the shareholders) and on each anniversary thereafter (each is referred to below as the "date of grant"), a director is awarded a grant of options to purchase 20,000 ordinary shares of the Company, provided the director is still in office at the time of the grant and vesting of the option. The options have the following terms: (i) the options vest over a period of three (3) years, 1/3 of which vest on the first anniversary date of the grant, and the additional 2/3 vest in eight (8) quarterly installments, (ii) the term of the options is seven (7) years after the grant date, unless they have been exercised or cancelled in accordance with the Plan, and (iii) the exercise price of each option is equal to the average price of our ordinary shares on Nasdaq in the last 30 days prior to the date of grant, but, with respect to U.S. taxpayers, not less than the fair market value under Section 409A of the Code.

In 2019, following the evaluation of our compensation committee, our board of directors evaluated the director compensation scheme and concluded that an amendment was appropriate with respect to the amount of cash paid to directors for service on a committee of the board and for acting as chair of a committee. The proposed amendment, which is pending shareholder approval, would update the additional annual payment to a non-employee director for service on a board committee as follows: $7,500 (or $15,000 for the chairperson) per membership at the audit committee, $6,000 (or $10,000 for the chairperson) per membership at the compensation committee and $5,000 (or $7,500 for the chairperson) per membership at the nominating and governance committee. It is being clarified that the payment for the chairpersons is in lieu of (and not in addition) to the payments referenced above for committee membership.

Equity Compensation Plans

We maintain the 2005 Share Option Plan, or the 2005 Plan, which was adopted by our board of directors on September 19, 2005, that provides for granting options to our directors, officers, employees, consultants, advisers and service providers. As of December 31, 2018, the 2005 Plan has expired, however 295,452 options that were previously granted under the 2005 Plan are still outstanding and remain subject to its terms and conditions. Such options will remain outstanding until the earlier of their exercise or expiration in accordance with the terms of the 2005 Plan and the applicable grant agreement. In addition, as of December 31, 2018, we had outstanding options to purchase 8,035 ordinary shares that were issued to consultants outside of the 2005 Plan; all of these options are vested and outstanding. Of such outstanding options, options to purchase 126,093 ordinary shares were vested as of December 31, 2018, with a weighted average exercise price of NIS 42.1 per share and will expire between 2019 and 2020.

The 2005 Plan permitted options to be awarded to Participants (as such term is defined in the 2005 Plan) pursuant to Section 102 of the Israeli Income Tax Ordinance (New Version) 1961, or the Ordinance, and Section 3(i) of the Ordinance, based on entitlement and compliance with the terms for receiving options under these sections of the Ordinance. Section 102 of the Ordinance provides to employees, directors and officers who are not controlling shareholders (i.e., such persons are not deemed to hold 10% of the company's share capital, or to be entitled to 10% of the company's profits or to appoint a director to the company's board of directors) and are Israeli residents, favorable tax treatment for compensation in the form of shares or options issued or granted, as applicable, to a trustee under the "capital gains track" for the benefit of the applicable employee, director or officer and are (or were) to be held by the trustee for at least two years after the date of grant or issuance. Options granted under Section 102 of the Ordinance will be deposited with a trustee appointed by the company in accordance with Section 102 of the Ordinance and the relevant income tax regulations and guidelines, and will be granted in the employee income track or the capital gains track. The 2005 Plan is managed by our board of directors or any other committee or person that our board of directors authorizes for this purpose. According to our board of directors' resolution of September 19, 2005, the options granted under Section 102 of the Ordinance were granted under the capital gains track. The 2005 Plan also permitted us to grant options to U.S. residents, which may qualify as "incentive stock options" within the meaning of Section 422 of the Code and to residents of other jurisdictions.

Options granted under the 2005 Plan are subject to applicable vesting schedules and generally for all awards granted after May 27, 2010, expire six years from the grant date (however, generally, awards granted prior to such date, expire ten years from the grant date).

Upon the termination of a Participant's engagement with us for any reason other than death, retirement, disability or due cause, all unvested options allocated will automatically expire 90 days after the termination, unless expired earlier due to their term. If the Participant's engagement was terminated for cause (as defined in the 2005 Plan), the Participant's right to exercise any unexercised options, awarded and allocated in favor of such Participant, whether vested or not, will immediately cease and expire as of the date of such termination. If the Participant dies, retires or is disabled, any vested but unexercised options will automatically expire 12 months from the termination of the engagement, unless expired earlier due to their term.

In the event of (i) the sale of all or substantially all of our assets; (ii) a sale (including an exchange) of all or substantially all of our share capital; or (iii) a merger, consolidation or like transaction of ours with or into another corporation, then, subject to obtaining the applicable approvals of the Israeli tax authorities, the board of directors in its sole discretion shall resolve: (a) if and how any unvested options shall be canceled, replaced or accelerated; (b) if and how any vested options (including options with respect to which the vesting period has been accelerated according to the foregoing) shall be exercised, replaced and/or sold by a trustee or us (as the case may be) on the behalf of the respective Israeli Participants; and (c) how any underlying shares issued upon exercise of the options and held by a trustee on behalf any Israeli Participants shall be replaced and/or sold by such trustee on behalf of the Israeli Participants.

On January 6, 2016, our board of directors adopted the 2015 Plan. Originally, the maximum number of ordinary shares reserved for issuance under the 2015 Plan was 700,000, subject to future adjustments. On July 25, 2016, the board of directors increased the aggregate number of shares issuable under the 2015 Plan by 700,000 shares, another increase by 2,100,000 was approved by the general meeting of our shareholders on December 11, 2017 and another increase by 1,000,000 was approved by the general meeting of our shareholders on June 28, 2018. In connection with the aforementioned increase of 2016, we did not obtain shareholder approval as required under Nasdaq listing rules and instead followed home practice rules that do not require such approval. Similar to the 2005 Plan, the 2015 Plan permits options to be awarded to Participants (as such term is defined in the 2015 Plan) pursuant to Section 102 of the Ordinance and Section 3(i) of the Ordinance, based on entitlement and compliance with the terms for receiving options under these sections of the Ordinance. The 2015 Plan also permits us to grant options to U.S. residents, which may qualify as "incentive stock options" within the meaning of Section 422 of the Code, and to residents of other jurisdictions.

Options under the 2015 Plan are subject to applicable vesting schedules and will generally expire up to ten years from the grant date.

Upon the termination of a Participant's engagement with us for any reason other than death, retirement, disability or due cause, any vested but unexercised options will automatically expire 90 days after termination, unless earlier expired due to their term, and all unvested options will expire upon the date of termination. If the Participant's engagement was terminated for cause (as defined in the 2015 Plan), the Participant's right to exercise any unexercised options, awarded and allocated in favor of such Participant, whether vested or not, will immediately cease and expire as of the date of such termination. If the Participant dies, retires or is disabled, any vested but unexercised options will automatically expire 12 months from the termination of the engagement, unless expired earlier due to their term and all unvested options will expire upon the date of termination.

As of December 31, 2018, outstanding awards under the 2015 Plan totaled 3,138,183 ordinary shares and an additional 1,343,593 awards were available for grant. Of the 3,138,183 outstanding options, options to purchase 879,529 ordinary shares were vested as of December 31, 2018, with a weighted average exercise price of $5.48 per share and will expire between 2024 and 2027.

The following table provides certain aggregate information with respect to our ordinary shares that may be issued under our equity compensation plans in effect as of December 31, 2018.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights(1)	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in first column)
Equity compensation plans approved by security holders	-	-	-
Equity compensation plans not approved by security holders-2015 Plan	3,138,183	$ 5.85	1,343,593
Equity compensation plans not approved by security holders-2005 Plan	303,487	NIS 26.8	-
Total	3,441,670		1,343,593

(1) The weighted average remaining term for the expiration of stock options under the 2005 Plan is 0.97 years. The weighted average remaining term for the expiration of stock options under the 2015 Plan is 6.51 years.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth information with respect to the beneficial ownership of our shares as of February 22, 2019 by:

- each person or entity known by us to beneficially own 5% or more of our outstanding ordinary shares;
- each of our executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

Applicable percentage ownership is based on 33,232,988 ordinary shares outstanding as of February 22, 2019. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power. Ordinary shares issuable under options or warrants that are exercisable within 60 days after February 22, 2019 are deemed beneficially owned and such shares are used in computing the percentage ownership of the person holding the options or warrants, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. The information contained in the following table is not necessarily indicative of beneficial ownership for any other purpose, and the inclusion of any shares in the table does not constitute an admission of beneficial ownership of those shares.

Unless otherwise indicated below, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares, except to the extent that authority is shared by spouses under community property laws. Unless otherwise indicated, the address of each beneficial owner is c/o Intec Pharma Ltd., 12 Hartom Street, Har Hotzvim, Jerusalem 9777512, Israel.

We are not owned or controlled, directly or indirectly, by another corporation or by any foreign government. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our Company.

Name of Beneficial Owner	Shares Beneficially Owned	
	Ordinary Shares	Percentage
Persons or entities holding 5% or more our outstanding ordinary shares		
Adage Capital Partners, L.P. (1)	1,700,000	5.1%
Meitav Dash Investments Ltd. (2)	2,720,446	8.2%
venBio Select Advisor LLC. (3)	2,500,000	7.5%
Dexcel Pharma Technologies Ltd. (4)	5,150,848	15.5%
Executive officers and directors		
Jeffrey A. Meckler	380,094(5)	1.1%
John W. Kozarich	201,413(6)	*
Nadav Navon	158,165(7)	*
Walt A. Linscott	88,333(8)	*
R. Michael Gendreau	83,333(9)	*
Nir Sassi	82,897(10)	*
Anthony J. Maddaluna	36,904(11)	*
Gil Bianco	43,251(12)	*
Issac Silberman	38,251(13)	*
Hila Karah	25,751(14)	*
Roger J. Pomerantz	6,667(15)	*
William B. Hayes	-	-
All executive officers and directors as a group (12 persons)	1,145,059(16)	3.3%

* Less than 1%

(1) Based on information contained in Schedule 13G/A filed with the SEC on February 13, 2019 jointly by Adage Capital Partners, L.P.("ACP"), Adage Capital Partners GP, L.L.C. ("ACPGP"), Adage Capital Advisors, L.L.C. ("ACA"), Robert Atchinson and Phillip Gross. ACP directly owns the referenced ordinary shares, ACPGP is the general partner of ACP, ACA is the managing member of ACPGP and general partner of ACP and Mr. Atchinson and Mr. Gross are managing members of ACA and ACPGP and the general partner of ACP. The address of the foregoing reporting persons is 200 Clarendon Street, 52nd floor, Boston, Massachusetts 02116.

(2) Based on information contained in a Schedule 13G/A filed with the SEC on February 7, 2019 jointly by Meitav Dash Investments Ltd. ("Meitav Investments") and Meitav Dash Provident Funds and Pension Ltd. ("Meitav Funds") The ordinary shares are beneficially owned by various direct or indirect, majority or wholly-owned subsidiaries of Meitav Investments (the "Subsidiaries"). Meitav Investments, Meitav Funds and the Subsidiaries disclaim any beneficial ownership of the ordinary shares referred to herein in excess of their actual pecuniary interest therein and each of Meitav Investments, Meitav Funds and the Subsidiaries disclaim beneficial ownership of any such ordinary shares. The address of Meitav Investments and Meitav Funds is 30 Derekh Sheshet Ha-Yamim, Bene-Beraq, Israel.

(3) Based on information contained in a Schedule 13G/A filed with the SEC on February 14, 2019 jointly by (i) venBio Select Advisor LLC, ("venBio"), which provides investment advisory and management services and has acquired our ordinary shares for investment purposes on behalf of venBio Select Fund LLC, and certain managed accounts and (ii) Dr. Behzad Aghazadeh who serves as the portfolio manager and controlling person of venBio. The address of venBio and Dr. Aghazadeh is 110 Greene Street, Suite 800, New York, NY 10012.

(4) Based on information contained in a Schedule 13G/A filed with the SEC on February 14, 2019 jointly by Dexcel Pharma Technologies Ltd. ("DPT") and Dan Oren. Dan Oren is the President and Chief Executive Officer and ultimately the sole shareholder of DPT. The address of DPT and Mr. Oren is 1 Dexcel Street, Or Akiva, 30600000, Israel.

(5) Consists of (i) 76,761 ordinary shares, and (ii) 303,333 ordinary shares issuable upon exercise of outstanding, of which 71,667 will vest within 60 days of February 22, 2019.

(6) Consists of (i) 51,761 ordinary shares, and (ii) 149,652 ordinary shares issuable upon exercise of outstanding options.

(7) Consists of (i) 19,456 ordinary shares, and (ii) 138,709 ordinary shares issuable upon exercise of outstanding options of which 15,344, will vest within 60 days of February 22, 2019.

(8) Consists of 88,333 ordinary shares issuable upon exercise of outstanding options of which 16,667 will vest within 60 days of February 22, 2019.

(9) Consists of 83,333 ordinary shares issuable upon exercise of outstanding options.

(10) Consists of 82,897 ordinary shares issuable upon exercise of outstanding options of which 8,540 will vest within 60 days of February 22, 2019.

(11) Consists of (i) 28,570 ordinary shares, and (ii) 8,334 ordinary shares issuable upon exercise of outstanding options of which 1,667 will vest within 60 days of February 22, 2019.

(12) Consists of (i) 10,000 ordinary shares, and (ii) 33,251 ordinary shares issuable upon exercise of outstanding options of which 7,500 will vest within 60 days of February 22, 2019.

(13) Consists of (i) 5,000 ordinary shares, and (ii) 33,251 ordinary shares issuable upon exercise of outstanding options of which 7,500 will vest within 60 days of February 22, 2019.

(14) Consists of 25,751 ordinary shares issuable upon exercise of outstanding options.

(15) Consists of 6,667 ordinary shares issuable upon exercise of outstanding options which will vest within 60 days of February 22, 2019.

(16) Consists of (i) 191,548 ordinary shares, and (ii) 953,511 ordinary shares issuable upon exercise of outstanding options, of which 135,552 will vest within 60 days of days of February 22, 2019.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Certain Relationships and Related Transactions

During years ended December 31, 2018 and 2017, except as set forth below, we did not participate in any transaction, and we are not currently participating in any proposed transaction, or series of transactions, in which the amount involved exceeded the lesser of $120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years, and in which, to our knowledge, any of our directors, officers, five percent beneficial security holders, or any member of the immediate family of the foregoing persons had, or will have, a direct or indirect material interest.

Agreements with Officers, Directors and Others

Compensation arrangements for our executive officers and directors are described in the section entitled "Item 10. Executive Compensation."

Giora Carni served as our Director of Technology from October 2014 as well as member of our board of directors from March 2016 to December 2017. In May 2017, following the resignation of Zeev Weiss, Mr. Carni became our interim Chief Executive Officer until July 2017 when Mr. Meckler, our current Chief Executive Officer, was appointed. As of our general meeting of shareholders held on December 11, 2017, Mr. Carni's services as a director of the Company ended, and he currently serves as a consultant (on a 50% basis). Prior to his resignation Mr. Carni was entitled to a monthly gross salary of NIS 35,000 (70% scope of employment), and to social benefits, such as annual paid vacation days, severance pay, recuperation pay, manager's insurance, sick leave and studies fund. In addition, we provided Mr. Carni with a leased company car and a mobile phone. In December 2017, following the lapse of this tenure as a member our board of directors, we entered into a new employment agreement with Mr. Carni. Mr. Carni's agreement (50% scope of employment) was for a term starting on December 12, 2017 and ending June 11, 2019 for a monthly fee of NIS 35,000.

Additionally, we have entered into employment agreements with our former directors, Messrs. Zeev Weiss, and Zvi Joseph for their continued service to the Company (on a reduced scope of work and for a limited term). Mr. Weiss' agreement (40% scope of employment) is for a term starting on October 1, 2017 and ending June 30, 2019 for a monthly fee of NIS 25,000, and Mr. Joseph's agreement (50% scope of employment) is for a term starting on December 12, 2017 and ending June 11, 2019 for a monthly fee of NIS 25,000.

As of December 31, 2018, Mr. Carni held options to purchase 70,909 ordinary shares with a weighted exercise price of NIS 16.25, of which all will vest in the event that a material agreement, as defined in our previous compensation policy, is signed between us and a third party. In addition, as of December 31, 2018, Mr. Carni also held options to purchase 148,000 ordinary shares that will vest over time with a weighted exercise price of $6.00, of which 80,000 will vest over time or immediately upon the earlier of: (i) the closing of a merger agreement, as defined in our 2015 Plan, or (ii) if Mr. Carni is terminated without cause prior to June 11, 2019. As of December 31, 2018, 83,438 options are vested.

As of December 31, 2018, Mr. Joseph held options to purchase 75,463 ordinary shares with a weighted exercise price of NIS 30.1, of which 26,000 are vested and 49,463 will vest in the event that a material agreement, as defined in our previous compensation policy, is signed between us and a third party. In addition, as of December 31, 2018, Mr. Joseph also held options to purchase 95,250 ordinary shares that will vest over time or immediately upon the earlier of: (i) the closing of a merger agreement, as defined in our 2015 Plan, or (ii) if Mr. Joseph is terminated without cause prior to June 11, 2019 with an exercise price of $6.15 per share. As of December 31, 2018, 54,219 options are vested.

As of December 31, 2018, Mr. Weiss held options to purchase 57,023 ordinary shares with a weighted exercise price of NIS 15.19, of which all will vest in the event that a material agreement, as defined in our previous compensation policy, is signed between us and a third party. In addition, as of December 31, 2018, Mr. Weiss also held options to purchase 35,000 ordinary shares that will vest over time (or immediately upon the earlier of: (i) the closing of a merger agreement, as defined in our 2015 Plan, or (ii) if Mr. Weiss is terminated without cause prior to June 30, 2019 with an exercise price of $7.44 per share. As of December 31, 2018, 21,385 options are vested.

Indemnification Agreements and Directors' and Officers' Liability Insurance

Our articles of association permit us to exculpate, indemnify and insure our directors and officeholders to the fullest extent permitted by the Companies Law. We have obtained directors' and officers' insurance for each of our officers and directors and have entered into indemnification agreements with all of our current officers and directors.

We have entered into indemnification and exculpation agreements with each of our current office holders and directors exculpating them to the fullest extent permitted by the law and our articles of association and undertaking to indemnify them to the fullest extent permitted by the law and our articles of association, including with respect to liabilities resulting from this Annual Report, to the extent such liabilities are not covered by insurance.

We also maintain an insurance policy that insures our directors and officers against certain liabilities, including liabilities arising under applicable securities laws.

2017 Private Placement

In March 2017, we completed a private placement of 2,289,638 of our ordinary shares with various investors at a price of $4.40 per share, for gross proceeds of approximately $10 million. The chairman of our board of directors, Dr. John Kozarich, and two other (former) directors, Messrs. Zvi Joseph and Giora Carni, participated in the private placement. On April 7, 2017, we filed a registration statement under the Securities Act to register for resale most of the ordinary shares issued in the private placement for those purchasers which elected to register their ordinary shares.

Policies and Procedures for Related Party Transactions

See "Item 10. Directors, Executive Officers and Corporate Governance — Corporate Governance — Approval of Related Party Transactions Under Israeli Law" for a discussion of our policies and procedures related to related party transactions and conflicts of interest.

Director Independence

Our board of directors has determined that all of our directors except for Mr. Meckler are independent under the Nasdaq listing rules.

Item 14. Principal Accounting Fees and Services.

Kesselman & Kesselman, Certified Public Accountant (Israel), a member firm of PricewaterhouseCoopers International Limited, an independent registered public accounting firm, served as our independent public accountants for the fiscal years ended December 31, 2018 and 2017, for which audited consolidated financial statements appear in this Annual Report.

The following table presents the aggregate fees for professional services rendered by such accountants to us during their respective term as our principal accountants in 2018 and 2017.

	2018	2017
	(US$ in thousands)	(US$ in thousands)
Audit Fees[1]	186	189
Audit-Related fees [2]	23	-
Tax Fees [3]	20	17
All Other Fees	-	-
Total	229	206

(1) Audit fees consists of services that would normally be provided in connection with statutory and regulatory filings or engagements, including services that generally only the independent accountant can reasonably provide and includes audit services in connection with our public offerings in the United States in 2017 and 2018.

(2) Audit-related fees consist of assurance and related services by the principal accountant that are reasonably related to the performance of the audit or review of our consolidated financial statements and are not reported under item (1).

(3) Tax fees relate to tax compliance, planning and advice.

Pre-Approval Policies and Procedures

Our audit committee provides assistance to our board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our audit committee also oversees the audit efforts of our independent accountants and takes those actions that it deems necessary to satisfy itself that the accountants are independent of management. Our audit committee has authorized all auditing and non-auditing services provided by Kesselman and Kesselman during 2018 and 2017 and the fees paid for such services.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report:

(1) The financial statements are filed as part of this Annual Report under "Item 8. Financial Statements and Supplementary Data."

(2) The financial statement schedules are omitted because they are either not applicable or the information required is presented in the financial statements and notes thereto under "Item 8. Financial Statements and Supplementary Data."

(3) The exhibits listed in the following Exhibit Index are filed, furnished or incorporated by reference as part of this Annual Report.

(b) Exhibits

See the Exhibit Index immediately preceding the signature page of this Annual Report.

Item 16. Form 10-K Summary

Not Applicable

Exhibit Index

Exhibit No.	Exhibit Description
3.1	Certificate of Incorporation of Orly Guy Ltd., dated October 23, 2000 (incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form F-1 filed with the SEC on June 9, 2015)
3.2	Certificate of Name Change of Orly Guy Ltd. to Intec Pharmaceutical (2000) Ltd., dated February 7, 2001 (incorporated herein by reference to Exhibit 3.2 to the Company's Registration Statement on Form F-1 filed with the SEC on June 9, 2015)
3.3	Certificate of Name Change of Intec Pharmaceutical (2000) Ltd. to Intec Pharma Ltd., dated March 15, 2004 (incorporated herein by reference to Exhibit 3.3 to the Company's Registration Statement on Form F-1 filed with the SEC on June 9, 2015)
3.4*	Articles of Association of Intec Pharma Ltd., as amended
4.1	Specimen share certificate (incorporated herein by reference to Exhibit 2.1 to the Company's Annual Report on Form 20-F filed with the SEC on March 9, 2018)
10.1†	Joint Venture for R&D, dated June 1, 2000, by and between Yissum Research Development Company of the Hebrew University of Jerusalem and Intec Pharmaceutical Partnership Ltd. (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form F-1 filed with the SEC on June 9, 2015)
10.2†	Notice of Extension Letter, dated October 5, 2004, from Intec Pharma Ltd. to Yissum Research Development Company of the Hebrew University of Jerusalem (incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form F-1 filed with the SEC on June 9, 2015)
10.3	Amendment, dated July 13, 2005, by and between Yissum Research Development Company of the Hebrew University of Jerusalem and Intec Pharma Ltd., to the Joint Venture for R&D Agreement dated June 1, 2000 (incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form F-1 filed with the SEC on June 9, 2015)
10.4	Research Agreement, dated January 15, 2008, by and between Yissum Research Development Company of the Hebrew University of Jerusalem and Intec Pharma Ltd. (incorporated herein by reference to Exhibit 10.4 to the Company's Registration Statement on Form F-1 filed with the SEC on June 9, 2015)
10.5	Compensation Policy for Intec Pharma Ltd.'s Directors and Officers, as amended (incorporated herein by reference to Appendix B to Exhibit 99.1 to the Company's Report on Form 6-K filed with the SEC on May 23, 2018)
10.6+	Intec Pharma Ltd. 2005 Share Option Plan (incorporated herein by reference to Exhibit 10.6 to the Company's Registration Statement on Form F-1 filed with the SEC on June 9, 2015)
10.7+	Intec Pharma Ltd. 2015 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8 filed with the SEC on February 25, 2016)
10.8	Unprotected Lease Agreement between Intec Pharma Ltd. and R.M.P.A. Assets Ltd., dated June 2, 2003, together with supplements thereto dated as of April 21, 2004, January 1, 2006, December 15, 2009, January 18, 2011, October 28, 2015 and December 31, 2017 (incorporated herein by reference to Exhibit 4.8 to the Company's Annual Report on Form 20-F filed with the SEC on March 9, 2018)
10.9+	Service Agreement, dated May 14, 2016, between Intec Pharma Ltd. and John Warren Kozarich (incorporated herein by reference to Exhibit 4.14 to the Company's Annual Report on Form 20-F filed with the SEC on April 7, 2017)
10.10+	Service Agreement, dated August 29, 2017, between Intec Pharma Ltd. and Jeffrey A. Meckler (incorporated herein by reference to Exhibit 4.10 to the Company's Annual Report on Form 20-F filed with the SEC on March 9, 2018)
10.11+	Employment Agreement, dated December 11, 2017, between Intec Pharma Inc., Intec Pharma Ltd. and Jeffrey A. Meckler (incorporated herein by reference to Exhibit 4.11 to the Company's Annual Report on Form 20-F filed with the SEC on March 9, 2018)

10.12+	Employment Agreement, dated January 15, 2006, between Intec Pharma Ltd. and Nadav Navon, as amended on May 29, 2011, March 2012, October 21, 2013 and January 1, 2018 (incorporated herein by reference to Exhibit 4.12 to the Company's Annual Report on Form 20-F filed with the SEC on March 9, 2018)
10.13+	Employment Agreement, dated February 23, 2010, between Intec Pharma Ltd. and Nir Sassi, as amended on March 28, 2012, October 21, 2013 and January 1, 2018 (incorporated herein by reference to Exhibit 4.13 to the Company's Annual Report on Form 20-F filed with the SEC on March 9, 2018)
10.14+	Employment Agreement, dated August 1, 2008, between Intec Pharma Ltd. and Giora Carni as amended on October 12, 2010 and on October 21, 2013 (incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement on Form F-1 filed with the SEC on June 9, 2015)
10.15+	Employment Agreement, dated December 12, 2017, between Intec Pharma Ltd. and Giora Carni(incorporated herein by reference to Exhibit 4.15 to the Company's Annual Report on Form 20-F filed with the SEC on March 9, 2018)
10.16+	Employment Agreement, dated June 1, 2009, between Intec Pharma Ltd. and Zeev Weiss as amended in 2012 and on November 11, 2013 (incorporated herein by reference to Exhibit 10.12 to the Company's Registration Statement on Form F-1 filed with the SEC on June 9, 2015)
10.17+	Employment Agreement, dated October 3, 2017, between Intec Pharma Ltd. and Zeev Weiss (incorporated herein by reference to Exhibit 4.17 to the Company's Annual Report on Form 20-F filed with the SEC on March 9, 2018)
10.18+	Employment Agreement, dated November 1, 2004, between Intec Pharma Ltd. and Zvi Joseph, as amended on October 20, 2009, July 28, 2011, October 21, 2013 and July 19, 2016(incorporated herein by reference to Exhibit 4.17 to the Company's Annual Report on Form 20-F filed with the SEC on April 7, 2017)
10.19+	Employment Agreement, dated December 12, 2017, between Intec Pharma Ltd. and Zvi Joseph (incorporated herein by reference to Exhibit 4.19 to the Company's Annual Report on Form 20-F filed with the SEC on March 9, 2018)
10.20	Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.20 to Amendment No. 2 to the Company's Registration Statement on Form F-1 filed with the SEC on July 28, 2015)
10.21	Form of Exemption from Liability (incorporated herein by reference to Exhibit 10.21 to Amendment No. 2 to the Company's Registration Statement on Form F-1 filed with the SEC on July 28, 2015)
10.22†	Amendment, dated March 12, 2015, by and between Yissum Research Development Company of the Hebrew University of Jerusalem and Intec Pharma Ltd., to the Joint Venture of R&D Agreement dated June 1, 2000. (incorporated herein by reference to Exhibit 10.17 to Amendment No. 1 to the Company's Registration Statement on Form F-1 filed with the SEC on July 16, 2015)
10.23	Form of Subscription Agreement, dated March 10, 2017, by and among Intec Pharma Ltd. and the investors identified on signature page thereto (incorporated herein by reference to Exhibit 4.23 to the Company's Annual Report on Form 20-F filed with the SEC on April 7, 2017)
10.24*+	Employment Agreement dated October 23, 2017 between Intec Pharma, Inc. and Walt Addison Linscott, Esq.
10.25*+	Employment Agreement dated February 1, 2018 between Intec Pharma, Inc. and Michael Gendreau, MD
10.26*†	Process Development Agreement dated as of December 17, 2018 by and between Intec Pharma Ltd. and LTS LOHMANN Therapie-Systeme AG
21.1	List of Subsidiaries (incorporated herein by reference to Exhibit 4.24 to the Company's Annual Report on Form 20-F filed with the SEC on March 9, 2018)
23.1*	Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), independent registered public accounting firm, a member of PricewaterhouseCoopers International Limited
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended

31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended
32.1#	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith
\# Furnished herewith
† Certain portions of this agreement have been omitted under a confidential treatment order pursuant to Rule 406 of the Securities Act of 1933, as amended, and Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and filed separately with the SEC.
\+ Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Intec Pharma Ltd.

Date: February 27, 2019

By: /s/ Jeffrey A. Meckler
Jeffrey A. Meckler
Chief Executive Officer and Vice Chairman

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Jeffrey Meckler and Nir Sassi, and each of them acting individually, as his attorney-in-fact, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorney to any and all amendments to said Report.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Jeffrey A. Meckler Jeffrey A. Meckler	Chief Executive Officer and Vice Chairman (Principal Executive Officer)	February 27, 2019
/s/ Nir Sassi Nir Sassi	Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2019
/s/ Dr. John Kozarich Dr. John Kozarich	Chairman of the Board of Directors	February 27, 2019
/s/ Gil Bianco Gil Bianco	Director	February 27, 2019
/s/ Hila Karah Hila Karah	Director	February 27, 2019
/s/ Isaac Silberman Isaac Silberman	Director	February 27, 2019
/s/ Anthony J. Maddaluna Anthony J. Maddaluna	Director	February 27, 2019
/s/ Dr. Roger J. Pomerantz Dr. Roger J. Pomerantz	Director	February 27, 2019
/s/ William B. Hayes William B. Hayes	Director	February 27, 2019

Exhibit 3.4

Articles of Association

of

Intec Pharma Ltd.

(the "Company")

Pursuant to

the Companies Law, 5759-1999
(the "Companies Law")

As amended on December 20, 2018

1. Name of the Company

The Company's name in Hebrew is "**Intec Pharma Ba'am**" and in English "Intec Pharma Ltd.".

2. Objects of the Company

The Company's object is to engage in any legal business.

3. Limited Liability

The shareholders' liability for the Company's debts is limited to the full amount (par value plus premium) that they were required to pay the Company for the shares and which has not yet been paid by them.

4. The Company's Share Capital and the Rights Attached to the Shares

4.1. The authorized share capital of the Company is comprised of 100,000,000 ordinary shares, no par value (the "**Ordinary Shares**").

4.2. The Ordinary Shares shall confer on their holders:

4.2.1. An equal right to participate in and vote at the Company's general meetings, whether ordinary meetings or special meetings, and each one of the Company's shares shall entitle its holder, who is present at the meeting and participates in the vote, in person, by proxy or by voting card, to one vote;

4.2.2. An equal right to participate in the distribution of dividends, whether in cash or in stock dividends, in the distribution of assets or in any other distribution, according to the ratio of the par value of the shares held by them;

4.2.3. An equal right to participate in the distribution of surplus assets of the Company upon dissolution thereof according to the ratio of the par value of the shares held by them.

4.3. The board of directors may issue shares and other securities, convertible for or exercisable into shares, up to the Company's authorized share capital. For the purpose of calculation of the authorized capital, the securities convertible for or exercisable into shares shall be deemed as having been converted or exercised on the date of issuance thereof.

5. Co-Holding of Shares and Share Certificates

5.1. A shareholder registered in the shareholders' register is entitled to receive from the Company, free of charge, within a period of three months after the allotment or registration of the transfer, a single share certificate signed with the Company's stamp, in respect of all of the shares registered in his name, which shall specify the number of shares. In the case of a co-held share, the Company shall issue one share certificate to all of the co-holders of the share, and delivery of such certificate to one of the partners shall be deemed as delivery to all of them.

Each share certificate shall be signed by any two office holders of the Company or by any other person appointed by the board of directors for such purpose, plus the Company's stamp or printed name.

5.2. A share certificate that is defaced, destroyed or lost may be renewed based on proof and guarantees as the Company shall demand from time to time.

6. The Company's Remedies in relation to Shares not Fully Paid Up

6.1. If the consideration that the shareholder undertook to pay to the Company in consideration for his shares is not given, in whole or in part, on such date and under such conditions as are determined in the terms of allotment of his shares and/or in the call mentioned in Section 6.2 below, the Company may, in a resolution of the board of directors, forfeit the shares, the consideration for which was not paid in full. The shares will be forfeited provided that the Company shall have sent the shareholder a written warning of its intention to forfeit his shares within at least 7 days from the date of receipt of the warning in the event that the payment is not made during the period set forth in the warning letter.

The board of directors may, at any time before the date on which a forfeited share is sold, re-alloted or otherwise transferred, cancel the forfeiture under such conditions as it deems fit.

The forfeited shares will be held by the Company as treasury shares or sold to another.

6.2. If, according to the terms of issuance of shares, there is no fixed date for payment of any part of the price to be paid therefor, the board of directors may, from time to time, make calls on the shareholders for the unpaid money for the shares held by them, and each shareholder will be obligated to pay the Company the amount called from him on the date determined as aforesaid, provided that he receives prior notice of 14 days of the time and place of payment ("**Call**"). The notice will specify that non-payment on or before the date fixed at the place specified may result in forfeiture of the shares in relation to which the call was made. A Call may be retracted or postponed to another date, all as the board of directors shall decide.

6.3. Unless determined otherwise in the terms of allotment of the shares, a shareholder will not be entitled to receive a dividend or to exercise any right as a shareholder in respect of shares not yet fully paid up.

6.4. Persons who are co-holders of a share will be jointly and severally liable for payment of the amounts due to the Company in respect of the share.

6.5. The provisions of this section do not derogate from any other remedy of the Company vis-à-vis a shareholder who shall not have paid his debt to the Company in respect of his shares.

7. <u>Transfer of Shares</u>

7.1. The Company's shares may be transferred.

7.2. Any transfer of shares must be done in writing and shall not be registered unless –

7.2.1. A valid share transfer deed is delivered to the Company at its registered office together with the certificates of the shares to be transferred, if issued. A transfer deed will be signed by the transferor and by a witness certifying the transferor's signature. In the case of a transfer of shares that shall not have been fully paid up on the date of the transfer, the transfer deed will also be signed by the share recipient and by a witness certifying the share recipient's signature; or

7.2.2. A court order is delivered to the Company to amend the registration; or

7.2.3. It is proven to the Company that legal conditions for endorsement of the right in the share have been fulfilled.

7.3. A transfer of shares that have not been fully paid up requires the approval of the board of directors, which may refuse to give its approval at its absolute discretion and without giving reasons therefor.

7.4. A transfer recipient shall be deemed as the shareholder in relation to the transferred shares from the moment of registration of his name in the shareholders' register.

7.5. The guardians and executors of the estate of an individual shareholder who passes away or, in the absence of executors of the estate or guardians, persons who hold a right as the heirs of the individual shareholder who passed away, will be the individuals whom the Company shall recognize as the holders of a right in the share that was registered in the deceased's name.

7.6. If a share is registered in the name of two or more holders, the Company shall only recognize the surviving partner or the surviving partners as the persons holding the right in the share or a benefit therein. If a share is registered in the name of several co-holders as aforesaid, each one of them will be entitled to transfer his right.

7.7. The Company may recognize a receiver or liquidator of a shareholder that is a corporation in liquidation or dissolution or a trustee in bankruptcy or any receiver of a bankrupt shareholder as the holders of a right to the shares registered in the name of such shareholder.

7.8. Any person who gains a right in shares due to the death of a shareholder will be entitled, upon presenting proof of probate or the appointment of a guardian or the issuance of an inheritance order, attesting that he holds the right to the deceased shareholder's shares, to be registered as shareholder in respect of such shares, or may, subject to the provisions of these articles, transfer such shares.

7.9. The receiver or liquidator of a shareholder that is a corporation in liquidation or dissolution or the trustee in bankruptcy or any receiver of a bankrupt shareholder may, after having provided such evidence as the board of directors shall require of him, which testify that he has the right to the shares of the shareholder in liquidation or dissolution or in bankruptcy, with the board of directors' consent, be registered as shareholder in respect of such shares, or may, subject to the provisions of these articles, transfer such shares.

8. Change in Capital

The general meeting may, by a simple majority of the shareholders present at the general meeting:

8.1. Increase the Company's authorized share capital by creating new shares of an existing class or of a new class, all as shall be determined in a resolution of the general meeting.

8.2. Cancel authorized share capital that has not yet been allotted, provided that there is no undertaking of the Company, including a contingent undertaking, to allot the shares.

8.3. Consolidate and re-divide its share capital, or any part thereof, into shares of a greater par value than the amount of the par value of the existing shares.

8.4. Re-divide its share capital, in whole or in part, by re-dividing its existing shares, in whole or in part, into shares of a lesser par value than the par value of the existing shares.

8.5. Reduce its share capital and any capital redemption reserve fund in such manner and under such conditions and upon receipt of such approval as the Companies Law shall require.

8.6. Reduce shares in the Company's issued capital, such that these shares shall be cancelled and any and all consideration paid in respect of the par value of the shares that were cancelled as aforesaid shall be recorded on the Company's books as a capital reserve, which will be deemed, for all intents and purposes, as a premium paid on the shares that shall remain in the Company's issued capital.

9. Change in Rights of Share Classes

9.1. Unless determined otherwise in the terms of issuance of the shares, and subject to the provisions of any law, the rights of any class of shares may be changed after the adoption of a resolution of the Company's board of directors and with the approval of the general meeting of the holders of shares of the same class or written consent of all of the holders of the shares of the same class. The provisions of the Company's articles regarding general meetings shall apply, *mutatis mutandis*, to a general meeting of the holders of such class.

9.2. The rights conferred on holders of shares of a certain class that were issued with special rights shall not be deemed as having been changed by the creation or issuance of additional shares ranking *pari passu* therewith, unless provided otherwise in the terms of issuance of such shares.

10. General Meetings

10.1. Resolutions of the Company on the following matters shall be adopted at the general meeting -

10.1.1. Changes to the articles;

10.1.2. Exercise of authorities of the board of directors when the board of directors is unable to perform its duties;

10.1.3. Appointment of the Company's auditor and termination of his employment;

10.1.4. Appointment of directors, including outside directors (to the extent outside directors are required to be elected under applicable law or should the Company elect to have outside directors serve on the board of directors of the Company);

10.1.5. Approval of actions and transactions which require the approval of the general meeting pursuant to the provisions of the Companies Law and any other law;

10.1.6. Increase and reduction of the authorized share capital;

10.1.7. Merger, as defined in the Companies Law; and

10.1.8. Authorization of the chairman of the board or a relative thereof to perform the duties or exercise the powers of the CEO, and authorization of the CEO or a relative thereof to perform the duties or exercise the powers of the chairman of the board, as stated in Section 121(c) of the Companies Law.

11. Convening of General Meetings

11.1. Annual general meetings shall be convened at least once a year at such place and time as the board of directors shall determine, but no later than 15 months after the last annual general meeting. These general meetings shall be referred to as "Annual Meetings". The other general meetings of the Company shall be referred to as "Special Meetings".

11.2. The Annual Meeting shall appoint an auditor, appoint the directors according to these articles and discuss any and all other matters that need to be discussed at the annual general meeting of the Company, according to these articles or pursuant to the Companies Law, as well as any other matter as the board of directors shall determine.

11.3. The board of directors may convene a Special Meeting according to a resolution thereof and is obligated to convene a Special Meeting if it receives a written demand from any one of the following (the "**Demand to Convene**") –

11.3.1. Two incumbent directors; and/or

11.3.2. One or more shareholders who hold at least five percent of the voting rights in the Company.

11.4. Any Demand to Convene needs to specify the objectives for which a meeting needs to be called and shall be signed by the demanding parties and be delivered to the Company's registered office. The demand may comprise several documents in identical language, each one of which signed by one or more demanding parties.

11.5. The board of directors, if required to summon a Special Meeting, shall summon the same within twenty-one days from the date that the Demand to Convene is submitted thereto, for a date to be determined in the invitation according to Section 11.6 below and subject to any law.

11.6. Notice to the Company's members regarding the convening of a general meeting shall be made in accordance with applicable law. The Company is not obligated to deliver personal notices of the convening of a meeting to the shareholders registered in the shareholders' register of the Company.

12. Deliberation at the General Meetings

12.1. Deliberations at the general meeting shall not be opened unless a legal quorum is present at the time of opening of the deliberation. Legal quorum shall be formed upon the presence (including by proxy or by voting card) of at least two shareholders holding at least 33⅓% (thirty three and one-third of a percent) of the voting rights within one half hour from the time scheduled for the opening of the meeting.

12.2. In the event that one half hour after the time scheduled for the meeting to begin legal quorum shall not have been formed at a general meeting, the meeting shall stand adjourned for one week, to the same day, time and place, or to a later date, if stated in the invitation to the meeting or in the notice of the meeting (the "**Adjourned Meeting**").

12.3. Legal quorum for commencement of the Adjourned Meeting will be at least two shareholders holding at least 33⅓% (thirty three and one-third of a percent) of the voting rights within one half hour from the time scheduled for the opening of the Adjourned Meeting.

12.4. The chairman of the board will act as chairman of the general meeting, and in his absence the chairman of the meeting shall be elected by the persons participating in the meeting at the beginning of the meeting.

12.5. A general meeting at which a legal quorum is present may decide to postpone the meeting to another place and to another time, to be determined, in which case notices of the said place and time shall be published in the manner of publication set forth in the Companies Regulations (Notice and Announcement of a General Meeting and a Class Meeting at a Public Company), 5760-2000.

13. Voting at the General Meeting

13.1. A shareholder of the Company will be entitled to vote at the general meetings in person or by proxy or by voting card. The shareholders entitled to participate in and vote at the general meeting are the shareholders on the date that shall be determined by the board of directors in the resolution to summon the general meeting, and subject to any law.

13.2. At any vote, each shareholder shall have a number of votes in accordance with the number of shares held by him.

13.3. A resolution at the general meeting shall be adopted by a simple majority, unless another majority is determined in the Companies Law or in these articles.

13.4. A declaration by the chairman of the meeting that a resolution was adopted unanimously or by a certain majority, or was voted down or that a certain majority was not attained will be *prima facie* evidence thereof.

13.5. If the votes at the meeting are tied, the chairman of the meeting will not have the right to another or casting vote, and the resolution shall be voted down.

The Company's shareholders may vote at a general meeting (including at a class meeting) via a voting card on issues on which they are entitled to do so pursuant to Section 87 of the Companies Law, as being from time to time.

13.6. A shareholder may state the manner of his vote on the voting card and deliver it to the Company up to 48 hours before the time of commencement of the meeting. A voting card on which a shareholder stated the manner of his vote which reached the Company at least 48 hours before the time of commencement of the meeting (and with respect to an Adjourned Meeting– 48 hours before the time of the Adjourned Meeting) shall be deemed as presence at the meeting, including for purposes of forming the legal quorum as stated in Section 12.1 above.

13.7. A proxy will be appointed in writing, signed by the principal ("**Power of Attorney**"). A corporation shall vote through its representatives who shall be appointed by a document that shall be duly signed by the corporation ("**Letter of Appointment**").

13.8. Voting in accordance with the terms and conditions of the Power of Attorney shall be lawful even if the principal shall have previously passed away or become incapacitated, been dissolved, become bankrupt or shall have cancelled the Letter of Appointment or transferred the share in respect of which it was cast, unless written notice shall have been received at the office, prior to the meeting, that the shareholder passed away, became incapacitated, was dissolved, became bankrupt, or cancelled the Letter of Appointment or transferred the share as aforesaid.

13.9. The Letter of Appointment and Power of Attorney or a copy thereof shall be delivered to the Company's registered office (by personal delivery or via fax) at least forty-eight (48) hours before the time scheduled for the meeting or for the adjourned meeting at which the person mentioned in the document intends to vote according thereto.

13.10. A shareholder of the Company will be entitled to vote at meetings of the Company through several proxies, who shall be appointed by him, provided that each proxy shall be appointed in respect of different portions of the shares held by the shareholder. There will be no impediment to each proxy as aforesaid voting differently at meetings of the Company.

13.11. If a shareholder is incapacitated, he may vote through his trustees, receiver, natural guardian or another legal guardian, and they will be entitled to vote in person or by proxy or by voting card.

13.12. Where two or more persons are co-holders of a share, at a vote on any matter, the vote of the person named first in the shareholders' register as the holder of such share will be accepted, whether in person or by proxy, and he shall be entitled to deliver voting cards to the Company.

14. Amendment of the Articles

A resolution to amend these articles will require a simple majority of the shareholders present at the general meeting, whose agenda shall include amendment of the articles.

15. The Board of Directors

The board of directors will outline the Company's policy and supervise performance of the CEO's duties and actions. The board of directors may exercise any authority of the Company that is not conferred in the Companies Law or in the articles on another organ.

16. Appointment of the Board of Directors and Termination of Office

16.1. The number of directors of the Company (including outside directors – to the extent outside directors are required to be elected under applicable law or should the Company elect to have outside directors serve on the board of directors of the Company) shall be determined from time to time by the annual general meeting (subject to Section 16.3 below), provided that it is no less than four and no more than nine.

16.2. The Company's directors will be elected at an Annual Meeting and/or at a Special Meeting, and shall hold office until the end of the next coming Annual Meeting (i.e., at the end of the Annual Meeting all of the Company's directors who served until such meeting shall resign, with the exception of outside directors, for as long as the Company is required under applicable law or otherwise elected to have such outside directors serve on the board of directors of the Company, subject to the provisions at the end of this section below), or until they resign or until they cease to hold office according to the provisions of the articles or any law, all whichever is earlier. If, at a general meeting of the Company, new directors are not elected in the minimum number determined according to the articles, the directors who served until such meeting shall continue to hold office until their replacement by the Company's general meeting.

16.3. In addition to the provisions of Section 16.2 above, the directors may appoint a director in lieu of a director whose position was vacated and/or as an addition to the board of directors, subject to the maximum number of directors on the board of directors as stated in Section 16.1 above. Appointment of a director by the board of directors will be valid until the next Annual Meeting or until he ceases to hold office according to the provisions of the articles or any law, all whichever is earlier.

16.4. A director whose term of office has ended may be reelected.

16.5. The term of office of a director shall begin on the date of his appointment by the Annual Meeting and/or the Special Meeting and/or the board of directors or on a later date if such date is determined in the appointment resolution of the Annual Meeting and/or the Special Meeting and/or the board of directors.

16.6. The board of directors shall elect the chairman of the board from among its members. If no chairman is elected or if the chairman is not present 15 minutes after the time scheduled for the meeting, the directors present shall elect one of them to preside over the meeting, and the elected director shall chair the meeting and sign the minutes.

The chairman of the board will not be the Company's CEO other than upon the fulfillment of the conditions listed in Section 121(c) of the Companies Law.

16.7. The general meeting may remove from office any director before the end of his term of office, regardless of whether the director was appointed thereby by virtue of Section 16.2 above or the director was appointed by the board of directors by virtue of Section 16.3 above, provided that the director is given a reasonable opportunity to present his position to the general meeting.

16.8. If a director's position is vacated, the remaining directors will be entitled to continue to act so long as the number of remaining directors shall not have fallen below the minimum number of directors determined in the articles. In a case in which the number of directors is less than the said minimum number, the remaining directors will be entitled to act only in order to fill the vacancy as stated in Section 16.3 above or in order to summon a general meeting of the Company, and until the convening of the general meeting as aforesaid, they may act for the management of the Company's business only on urgent matters.

16.9. Each board member may, with the consent of the board of directors, appoint for himself an alternate ("**Alternate Director**"), subject to the provisions of the law.

Appointment or termination of office of an Alternate Director shall be made in a written document, signed by the director who appointed him, although in any event, an Alternate Director's office shall end upon the occurrence to the Alternate Director of one of the cases specified in the paragraphs in Section 16.10 below or if the office of the board member for whom he acts as an alternate shall be vacated for whatever reason.

An Alternate Director is deemed as a director and he shall be subject to all of the legal provisions and the provisions of these articles, with the exception of the provisions regarding the appointment and/or termination of a director set forth in these articles.

16.10. A director's position shall be vacated in any one of the following cases:

16.10.1. He resigned from office by a letter signed by him that was submitted to the Company and which specifies the reasons for his resignation;

16.10.2. He is removed from office by the general meeting;

16.10.3. He is convicted of an offense as stated in Section 232 of the Companies Law;

16.10.4. According to a court decision, as stated in Section 233 of the Companies Law;

16.10.5. He is declared incapacitated; and

16.10.6. He is declared bankrupt.

17. <u>Board Meetings</u>

17.1. The board of directors shall convene for a meeting according to the needs of the Company and at least once every three months.

17.2. The chairman of the board may convene the board of directors at any time. In addition, the board of directors shall hold a meeting, on an issue to be specified, in the following cases:

17.2.1. At the demand of two directors, although if on such date the board of directors comprises five directors or less – at the demand of one director;

17.2.2. At the demand of one director if he stated in his demand to convene the board of directors that he has learned of a matter of the Company ostensibly revealing a breach of law or improper business conduct;

17.2.3. A notice or report of the CEO requires action by the board of directors; and

17.2.4. The auditor has given notice to the chairman of the board of material deficiencies in the Company's accounting control.

17.3. Notice of a board meeting shall be delivered to all of its members at least three days before the date of convening of the board of directors or by shorter notice with the consent of all of the directors. The notice shall be delivered to the address of the director that was provided to the Company in advance, and shall state the date of the meeting and the place at which it shall convene, as well as a reasonable specification of all of the issues on the agenda.

The aforesaid notwithstanding, the board of directors may convene for a meeting without notice with the consent of all of the directors.

17.4. The legal quorum for opening a board meeting will be a majority of the board members. If legal quorum is not present at the board meeting one half hour after the time scheduled for the meeting to begin, the meeting shall stand adjourned to another date to be decided on by the chairman of the board, or in his absence the directors who were present at the meeting summoned, provided that notice of the date of the adjourned meeting shall be delivered to all of the directors two days in advance. The legal quorum for opening an adjourned meeting will be any number of participants. The aforesaid notwithstanding, the legal quorum for discussions and resolutions at the board of directors regarding the termination or suspension of the internal auditor will be a majority of the board members.

17.5. The board of directors may hold meetings through the use of any means of communication, provided that all of the directors participating are able to hear one another simultaneously.

17.6. The board of directors may adopt resolutions even without convening in practice, provided that all of the directors who are entitled to participate in the deliberation and to vote on the matter presented for resolution have agreed thereto (i.e. agreed that the resolution be adopted without actually convening). If resolutions are adopted as stated in this section, the chairman of the board shall record minutes of the resolutions stating the manner of the vote of each director on the matters presented for resolution, as well as the fact that all of the directors agreed to adopt the resolution without convening.

18. <u>Voting at the Board of Directors</u>

18.1. At a vote at the board of directors, each director shall have one vote.

18.2. Resolutions of the board of directors shall be adopted by a majority of votes. The chairman of the board will not have an additional or casting vote, and in the case of a tied vote, the resolution shall be voted down.

19. Borrowing Powers

The board of directors may, from time to time, at its sole discretion, borrow or secure any amount or amounts of money for the Company's objects. The Company's board of directors will be entitled to obtain or secure payment of any such amount or amounts in such manner, on such dates and under such conditions as it deems fit, and in particular by the issuance of guaranties, fixed or redeemable bonds, bond stock or any mortgage, pledge or floating charge or any other security on the Company's property, in whole or in part, whether in the present or the future, including the uncalled share capital and the share capital called up but unpaid.

20. Board Committees

20.1. The Company's board of directors may set up committees and appoint thereto members from among the board members ("**Board Committee**"). If Board Committees are set up, the board of directors shall determine (in accordance with applicable law), in the terms and conditions of authorization thereof, whether certain authorities of the board of directors be delegated to the Board Committee, such that a resolution of the Board Committee be deemed as a resolution of the board of directors or whether a resolution of the Board Committee shall constitute a recommendation only, which is subject to the approval of the board of directors, provided that no deciding powers shall be delegated to a committee on the matters listed in Section 112 of the Companies Law.

20.2. The meetings and deliberations of any Board Committee comprising two or more members shall be subject to the provisions included in these articles regarding board meetings and voting therein, *mutatis mutandis* and subject to resolutions of the board of directors regarding committee meeting procedures (if any).

21. Audit Committee

21.1. The Company's board of directors shall appoint an audit committee from among its members. The number of members of the audit committee will be no less than three. For as long as the Company is required under applicable law or otherwise elected to have outside directors serve on the board of directors of the Company, all of the outside directors will be members thereof. Neither the chairman of the board nor any director employed by the Company or who regularly provides services thereto nor the Company's controlling shareholder nor his relative shall be appointed as members of the committee.

21.2. The audit committee's duties will be –

21.2.1. To point out deficiencies in the Company's business conduct, *inter alia* in consultation with the Company's internal auditor or with the auditor, and to suggest to the board of directors ways to correct the same; and

21.2.2. To decide whether to approve actions and transactions requiring the approval of the audit committee pursuant to the Companies Law.

22. Management of the Company

22.1. The Company's board of directors will be authorized to appoint and, at its discretion, terminate or suspend officers (with the exception of directors), a CEO, secretary, clerk, employee or principal, regardless of whether they are employed permanently or temporarily or for special services, as the board of directors shall deem fit from time to time, and to define their powers and duties and to determine their salaries and fees and to demand collateral in such cases and amounts as the board of directors shall deem fit.

22.2. The CEO will be responsible for the current management of the Company's affairs in the framework of the policy determined by the board of directors and subject to its instructions.

23. Exemption, Insurance and Indemnification

23.1. Exemption from liability

The Company is entitled, in a resolution adopted in the manner set forth in the Companies Law, to exempt an officer thereof in advance from his liability, in whole or in part, due to a breach of the duty of care thereto.

23.2. Liability insurance

Subject to the provisions of the Companies Law, the Company is entitled to enter into a contract for insurance of the liability of an officer thereof due to a liability that shall be imposed on him due to an action taken in his capacity as an officer thereof, in whole or in part, for any one of the following:

23.2.1. Breach of the duty of care vis-à-vis the Company or vis-à-vis another person;

23.2.2. Breach of the fiduciary duty vis-à-vis the Company, provided that the officer acted in good faith and had reasonable grounds to believe that the action would not prejudice the best interests of the Company;

23.2.3. Monetary liability that shall be imposed on him in favor of another person;

23.2.4. Another action that may be insured pursuant to the Companies Law;

23.2.5. Expenses incurred by or charged to the officer, in connection with an administrative enforcement proceeding conducted with respect to him, including reasonable litigation expenses, including legal fees. In this paragraph –

(a) "Administrative enforcement proceeding" – an administrative enforcement proceeding pursuant to the provisions of any law, including the Streamlining of Enforcement Procedures Law and the Securities Law, 5728-1968 ("**Securities Law**"), including an administrative petition or an appeal in connection with the said proceeding;

(b) "Streamlining of Enforcement Procedures Law" – The Streamlining of ISA Enforcement Procedures Law (Legislative Amendments), 5771-2011, as shall be updated from time to time; and

23.2.6. Payment to a party injured by a breach as stated in Section 52BBB of the Securities Law, as amended in the Streamlining of Enforcement Procedures Law ("**Payment to a Party Injured by a Breach**").

If the insurance contract mentioned in this section covers the Company's liability, the officers will have priority, over the Company, in receiving the insurance proceeds.

23.3. Indemnification

Subject to the provisions of the Companies Law, the Company may, in a resolution adopted in the manner set forth in the Companies Law, indemnify an officer thereof due to liability or an expense as specified below, imposed on him due to an action taken in his capacity as an officer thereof:

23.3.1. A monetary liability imposed on him in favor of another person in a judgment, including a judgment issued in a settlement or an arbitration award that was approved by the court;

23.3.2. Reasonable litigation expenses, including legal fees, incurred by an officer due to an investigation or proceeding that was conducted against him by an authority which is authorized to conduct an investigation or proceeding, and which has ended without the filing of an indictment against him and without a monetary liability being imposed on him as a substitute for a criminal proceeding, or which has ended without the filing of an indictment against him but with the imposition of a monetary liability as a substitute for a criminal proceeding in an offense which requires no proof of general intent; in this paragraph –

(a) "A proceeding ended without the filing of an indictment in a case in which a criminal investigation has been made" - means the closing of the case pursuant to Section 62 of the Criminal Procedure Law [Consolidated Version], 5742-1982 (in this section: the "**Criminal Procedure Law**"), or a stay of proceedings by the Attorney General pursuant to Section 231 of the Criminal Procedure Law;

(b) "Monetary liability as a substitute for a criminal proceeding" – a monetary liability imposed by law as a substitute for a criminal proceeding, including an administrative fine pursuant to the Administrative Offenses Law, 5746-1985, a fine for an offense determined as an infraction pursuant to the provisions of the Criminal Procedure Law, a pecuniary sanction or a sanction;

23.3.3. Reasonable litigation expenses, including legal fees, incurred by or charged to the officer by a court, in a proceeding filed against him by or on behalf of the Company or by another person, or in a criminal indictment from which he is acquitted, or in a criminal indictment in which he is convicted of an offense requiring no proof of general intent;

23.3.4. Expenses incurred by or charged to the officer in connection with an administrative enforcement proceeding conducted with respect to him, including reasonable litigation expenses, and including legal fees;

23.3.5. Payment to a party injured by a breach;

23.3.6. Any liability or other expense for which it is and/or will be permitted to indemnify an officer;

23.3.7. The Company may undertake in advance to indemnify an officer thereof, provided that an indemnification undertaking pertaining to the provisions of Section 23.3 on the whole shall be restricted to such amount or criterion as the board of directors shall have determined are reasonable under the circumstances, and that the indemnification undertaking states the events which, in the board of directors' opinion, are foreseeable in view of the Company's business in practice at the time of the granting of the undertaking, as well as the amount or the criterion determined by the board of directors to be reasonable under the circumstances;

23.3.8. The Company may indemnify an officer thereof retroactively.

24. Internal Auditor

24.1. The Company's board of directors shall appoint an internal auditor in accordance with the Audit Committee's proposal. No person who is an interested party of the Company, an officer of the Company, a relative of any one of the above, or the auditor or anyone on his behalf shall serve as the Company's internal auditor.

24.2. The board of directors shall determine which officer will be the organizational supervisor of the internal auditor.

24.3. The internal audit plan that shall be prepared by the auditor will be submitted for the audit committee's approval, although the board of directors may determine that the plan be submitted for the board of directors' approval.

25. Auditor

25.1. The Annual Meeting shall appoint an auditor for the Company, and the auditor shall hold office until the end of the following Annual Meeting.

25.2. The auditor's fee for the audit function shall be determined by the board of directors. The board of directors will be entitled to delegate this power to a board committee.

25.3. The board of directors shall report to the Annual Meeting on the auditor's fee.

26. Signature on behalf of the Company

26.1. The signatory rights on behalf of the Company shall be determined from time to time by the Company's board of directors.

26.2. The person signing on the Company's behalf will do so together with an imprint of the Company's stamp or on or alongside its printed name.

27. Dividend and Stock Dividends

27.1. A resolution of the Company regarding the distribution of a dividend and/or the distribution of stock dividends will be adopted by the Company's board of directors.

27.2. The shareholders entitled to a dividend are the shareholders on the date of the resolution regarding the dividend or on a later date if another date is determined in the resolution regarding the distribution of the dividend.

27.3. If the Company's board of directors does not determine otherwise, it will be permissible to pay any dividend by check or payment order sent by mail according to the registered address of the shareholder or the person entitled thereto, or in the case of registered co-holders, to the shareholder named first in the shareholders' register in relation to the co-holding. Any such check shall be drawn to the order of the person to whom it is sent. A receipt of a person whose name, on the date of declaration of the dividend, is registered in the shareholders' register as the holder of any share or, in the case of co-holders, of one of the co-holders, shall serve as confirmation pertaining to all of the payments made in connection with such share and in respect of which the receipt was received.

27.4. For the purpose of performance of any resolution according to the provisions of this section, the Company's board of directors may resolve, as it deems fit, any difficulty that arises with respect to the distribution of the dividend and/or the stock dividends, and in this context determine the value, for the purpose of the said distribution, of certain assets and decide that payments in cash shall be made to members based on the value so determined, determine provisions in respect of share fractions or in respect of non-payment of amounts smaller than NIS 200.

28. Redeemable Securities

The Company may, subject to any law, issue redeemable securities under such conditions as the board of directors shall determine, provided that the approval of the general meeting is given for the board of directors' recommendation and the conditions determined thereby.

29. Invoices

29.1. The Company shall keep books and prepare financial statements pursuant to the Securities Law and any law.

29.2. The books shall be kept at the Company's registered office or at such other site as the directors shall deem fit, and will be open for the directors' inspection during normal working hours.

30. Dissolution of the Company

In the case of dissolution of the Company, whether voluntary or otherwise, unless explicitly determined otherwise in these articles or in the terms of issuance of any share, the following provisions shall apply:

30.1. The liquidator will first use all of the Company's assets to pay its debts (the Company's assets after payment of its debts shall hereinafter be referred to as: the "**Surplus Assets**").

30.2. Subject to special rights attached to the shares, the liquidator shall distribute the Surplus Assets among the shareholders proportionately to the par value of the shares, *pari passu*.

30.3. In the Company's approval in a resolution that shall be adopted at the general meeting by a majority of at least 50% of the shareholders' votes, the liquidator may distribute the Company's Surplus Assets or any part thereof among the shareholders in kind and deliver any of the Surplus Assets to a trustee in a deposit for the benefit of the shareholders, as the liquidator shall deem fit.

31. Notices

31.1. Subject to any law, a notice or any other document that the Company shall deliver and which it is entitled or required to give according to the provisions of these articles and/or the Companies Law, shall be delivered by the Company to each person either personally, by delivery by mail in a letter addressed according to the registered address of such shareholder in the shareholders' register or according to such address as the shareholder stated in writing to the Company as the address for delivery of notices or other documents, or by delivery via facsimile according to the number stated by the shareholder as the number for delivery of notices via facsimile. Notices that the Company shall publish for all of the shareholders shall be published in accordance with applicable law.

31.2. Any notice that must be given to the shareholders shall be given in relation to jointly held shares to the person named first in the shareholders' register as the holder of such share, and any notice given in this manner shall be sufficient notice to the holders of such share.

31.3. Any notice or other document that shall be sent according to the provisions of Section 31.1 shall be deemed as having arrived at its destination within 3 business days if sent by registered mail and/or by regular mail in Israel, and if hand delivered or sent via facsimile, it shall be deemed as having arrived at its destination on the first business day after receipt thereof. For the purpose of proving the delivery, it shall be sufficient to prove that the letter that was sent by mail that contains the notice and that the document was addressed to the correct address and was delivered to the post office as a letter bearing stamps or as a registered letter bearing stamps, and in respect of a facsimile it is sufficient to provide a transmission confirmation page from the transmitting machine. With respect to notice published for all of the shareholders – the date of the publication (in whatever media permitted under applicable law) shall be deemed as the date of delivery of the notice to all of the shareholders.

31.4. Any record ordinarily made in the Company's books shall be deemed as *prima facie* evidence regarding the delivery, as recorded therein.

31.5. When it is necessary to give prior notice of a certain number of days or notice which is valid for any period, the delivery date shall be counted in the number of days or the period.

32. Donations

The Company may donate a reasonable sum of money to a worthy cause.

33. Interpretation

33.1. Anything stated herein in the singular shall also import the plural and *vice versa*, anything stated in the masculine shall also import the feminine and *vice versa*.

33.2. Unless special definitions for certain terms are included in these articles, any word and expression in these articles shall bear the meaning afforded thereto in the Companies Law, unless the same contradicts the subject matter or content of the text.

33.3. For the avoidance of doubt, it is clarified that in respect of matters regulated in the Companies Law such that the arrangements in respect thereof may be modified in articles of association, and in respect of which these articles do not provide otherwise than in the Companies Law, the provisions of the Companies Law shall apply thereto.

* * *

Exhibit 10.24

EMPLOYMENT AGREEMENT

This Employment Agreement **("Agreement")** is made and entered into on this 23rd day of October 2017, by and between Intec Pharma Inc. (the "**Company**"**),** a subsidiary of Intec Pharma Ltd., an Israeli corporation, **("Intec"),** and Walt Addison Linscott, Esq. (hereinafter, the "**Executive**"**).**

W I T N E S S E T H:

WHEREAS, the Company desires to hire the Executive in an executive capacity and to compensate him for such employment; and

WHEREAS, the Executive is willing to be employed by the Company upon the terms and subject to the conditions contained in this Agreement.

NOW THEREFORE, in consideration of the premises and mutual covenants contained herein and for other good and valuable consideration, the adequacy and receipt of which are hereby acknowledged, the parties agree as follows:

1. ***Definitions***. When used in this Agreement, the following terms shall have the following meanings:

(a) ***"Accrued Obligations***" means:

(i) all accrued but unpaid Base Salary through the end of the Term of Employment;

(ii) any unpaid or unreimbursed expenses incurred in accordance with Company policy, including amounts due under Section 5(a) hereof, to the extent incurred during the Term of Employment;

(iii) any accrued but unpaid benefits provided under the Company's employee benefit plans, subject to and in accordance with the tenns of those plans;

(iv) any unpaid Bonus in respect to any completed fiscal year that has ended on or prior to the end of the Term of Employment;

(v) rights to indemnification by virtue of the Executive's position as an officer or director of the Company and Intec or their subsidiaries and the benefits under any directors' and officers' liability insurance policy maintained by the Company or Intec, in accordance with its terms thereof; and

(vi) payments for any accrued but unused vacation or other paid time off.

(b) "***Affiliate***" means any entity that controls, is controlled by, or is undercommon control with, either member of the Intec Group.

(c) ***"Base Salary***" means the salary provided for in Section 4(a) hereof or any increased salary granted to Executive pursuant to Section 4(a) hereof.

(d) "***Board***" means the Board of Directors of Intec.

(e) "***Bonus***" means any bonus payable to the Executive pursuant to Section 4(b) hereof.

(f) "***Cause***" means:

(i) willful misconduct or gross negligence in the performance of Executive's duties, a material violation of any of the provisions of this Agreement, or a willful continued failure by the Executive to carry out the reasonable and lawful directions of the Board, provided that the Company has provided notice to the Executive of such willful misconduct or gross negligence or material violation or willful continued failure, and the Executive has failed to cure the foregoing within thirty (30) days of receipt of such notice.

(ii) a finding by a court of law or arbitrator of unlawful harassment of any employees of the Intec Group or any Affiliate;

(iii) knowingly and on Executive's own initiative causing or permitting to occur a violation of any law or regulation which subjects or may reasonably be expected to subject the Intec Group or any of its Affiliates to material liability;

(iv) a conviction of the Executive, or a plea of nolo contendere, to a felony involving moral turpitude; or

(v) fraud, embezzlement, theft or dishonesty of a material nature by the Executive against a member of the Intec Group or any Affiliate, or a willful material violation by the Executive of a policy or procedure of a member of the Intec Group or any Affiliate, resulting, in any case, in material economic harm to either member of the Intec Group or any Affiliate.

For purposes of this Section 1(f), no act, or failure to act, on the Executive's part shall be considered "willful" unless done, or omitted to be done, by the Executive not in good faith or without reasonable belief that the Executive's act, or failure to act, was in the best interest of the Company.

(g) ***"Change in Control*** means (i) (A) a sale of all or substantially all of the assets of the Company or Intec; or (B) a sale (including an exchange) of all or substantially all of the shares of the capital stock of the Company or Intec, in either case to any person or entity that is not an Affiliate of the Intec Group, or a shareholder thereof, immediately prior to such transaction or transactions; or (ii) a merger, consolidation or like transaction of the Company or Intec into another corporation in which the holders of the outstanding share capital of the Company or Intec immediately before such consolidation or merger do not, immediately after such consolidation or merger, retain either (x) stock representing a majority of the voting power of the surviving entity, or (y) stock representing a majority of the voting power of an entity that wholly owns, directly or indirectly, the surviving entity; provided, however, that such sale, transfer or other event results in a "change in control" within the meaning of Section 409A of the Code.

(h) ***"Code"*** means the Internal Revenue Code of 1986, as amended.

(i) "***Competitive Activity"*** means services or activity in material competition with the Intec Group in any of the States within the United States, or countries within the world, in which the Intec Group or any of its Affiliates conducts a significant level of business in which the Intec Group or any of its Affiliates engaged while the Executive was employed by the Company

(j) "***Confidential Information"*** means all trade secrets and information about the Intec Group or any of its Affiliates or its business, disclosed to the Executive or known by the Executive as a consequence of, or through the unique position of his employment with, the Company (including information conceived, originated, discovered or developed by the Executive and information acquired by the Intec Group or any of its Affiliates from others) prior to or after the date hereof, and not generally or publicly known (other than as a result of unauthorized disclosure by the Executive). Confidential Information includes, but is not limited to, inventions, ideas, designs, computer programs, circuits, schematics, formulas, algorithms, trade secrets, works of authorship, mask works, developmental or experimental work, processes, techniques, improvements, methods of manufacturing, know-how, data, financial information and forecasts, product plans, marketing plans and strategies, price lists, customer lists and contractual obligations and terms thereof, data, documentation and other information, in whatever form disclosed, relating to the Intec Group or any Affiliates, including, but not limited to, financial statements, financial projections, business plans, listings and contractual obligations and terms thereof, components of intellectual property, unique designs, methods of manufacturing or other technology of the Intec Group or any Affiliate.

(k) "***Disability"*** means the Executive's inability, or failure, to perform the essential functions of his position, with or without reasonable accommodation, by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months.

(l) ***"Expiration Date"*** means the date on which the Term of Employment shall expire.

(m) *"**Good Reason**" means*

(i) the assignment to the Executive of any duties inconsistent in any material respect with the Executive's position (including status, titles and reporting requirements), authority, duties or responsibilities as contemplated by Section 2(b) of this Agreement, or any other action by the Company that results in a material diminution in such position, authority, duties or responsibilities, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by the Executive;

(ii) any material failure by the Company to comply with any of the provisions of Section 4 or Section 5 of this Agreement, other than an isolated, insubstantial and inadvertent failure not occurring in bad faith and that is remedied by the Company promptly after receipt of notice thereof given by the Executive, and other than a reduction of compensation as part of an across-the-board reduction in all salaries for employees of the Intec Group; or

(iii) the Company's requiring the Executive to be based at any office or location outside of thirty-five (35) miles from Atlanta, Georgia except for travel reasonably required in the performance of the Executive's responsibilities.

(n) "***Intec Group***" means the Company and Intec.

(0) ***"Ordinary Shares***" means the ordinary shares of Intec.

(p) "***Restricted Period"*** shall be the Term of Employment and the six (6) month period immediately following termination of the Term of Employment.

(q) "***Severance Amount***" shall mean an amount equal to the sum of (i) 25% of the Executive's annual Base Salary as in effect immediately prior to the Termination Date; and (ii) an amount equal to the Executive's cost of continued health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act under the Company's group health plan (or the monthly payment provided under Section 5(b), as applicable) for three (3) months.

(r) "***Severance Term***" means the three (3) month period following the date on which the Term of Employment ends.

(s) "***Term of Employment"*** means the period during which the Executive shall be employed by the Company pursuant to the terms of this Agreement.

(t) "***Termination Date***" means the date on which the Term of Employment ends.

2. ***Employment***

(a) ***Employment and Term.*** The Company hereby agrees to employ the Executive and the Executive hereby agrees to serve the Intec Group during the Term of Employment on the terms and conditions set forth herein. The Executive's principal place of employment shall be in Atlanta, Georgia except for such travel that may be necessary to fulfill his responsibilities.

(b) ***Duties of Executive.*** During the Term of Employment, the Executive shall be employed and serve as the Chief Administrative Officer of the Company, and shall have such duties typically associated with such title, including, without limitation supervising operations and management of the Company and its Affiliates and, in addition, consistent with Executive's license to practice law, the provision of legal advice to the Company. The Executive shall faithfully and diligently perform all services as may be assigned to him by the Chief Executive Officer (the **"CEO")** of the Company or the Board, and shall exercise such power and authority as may from time to time be delegated to him by the CEO or the Board. The Executive shall not engage in any other business or occupation during the Term of Employment, including, without limitation, any activity that (i) conflicts with the interests of the Intec Group or its Affiliates, (ii) interferes with the proper and efficient performance of his duties for the Company, or (iii) interferes with the exercise of his judgment in the Intec Group's best interests.

3. ***Term.***

The Term of Employment under this Agreement, and the employment of the Executive hereunder, shall commence on the date hereof until terminated in accordance with Section 6 hereof.

4. ***Compensation.***

(a) ***Base Salary.*** The Executive shall receive a Base Salary at the annual rate of $300,000 during the Term of Employment, with such Base Salary payable in installments consistent with the Company's normal payroll schedule, subject to applicable withholding and other taxes. As an exempt employee, the Executive will be expected to work additional hours as required by the nature of his position and will not receive any overtime pay. The Executive's Base Salary will be reviewed annually in accordance with the established procedures of the Company.

(b) ***Bonuses.*** Upon signing of this Agreement by the Executive and the Company, the Executive shall be granted a signing bonus of $75,000, subject to applicable tax withholdings. For each calendar year beginning on or after January 1, 2018, during which Term of Employment continues through December 31st, the Executive shall be eligible to receive a Bonus of up to 50% of Base Salary, subject to the achievement of certain goals to be set by the Board after consultation with the Executive. Any Bonus under this Section 4(b) shall be payable, subject to applicable tax withholdings, as soon as administratively feasible, but in no event later than March 15 after the calendar year in which the Bonus was earned. The annual bonus opportunity shall also be reviewed annually in accordance with the compensation policies of the Company.

5. ***Expense Reimbursement and Other Benefits.***

(a) ***Reimbursement of Expenses.*** Upon the submission of proper substantiation by the Executive, and subject to such rules and guidelines as the Company may from time to time adopt with respect to the reimbursement of expenses of executive personnel, the Company shall reimburse the Executive for all reasonable expenses actually paid or incurred by the Executive during the Term of Employment in the course of and pursuant to the business of the Company. The Executive shall account to the Company in writing for all expenses for which reimbursement is sought and shall supply to the Company copies of all relevant invoices, receipts or other evidence reasonably requested by the Company.

(b) ***Compensation/Benefit Programs.*** During the Term of Employment, the Executive shall be entitled to participate in all medical, dental, hospitalization, accidental death and dismemberment, disability, travel and life insurance plans, and any and all other plans as are presently and hereinafter offered by the Company to its personnel, including savings, pension, profit-sharing and deferred compensation plans, subject to the general eligibility and participation provisions set forth in such plans. Notwithstanding the foregoing, for each month during the Term of Employment in which the Company has not established a group health plan pursuant to which the Executive shall be eligible to receive medical benefits, the Company shall pay the Executive with a taxable cash payment equal to $4,000, payable on the first payroll date of each such month, subject to the Term of Employment under this Agreement, and the employment of the Executive hereunder, continuing on and through such payment date.

(c) ***Stock Options.*** Subject to the Term of Employment under this Agreement, and the employment of the Executive hereunder, continuing on and through the applicable grant date, the Company shall grant to the Executive options to purchase up to 200,000 shares of Intec's Ordinary Shares (the **"Stock Options"),** 140,000 of which shall be granted, subject to the approval of Intec's shareholders of available pool under Intec's equity plan, in each case at a per share exercise price equal to the average closing sale price of Intec's Ordinary Shares on NASDAQ Capital Market over the 30 trading day period immediately preceding the date of approval by the Board, or the fair market value (as determined in accordance with Section 409A of the Code) of an Ordinary Share of Intec on that date, whichever amount is greater. Subject to the Term of Employment under this Agreement, and the employment of the Executive hereunder, continuing on and through each vesting date (except as provided in Section 6 below), the Stock Options will vest over three (3) years according to the following schedule: 33% of the Stock Options shall vest and become exercisable on the first anniversary of the grant date, and the remaining portion of the Stock Options shall vest and become exercisable in eight equal quarterly installments thereafter. The Stock Options shall be subject to a ten (10) year expiration from the applicable grant date, and such other terms and conditions set forth in the stock option agreement and the provisions of Intec's equity plan pursuant to which the Stock Options grant is being made. In the event of (i) a Change in Control or (ii) the entry into a "Material Agreement" (as shall be defined by the compensation committee of the Board and the Board) any Stock Options that have not previously vested shall become vested and exercisable immediately prior to such event. The Executive shall also be eligible for additional share option grants, or any other equity or equity related compensation plan or arrangement that may be made available to senior executives, in each case, at the discretion of the Board.

(d) ***Other Benefits.*** The Executive shall be entitled to (i) paid holidays as generally provided by Intec to its personnel, and (ii) foiu4) -) weeks of paid vacation each calendar year during the Term of Employment, to be taken at such times as the Executive and the Company shall mutually determine, and provided that such vacation time shall not adversely affect in any mateiial way the Executive's performance of his duties required to be rendered by the Executive under this Agreement. Any vacation time accrued but not taken by the Executive during any calendar year may not be earned forward into any succeeding calendar year. The Executive shall receive such additional benefits, if any, as the Board shall from time to time determine.

(f) ***Israeli Taxes***. To the extent any component of the Executive's compensation under this Agreement shall be subject to withholdings, taxes or other govemmentally imposed taxes or tariffs under Israeli law ***("Israeli Taxes***"), the Company shall pay directly to the tax counsel or other expert tax advisor(s) engaged by either the Company or Intec (with the Executive's approval, which shall not be unreasonably withheld) any fees, expenses or other costs incurred in order to provide counsel, advice and representation on the Executive's behalf with regard to liability for any such Israeli Taxes. If the Executive is subject to any inquiry (including, without limitation, an audit, examination or investigation) by an agent or agency of the Israeli government, the Company shall pay directly to the auditor(s), accountant(s), attorney(s) or other person(s) engaged by either the Company or Intec (with the Executive's approval, which shall not be unreasonably withheld) any fees, expenses or other costs incurred that relate to any such inquiry.

6. ***Termination.***

(a) ***General***. The Term of Employment shall terminate upon the earliest to occur of (i) the Executive's death, (ii) a termination by the Company (in accordance with all applicable law, including, without limitation, the Americans with Disabilities Act) or the Executive by reason of the Executive's Disability, (iii) a termination by the Company with or without Cause, or (iv) a termination by the Executive with or without Good Reason. Upon any termination of the Executive's employment for any reason, except as may otherwise be requested by the Company in writing and agreed upon in writing by the Executive, the Executive shall resign from any and all directorships, committee memberships or any other positions the Executive holds with the Company or any of its Affiliates.

(b) ***Termination By Company for Cause.*** The Company shall at all times have the right, upon written notice to the Executive, to terminate the Term of Employment for Cause with an immediate effect (subject to the cure period, if applicable, as provided herein in this Section 6(b)). In no event shall a termination of the Executive's employment for Cause occur unless the Company gives written notice to the Executive in accordance with this Agreement stating with reasonable specificity the events or actions that constitute Cause and providing the Executive with an opportunity to cure (if curable) within a reasonable period of time, and if not cured within such period, the Executive's termination shall be effective upon the date immediately following the expiration of such period. Cause shall in no event be deemed to exist except upon a decision made by the Board, at a meeting, duly called and noticed, to which the Executive (and the Executive's counsel) shall be invited upon proper notice. For purposes of this Section 6(b), a reasonable, good faith determination of Cause by the Board (based on all relevant facts and circumstances) shall be binding and conclusive on all interested parties. In the event that the Term of Employment is terminated by the Company for Cause, the Executive shall be entitled only to the Accrued Obligations, payable as of the termination date of the Term of Employment.

(c) ***Disability.*** Either the Company (in accordance with all applicable law, including, without limitation, the Americans with Disabilities Act) or the Executive shall have the option to terminate the Term of Employment, upon written notice to the other party, at any time during which the Executive is suffering from a Disability. In the event that the Term of Employment is terminated due to the Executive's Disability, the Executive shall be entitled to (i) the Accrued Obligations, payable as of the termination date of the Term of Employment, and (ii) vesting, immediately prior to such termination, in any Stock Options that have not previously vested.

(d) ***Death***. In the event that the Term of Employment is terminated due to the Executive's death, the Executive shall be entitled to (i) the Accrued Obligations, payable as of the termination date of the Term of Employment, and (ii) vesting, immediately prior to such termination, in any Stock Options that have not previously vested.

(e) ***Termination Without Cause***. The Company may terminate the Term of Employment at any time without Cause, by written notice to the Executive not less than 30 days prior to the effective date of such termination. In the event that the Term of Employment is terminated by the Company without Cause (other than due to the Executive's death or Disability) the Executive shall be entitled to (i) the Accrued Obligations, payable as of the termination date of the Term of Employment, and (ii) the Severance Amount, payable in equal monthly installments during the Severance Term.

(f) ***Termination by Executive for Good Reason.*** The Executive may terminate the Term of Employment for Good Reason by providing the Company thirty (30) days' written notice setting forth in reasonable specificity the event that constitutes Good Reason, which written notice, to be effective, must be provided to the Company within sixty (60) days of the occurrence of such event. During such thirty (30) day notice period, the Company shall have a cure right (if curable), and if not cured within such period, the Executive's termination shall be effective upon the date immediately following the expiration of the thirty (30) day notice period, and the Executive shall be entitled to the same payments and benefits as provided in Section 6(e) above for a termination without Cause.

(g) ***Termination by Executive Without Good Reason.*** The Executive may terminate his employment without Good Reason by providing the Company ninety (90) days' written notice of such termination. In the event of a termination of employment by the Executive under this Section 6(g), the Executive shall be entitled only to the Accrued Obligations, payable as of the termination date of the Term of Employment. In the event of termination of the Executive's employment under this Section 6(g), the Company may, in its sole and absolute discretion, by written notice of at least five (5) business days, accelerate such date of termination and still have it treated as a termination without Good Reason.

(h) ***Change in Control of the Company***. In the event of a Change in Control, any Stock Options granted to the Executive that have not previously vested shall become fully vested and exercisable immediately prior to such Change in Control, pursuant to Section 5(d). If the Executive's employment is terminated by the Company without Cause or by the Executive for Good Reason during the one (1) year period immediately following a Change in Control, then in lieu of any amounts otherwise payable under Section 6(e) or 6(f) hereof, the Executive shall be entitled to (i) the Accrued Obligations, payable as of the termination date of the Term of Employment and (ii) a lump-sum payment equal to the Severance Amount, payable on the first day after the general release of claims (as described in Section 6(i), below) becomes irrevocable in accordance with the provisions of such general release of claims.

(i) ***Release.*** Any payments or benefits due to Executive under this Section 6 (other than the Accrued Obligations) shall be conditioned upon the Executive's execution of a general release of claims substantially in the form attached hereto as Exhibit A (subject to such modifications as the Company or the Executive reasonably may request) that becomes irrevocable in accordance with the provisions of such general release of claims. The vesting of the Stock Options and payment of any amounts subject to the Executive's release shall be delayed until the first day after the date such release becomes irrevocable in accordance with the provisions of such general release of claims (the **"Payment Commencement Date"),** and any payments or benefits that are so delayed shall be paid or made effective on the Payment Commencement Date.

(j) ***Section 280G Reductions.***

(i) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (a "Payment"), would be nondeductible by the Company for Federal income tax purposes because of Section 280G of the Code, then the aggregate present value of amounts payable or distributable to or for the benefit of the Executive pursuant to this Agreement (such payments or distributions pursuant to this Agreement are hereinafter referred to as "Agreement Payments") shall be reduced to the Reduced Amount. The "Reduced Amount" shall be an amount expressed in present value which maximizes the aggregate present value of Agreement Payments without causing any Payment to be nondeductible by the Company because of Section 280G of the Code. Anything to the contrary notwithstanding, if the Reduced Amount is zero and it is determined further that any Payment which is not an Agreement Payment would nevertheless be nondeductible by the Company for Federal income tax purposes because of Section 280G of the Code, then the aggregate present value of Payments which are not Agreement Payments shall also be reduced (but not below zero) to an amount expressed in present value which maximizes the aggregate present value of Payments without causing any Payment to be nondeductible by the Company because of Section 280G of the Code. For purposes of this Section 6(lc), present value shall be determined in accordance with Section 280G(d)(4) of the Code.

(ii) All determinations required to be made under this Section 6(lc) shall be made by Price Waterhouse Coopers, LLC (the **"Accounting Firm"),** which shall provide detailed supporting calculations both to the Company and the Executive within twenty (20) business days of the Company's "change in control" determined in accordance with Section 280G of the Code or such other time as is requested by the Company and an opinion to the Executive that he has substantial authority not to report any excise tax on his Federal income tax return with respect to any Payments. Any such determination by the Accounting Firm shall be binding upon the Company and the Executive. The Company shall elect which and how much of the Payments shall be eliminated or reduced consistent with the requirements of this Section 6(k) and shall notify the Executive promptly of such election. If and to the extent necessary to avoid a violation of Section 409A, no amounts payable under any "nonqualified deferred compensation plan" subject to Section 409A shall be reduced until after all other Payments have been reduced. Within five business days thereafter, the Company shall pay to or distribute to or for the benefit of the Executive such amounts as are then due to the Executive under this Agreement. All fees and expenses of the Accounting Firm incurred in connection with the determinations contemplated by this Section 6(k) shall be borne by the Company.

(k) ***Cooperation.*** Following the Term of Employment, the Executive shall give his assistance and cooperation willingly, upon reasonable advance notice with due consideration for his other business or personal commitments, in any matter relating to his position with the Intec Group, or his expertise or experience as the Intec Group may reasonably request, including his attendance and truthful testimony where deemed appropriate by the Intec Group, with respect to any investigation or the Intec Group's defense or prosecution of any existing or future claims or litigations or other proceedings relating to matters in which he was involved or potentially had knowledge by virtue of his employment with the Company. In no event shall his cooperation materially interfere with his services for a subsequent employer or other similar service recipient. To the extent permitted by law, the Company agrees that (i) it shall promptly reimburse the Executive for his reasonable and documented expenses in connection with his rendering assistance and/or cooperation under this Section 6(1) upon his presentation of documentation for such expenses and (ii) the Executive shall be reasonably compensated for any continued material services as required under this Section 6(1).

(l) ***Return of Company Property***. Following the Termination Date, the Executive or his personal representative shall return all Intec Group property in his possession, including but not limited to all computer equipment (hardware and software), telephones, facsimile machines, palm pilots and other communication devices, credit cards, office keys, security access cards, badges, identification cards and all copies (including drafts) of any documentation or information (however stored) relating to the business of the Intec Group, its customers and clients or its prospective customers and clients (provided that the Executive may retain a copy the addresses contained in his rolodex, palm pilot, PDA or similar device).

(m) ***Compliance with Section 409A.***

(i) ***General*** It is the intention of both the Company and the Executive that the benefits and rights to which the Executive could be entitled pursuant to this Agreement comply with Section 409A of the Code and the Treasury Regulations and other guidance promulgated or issued thereunder **("Section 409A"),** to the extent that the requirements of Section 409A are applicable thereto, and the provisions of this Agreement shall be construed in a manner consistent with that intention. If the Executive or the Company believes, at any time, that any such benefit or right that is subject to Section 409A does not so comply, it shall promptly advise the other and shall negotiate reasonably and in good faith to amend the terms of such benefits and rights such that they comply with Section 409A (with the most limited possible economic effect on the Executive and on the Company).

(ii) ***Distributions on Account of Separation from Service.*** If and to the extent required to comply with Section 409A, no payment or benefit required to be paid under this Agreement on account of termination of the Executive's employment shall be made unless and until the Executive incurs a "separation from service" within the meaning of Section 409A.

(iii) ***6 Month Delay for Specified Employees***.

(A) If the Executive is a "specified employee", then no payment or benefit that is payable on account of the Executive's "separation from service", as that term is defined for purposes of Section 409A, shall be made before the date that is six (6) months after the Executive's "separation from service" (or, if earlier, the date of the Executive's death) if and to the extent that such payment or benefit constitutes deferred compensation (or may be nonqualified deferred compensation) under Section 409A and such deferral is required to comply with the requirements of Section 409A. Any payment or benefit delayed by reason of the prior sentence shall be paid out or provided in a single lump sum at the end of such required delay period in order to catch up to the original payment schedule.

(B) For purposes of this provision, the Executive shall be considered to be a "specified employee" if, at the time of his or her separation from service, the Executive is a "key employee", within the meaning of Section 416(i) of the Code, of the Company (or any person or entity with whom the Company would be considered a single employer under Section 414(b) or Section 414(c) of the Code) any stock in which is publicly traded on an established securities market or otherwise.

(iv) ***No Acceleration of Payments.*** Neither the Company nor the Executive, individually or in combination, may accelerate any payment or benefit that is subject to Section 409A, except in compliance with Section 409A and the provisions of this Agreement, and no amount that is subject to Section 409A shall be paid prior to the earliest date on which it may be paid without violating Section 409A,

(v) ***Treatment of Each Installment as a Separate Payment***. For purposes of applying the provisions of Section 409A to this Agreement, each separately identified amount to which the Executive is entitled under this Agreement shall be treated as a separate payment. In addition, to the extent permissible under Section 409A, any series of installment payments under this Agreement shall be treated as a right to a series of separate payments.

(vi) ***Taxable Reimbursements and In-Kind Benefits.***

(A) Any reimbursements by the Company to the Executive of any eligible expenses under this Agreement that are not excludable from the Executive's income for Federal income tax purposes (the **"Taxable Reimbursements")** shall be made by no later than the last day of the taxable year of the Executive following the year in which the expense was incurred.

(B) The amount of any Taxable Reimbursements, and the value of any in-kind benefits to be provided to the Executive, during any taxable year of the Executive shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year of the Executive.

(C) The right to Taxable Reimbursement, or in-kind benefits, shall not be subject to liquidation or exchange for another benefit.

(vii) ***Tax Gross-Ups,*** Payment of any tax reimbursements under this Agreement must be made by no later than the end of the taxable year of the Executive following the taxable year of the Executive in which the Executive remits the related taxes.

(viii) ***No Guaranty of 409A Compliance.*** Notwithstanding the foregoing, the Company does not make any representation to the Executive that the payments or benefits provided under this Agreement are exempt from, or satisfy, the requirements of Section 409A, and the Company shall have no liability or other obligation to indemnify or hold harmless the Executive or any beneficiary of the Executive for any tax, additional tax, interest or penalties that the Executive or any beneficiary of the Executive may incur in the event that any provision of this Agreement, or any amendment or modification thereof, or any other action taken with respect thereto, is deemed to violate any of the requirements of Section 409A.

7. ***Restrictive Covenants.***

(a) ***Non-competition.*** At all times during the Restricted Period, the Executive shall not, directly or indirectly (whether as a principal, agent, partner, employee, officer, investor, owner, consultant, board member, security holder, creditor or otherwise), engage in any Competitive Activity, or have any direct or indirect interest in any sole proprietorship, corporation, company, partnership, association, venture or business or any other person or entity that directly or indirectly (whether as a principal, agent, partner, employee, officer, investor, owner, consultant, board member, security holder, creditor, or otherwise) engages in a Competitive Activity; provided that the foregoing shall not apply to the Executive's ownership of Ordinary Shares of the Company or the acquisition by the Executive, solely as an investment, of securities of any issuer that is registered under Section 12(b) or 12(g) of the Securities Exchange Act of 1934, and that are listed or admitted for trading on any United States national securities exchange or that are quoted on the Nasdaq Stock Market, or any similar system or automated dissemination of quotations of securities prices in common use, so long as the Executive does not control, acquire a controlling interest in or become a member of a group which exercises direct or indirect control of, more than five percent (5%) of any class of capital stock of such corporation.

(b) ***Nonsolicitation of Employees and Certain Other Third Parties.*** At all times during the Restricted Period, the Executive shall not, directly or indirectly, for himself or for any other person, firm, corporation, partnership, association or other entity (i) employ or attempt to employ or enter into any contractual arrangement with any employee, consultant or independent contractor performing services for the Intec Group, or any Affiliate, and/or (ii) call on, solicit, or engage in business with, any of the actual or targeted prospective customers or clients of the Intec Group or any Affiliate on behalf of any person or entity in connection with any Competitive Activity, nor shall the Executive make known the names and addresses of such actual or targeted prospective customers or clients, or any information relating in any manner to the trade or business relationships of the Intec Group or any Affiliates with such customers or clients, other than in connection with the performance of the Executive's duties under this Agreement, and/or (iii) persuade or encourage or attempt to persuade or encourage any persons or entities with whom the Intec Group or any Affiliate does business or has some business relationship to cease doing business or to terminate its business relationship with the Intec Group or any Affiliate or to engage in any Competitive Activity on its own or with any competitor of the Intec Group or any Affiliate.

(c) ***Confidential Information.*** The Executive shall not at any time divulge, communicate, use to the detriment of the Intec Group or any Affiliate or for the benefit of any other person or persons, or misuse in any way, any Confidential Information pertaining to the business of the Intec Group or any Affiliate. Any Confidential Information or data now or hereafter acquired by the Executive with respect to the business of the Intec Group or any Affiliate (which shall include, but not be limited to, information concerning the Intec Group's or any Affiliate's financial condition, prospects, technology, customers, suppliers, sources of leads and methods of doing business) shall be deemed a valuable, special and unique asset of the Intec Group and Affiliates that is received by the Executive in confidence and as a fiduciary, and the Executive shall remain a fiduciary to the Intec Group and its Affiliates with respect to all of such information. Notwithstanding the foregoing, nothing herein shall be deemed to restrict the Executive from disclosing Confidential Information as required to perform his duties under this Agreement or to the extent required by law or by a court of law or regulatory process. If any person or authority makes a demand on the Executive purporting to legally compel him to divulge any Confidential Information, the Executive immediately shall give notice of the demand to the Company so that the Company may first assess whether to challenge the demand prior to the Executive's divulging of such Confidential Information. The Executive shall not divulge such Confidential Information until the Company either has concluded not to challenge the demand, or has exhausted its challenge, including appeals, if any. Upon request by the Company, the Executive shall deliver promptly to the Company upon termination of his services for the Intec Group, or at any time thereafter as the Company may request, all memoranda, notes, records, reports, manuals, drawings, designs, computer files in any media and other documents (and all copies thereof) containing such Confidential Information.

(d) ***Owner ship of Developments.*** All processes, concepts, techniques, inventions and works of authorship, including new contributions, improvements, formats, packages, programs, systems, machines, compositions of matter manufactured, developments, applications and discoveries, and all copyrights, patents, trade secrets, or other intellectual property rights associated therewith conceived, invented, made, developed or created by the Executive during the Term of Employment either during the course of performing work for the Intec Group or its Affiliates, or their clients, or which are related in any manner to the business (commercial or experimental) of the Intec Group or its Affiliates or their clients (collectively, the "Work Product") shall belong exclusively to the Intec Group and its Affiliates and shall, to the extent possible, be considered a work made by the Executive for hire for the Intec Group and its Affiliates within the meaning of Title 17 of the United States Code. To the extent the Work Product may not be considered work made by the Executive for hire for the Intec Group and its Affiliates, the Executive agrees to assign, and automatically assign at the time of creation of the Work Product, without any requirement of further consideration, any right, title, or interest the Executive may have in such Work Product. Upon the request of the Company, the Executive shall take such further actions, including execution and delivery of instruments of conveyance, as may be appropriate to give full and proper effect to such assignment. The Executive shall further: (i) promptly disclose the Work Product to the Company; (ii) assign to the Company or its assignee, without additional compensation, all patent or other rights to such Work Product for the United States and foreign countries; (iii) sign all papers necessary to carry out the foregoing; and (iv)give testimony in support of his inventions, all at the sole cost and expense of the Company.

(e) ***Books and Records.*** All books, records, and accounts relating commercially or professionally to the customers or clients of the Intec Group or its Affiliates, whether prepared by the Executive or otherwise coming into the Executive's possession, shall be the exclusive property of the Intec Group and its Affiliates and shall be returned immediately to the Company on termination of the Executive's employment hereunder or on the Company's request at any time.

(f) ***Acknowledgment by Executive***. The Executive acknowledges and confirms that the restrictive covenants contained in this Section 7 (including without limitation the length of the term of the provisions of this Section 7) are reasonably necessary to protect the legitimate business interests of the Intec Group and its Affiliates, are not unreasonable and are not the result of duress or coercion of any kind. The Executive further acknowledges and confirms that the compensation payable to the Executive under this Agreement is in consideration for the duties and obligations of the Executive hereunder, including the restrictive covenants contained in this Section 7, and that such compensation is sufficient, fair and reasonable. The Executive acknowledges and confirms that given the position the Executive holds within the Intec Group and its Affiliates, the Company would not enter into this Agreement or otherwise employ or continue the employment of the Executive unless the Executive agrees to be bound by the restrictive covenants set forth in this Section 7. The Executive expressly agrees that upon any breach or violation of the provisions of this Section 7, the Intec Group shall be entitled, as a matter of right, in addition to any other rights or remedies it may have, to (i) injunctive relief in any court of competent jurisdiction as described in Section 7(i) hereof, and (ii) such damages as are provided at law or in equity.

(g) ***Reformation by Court***. In the event that a court of competent jurisdiction shall determine that any provision of this Section 7 is invalid or more restrictive than permitted under the governing law of such jurisdiction, then only as to enforcement of this Section 7 within the jurisdiction of such court, such provision shall be interpreted or reformed and enforced as if it provided for the maximum restriction permitted under such governing law.

(h) ***Extension of Time.*** If the Executive is in material violation of any provision of this Section 7, then each time limitation set forth in this Section 7 shall be extended for a period of time equal to the period of time during which such violation or violations occur.

(i) ***Injunction.*** It is recognized and hereby acknowledged by the parties hereto that a material breach by the Executive of any of the covenants contained in Section 7 of this Agreement may cause irreparable harm and damage to the Intec Group, and its Affiliates, the monetary amount of which may be impossible to ascertain. As a result, the Executive recognizes and hereby acknowledges that the Intec Group and its Affiliates shall be entitled to an injunction from any court of competent jurisdiction enjoining and restraining any violation of any or all of the covenants contained in Section 7 of this Agreement by the Executive or any of his agents, either directly or indirectly, and that such right to injunction shall be cumulative and in addition to whatever other remedies the Company may lawfully possess.

8. ***Representations and Warranties of Executive.*** The Executive represents and warrants to the Company that:

(a) the Executive's employment with the Company will not in any material way conflict with or result in his breach of any agreement to which he is a party or otherwise may be bound;

(b) the Executive has not violated, and in connection with his employment with the Company will not violate, any non-solicitation, non-competition or other similar covenant or agreement of a prior employer by which he is or may be bound; and

(c) in connection with the Executive's employment with the Company, he will not use any confidential or proprietary information that he may have obtained in connection with employment with any prior employer.

9 . ***Taxes.*** Anything in this Agreement to the contrary notwithstanding, all payments required to be made by the Company hereunder to the Executive or his estate or beneficiaries shall be subject to the withholding of such amounts relating to taxes as the Company may reasonably determine it should withhold pursuant to any applicable law or regulation. In lieu of withholding such amounts, in whole or in part, the Company may, in its sole discretion, accept other provisions for payment of taxes and withholding as required by law, provided it is satisfied that all requirements of law affecting its responsibilities to withhold have been satisfied.

10. ***Arbitration.***

(a) ***Exclusive Remedy.*** The parties recognize that litigation in federal or state courts or before federal or state administrative agencies of disputes arising out of the Executive's employment with the Company or out of this Agreement, or the Executive's termination of employment or termination of this Agreement, may not be in the best interests of either the Executive or the Company, and may result in unnecessary costs, delays, complexities, and uncertainty. The parties agree that any dispute between the parties arising out of or relating to the Executive's employment, or to the negotiation, execution, performance or termination of this Agreement or the Executive's employment, including, but not limited to, any claim arising out of this Agreement, claims under Title VII of the Civil Rights Act of 1964, as amended, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, Section 1981 of the Civil Rights Act of 1966, as amended, the Family Medical Leave Act, the Employee Retirement Income Security Act, and any similar federal, state or local law, statute, regulation, or any common law doctrine, whether that dispute arises during or after employment shall be resolved by arbitration in the New York, New York area, in accordance with the National Employment Arbitration Rules of the American Arbitration Association, as modified by the provisions of this Section 10. Except as set forth below with respect to Section 7 of this Agreement, the parties each further agree that the arbitration provisions of this Agreement shall provide each party with its exclusive remedy, and each party expressly waives any right it might have to seek redress in any other forum, except as otheiwise expressly provided in this Agreement. Notwithstanding anything in this Agreement to the contrary, the provisions of this Section 10 shall not apply to any injunctions that may be sought with respect to disputes arising out of or relating to Section 7 of this Agreement. The parties acknowledge and agree that their obligations under this arbitration agreement survive the expiration or termination of this Agreement and continue after the termination of the employment relationship between the Executive and the Company. **By election of arbitration as the means for final settlement of all claims, the parties hereby waive their respective rights to, and agree not to, sue each other in any action in a Federal, State or local court with respect to such claims, but may seek to enforce in court an arbitration award rendered pursuant to this Agreement. The parties specifically agree to waive their respective rights to a trial by jury, and further agree that no demand, request or motion will be made for trial by jury.**

(b) ***Arbitration Procedure and Arbitrator's Authority.*** In the arbitration proceeding, each party shall be entitled to engage in any type of discovery permitted by the Federal Rules of Civil Procedure, to retain its own counsel, to present evidence and cross- examine witnesses, to purchase a stenographic record of the proceedings, and to submit post- hearing briefs. In reaching his/her decision, the arbitrator shall have no authority to add to, detract from, or otherwise modify any provision of this Agreement. The arbitrator shall submit with the award a written opinion which shall include findings of fact and conclusions of law. Judgment upon the award rendered by the arbitrator may be entered in any court having competent jurisdiction.

(c) ***Effect of Arbitrator's Decision; Arbitrator's Fees*** . The decision of the arbitrator shall be final and binding between the parties as to all claims which were or could have been raised in connection with the dispute, to the full extent permitted by law. In all cases in which applicable federal law precludes a waiver of judicial remedies, the parties agree that the decision of the arbitrator shall be a condition precedent to the institution or maintenance of any legal, equitable, administrative, or other formal proceeding by the Executive in connection with the dispute, and that the decision and opinion of the arbitrator may be presented in any other forum on the merits of the dispute. If the arbitrator finds that the Executive was terminated in violation of law or this Agreement, the parties agree that the arbitrator acting hereunder shall be empowered to provide the Executive with any remedy available should the matter have been tried in a court, including equitable and/or legal remedies, compensatory damages and back pay. The arbitrator's fees and expenses and all administrative fees and expenses associated with the filing of the arbitration shall be borne by the non-prevailing party.

11. ***Section 162(m) Limits***. Notwithstanding any other provision of this Agreement to the contrary, if and to the extent that any remuneration payable by the Company to the Executive for any year would exceed the maximum amount of remuneration that the Company may deduct for that year under Section 162(m), payment of the portion of the remuneration for that year that would not be so deductible under Section 162(m) shall, in the sole discretion of the Board, be deferred and become payable at such time or times as the Board determines that it first would be deductible by the Company under Section 162(m), with interest at the "short-term applicable rate" as such teim is defined in Section 1274(d) of the Code. The limitation set forth under this Section 11 shall not apply with respect to any amounts payable to the Executive pursuant to Section 6 hereof.

12. ***Assignment***. The Company shall have the right to assign this Agreement and its rights and obligations hereunder in whole, but not in part, to any corporation or other entity with or into which the Company may hereafter merge or consolidate or to which the Company may transfer all or substantially all of its assets, if in any such case said corporation or other entity shall by operation of law or expressly in writing assume all obligations of the Company hereunder as fully as if it had been originally made a party hereto, but may not otherwise assign this Agreement or its rights and obligations hereunder. The Executive may not assign or transfer this Agreement or any rights or obligations hereunder (other than by will or the laws of descent and distribution).

13. ***Governing Law.*** To the extent not preempted by federal law, this Agreement shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to principles of conflict of laws.

14. ***Jurisdiction and Venue.*** The parties acknowledge that a substantial portion of the negotiations, anticipated performance and execution of this Agreement occurred or shall occur in New York, New York, and that, therefore, without limiting the jurisdiction or venue of any other federal or state courts, each of the parties irrevocably and unconditionally (i) agrees that any suit, action or legal proceeding arising out of or relating to this Agreement which is expressly permitted by the terms of this Agreement to be brought in a court of law, shall be brought in the courts of record of the State of New York in Kings County or the court of the United States, Second Circuit; (ii) consents to the jurisdiction of each such court in any such suit, action or proceeding; (iii) waives any objection which it or he may have to the laying of venue of any such suit, action or proceeding in any of such courts; and (iv) agrees that service of any court papers may be effected on such party by mail, as provided in this Agreement, or in such other manner as may be provided under applicable laws or court rules in such courts.

15. ***Entire Agreement.*** This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and, upon its effectiveness, shall supersede all prior agreements, understandings and arrangements, both oral and written, between the Executive and the Company (or any of its affiliates) with respect to such subject matter. This Agreement may not be modified in any way unless by a written instrument signed by both the Company and the Executive.

16. ***Survival***. The respective rights and obligations of the parties hereunder shall survive any termination of the Executive's employment hereunder, including without limitation, the Company's obligations under Section 6 and the Executive's obligations under Section 7 above, and the expiration of the Term of Employment, to the extent necessary to the intended preservation of such rights and obligations.

17. ***Notices.*** All notices required or permitted to be given hereunder shall be in writing and shall be personally delivered by courier, sent by registered or certified mail, return receipt requested, sent via email with receipt acknowledgment or sent by confirmed facsimile transmission addressed as set forth herein. Notices personally delivered, sent via email or by facsimile or sent by overnight courier shall be deemed given on the date of delivery, and notices mailed in accordance with the foregoing shall be deemed given upon the earlier of receipt by the addressee, as evidenced by the return receipt thereof, or three (3) days after deposit in the U.S. mail. Notice shall be sent (i) if to the Company, addressed to 12 Hartom St., Har Hotzvim, Jerusalem, Israel; Attention: Chief Financial Officer, and (ii) if to the Executive, to his address as reflected on the payroll records of the Company, or to such other address as either party shall request by notice to the other in accordance with this provision.

18. ***Benefits; Binding Effect.*** This Agreement shall be for the benefit of and binding upon the parties hereto and their respective heirs, personal representatives, legal representatives, successors and, where permitted and applicable, assigns, including, without limitation, any successor to the Company, whether by merger, consolidation, sale of stock, sale of assets or otherwise.

19. ***Right to Consult with Counsel; No Drafting Party.*** The Executive acknowledges having read and considered all of the provisions of this Agreement carefully, and having had the opportunity to consult with counsel of his own choosing, and, given this, the Executive agrees that the obligations created hereby are not unreasonable. The Executive acknowledges that he has had an opportunity to negotiate any and all of these provisions and no 111 le of construction shall be used that would interpret any provision in favor of or against a party on the basis of who drafted the Agreement.

20. ***Severability.*** The invalidity of any one or more of the words, phrases, sentences, clauses, provisions, sections or articles contained in this Agreement shall not affect the enforceability of the remaining portions of this Agreement or any part thereof, all of which are inserted conditionally on their being valid in law, and, in the event that any one or more of the words, phrases, sentences, clauses, provisions, sections or articles contained in this Agreement shall be declared invalid, this Agreement shall be construed as if such invalid word or words, phrase or phrases, sentence or sentences, clause or clauses, provisions or provisions, section or sections or article or articles had not been inserted. If such invalidity is caused by length of time or size of area, or both, the otherwise invalid provision will be considered to be reduced to a period or area which would cure such invalidity.

21. ***Waivers.*** The waiver by either party hereto of a breach or violation of any term or provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or violation.

22. ***Damages; Attorneys Fees.*** Nothing contained herein shall be construed to prevent the Company or the Executive from seeking and recovering from the other damages sustained by either or both of them as a result of its or his breach of any term or provision of this Agreement. In the event that either party hereto seeks to collect any damages resulting from, or the injunction of any action constituting, a breach of any of the terms or provisions of this Agreement, then the party found to be at fault shall pay all reasonable costs and attorneys' fees of the other.

23. ***Waiver of Jury Trial.*** The Executive hereby knowingly, voluntarily and ' intentionally waives any right that the Executive may have to a trial by jury in respect of any litigation based hereon, or arising out of, under or in connection with this Agreement and any agreement, document or instrument contemplated to be executed in connection herewith, or any course of conduct, course of dealing statements (whether verbal or written) or actions of any party hereto.

24. ***Section Headings.*** The article, section and paragraph headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

25. ***No Third Party Beneficiary.*** Nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Company, the parties hereto and their respective heirs, personal representatives, legal representatives, successors and permitted assigns, any rights or remedies under or by reason of this Agreement.

26. ***Counterparts.*** This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument and agreement.

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the date first above written.

COMPANY:

Intec Pharma Inc.

By: /s/ Jeffrey A. Meckler
Name: Jeffrey A. Meckler
Title: CEO

EXECUTIVE:

/s/ Walt Addison Linscott
Walt Addison Linscott, Esq,

EXHIBIT A
FORM OF RELEASE

GENERAL RELEASE OF CLAIMS

1. ("Executive") for himself and his family, heirs, executors, administrators, legal representatives and their respective successors and assigns, in exchange for the consideration received pursuant to Section 6 (other than the Accrued Obligations) of the Employment Agreement to which this release is attached as Exhibit A (the "Employment Agreement"), does hereby release and forever discharge Intec Pharma, Inc. (the "Company"), its subsidiaries, affiliated companies, successors and assigns, and its current or former directors, officers, employees, shareholders or agents in such capacities (collectively with the Company, the "Released Parties") from any and all actions, causes of action, suits, controversies, claims and demands whatsoever, for or by reason of any matter, cause or thing whatsoever, whether known or unknown including, but not limited to, all claims under any applicable laws arising under or in connection with Executive's employment or termination thereof, whether for tort, breach of express or implied employment contract, wrongful discharge, intentional infliction of emotional distress, or defamation or injuries incurred on the job or incurred as a result of loss of employment. Executive acknowledges that the Company encouraged him to consult with an attorney of his choosing, and through this General Release of Claims encourages him to consult with his attorney with respect to possible claims under the Age Discrimination in Employment Act ("ADEA") and that he understands that the ADEA is a Federal statute that, among other things, prohibits discrimination on the basis of age in employment and employee benefits and benefit plans. Without limiting the generality of the release provided above, Executive expressly waives any and all claims under ADEA that he may have as of the date hereof. Executive further understands that by signing this General Release of Claims he is in fact waiving, releasing and forever giving up any claim under the ADEA as well as all other laws within the scope of this paragraph 1 that may have existed on or prior to the date hereof. Notwithstanding anything in this paragraph 1 to the contrary, this General Release of Claims shall not apply to (i) any rights to receive any payments or benefits pursuant to Section 6 of the Employment Agreement, (ii) any rights or claims that may arise as a result of events occurring after the date this General Release of Claims is executed, (iii) any indemnification rights Executive may have as a former officer or director of the Company or its subsidiaries or affiliated companies, (iv) any claims for benefits under any directors' and officers' liability policy maintained by the Company or its subsidiaries or affiliated companies in accordance with the terms of such policy, and (v) any rights as a holder of equity securities of the Company.

2. Executive represents that he has not filed against the Released Parties any complaints, charges, or lawsuits arising out of his employment, or any other matter arising on or prior to the date of this General Release of Claims, and covenants and agrees that he will never individually or with any person file, or commence the filing of, any charges, lawsuits, complaints or proceedings with any governmental agency, or against the Released Parties with respect to any of the matters released by Executive pursuant to paragraph 1 hereof (a "Proceeding"); provided, however. Executive shall not have relinquished his right to commence a Proceeding to challenge whether Executive knowingly and voluntarily waived his rights under ADEA.

3. Executive hereby acknowledges that the Company has informed him that he has up to twenty-one (21) days to sign this General Release of Claims and he may knowingly and voluntarily waive that twenty-one (21) day period by signing this General Release of Claims earlier. Executive also understands that he shall have seven (7) days following the date on which he signs this General Release of Claims within which to revoke it by providing a written notice of his revocation to the Company.

4. Executive acknowledges that this General Release of Claims will be governed by and construed and enforced in accordance with the internal laws of the State of New York applicable to contracts made and to be performed entirely within such State.

5. Executive acknowledges that he has read this General Release of Claims, that he has been advised that he should consult with an attorney before he executes this general release of claims, and that he understands all of its terms and executes it voluntarily and with full knowledge of its significance and the consequences thereof.

6. This General Release of Claims shall take effect on the eighth day following Executive's execution of this General Release of Claims unless Executive's written revocation is delivered to the Company within seven (7) days after such execution.

7. Notwithstanding any of the foregoing provisions of this General Release of Claims, in the event that the period within which the Executive had the right to execute or revoke execution of this Release extends from one tax year of the Executive to the subsequent tax year of the Executive, such execution or revocation shall be deemed to be made in the subsequent tax year of the Executive, in compliance with Section 409A of the Internal Revenue Code of 1986, as amended.

October 23, 2017

Exhibit 10.25

EMPLOYMENT AGREEMENT

This Employment Agreement ("**Agreement**") is made and entered into on this 1st day of February 2018. by and between Intec Pharma Inc. (the "**Company**"), a subsidiary of Intec Pharma Ltd., an Israeli corporation, ("**Intec**"), and Michael Gendreau, MD (hereinafter, the "**Executive**").

W I T N E S S E T H:

WHEREAS, the Company desires to hire the Executive in an executive capacity and to compensate him for such employment; and

WHEREAS, the Executive is willing to be employed by the Company upon the terms and subject to the conditions contained in this Agreement.

NOW THEREFORE, in consideration of the premises and mutual covenants contained herein and for other good and valuable consideration, the adequacy and receipt of which are hereby acknowledged, the parties agree as follows:

1. ***Definitions.*** When used in this Agreement, the following terms shall have the following meanings:

(a) ***"Accrued Obligations"*** means:

(i) all accrued but unpaid Base Salary through the end of the Term of Employment;

(ii) any unpaid or unreimbursed expenses incurred in accordance with Company policy, including amounts due under Section 5(a) hereof, to the extent incurred during the Term of Employment;

(iii) any accrued but unpaid benefits provided under the Company's employee benefit plans, subject to and in accordance with the terms of those plans;

(iv) any unpaid Bonus in respect to any completed fiscal year that has ended on or prior to the end of the Term of Employment;

(v) rights to indemnification by virtue of the Executive's position as an officer or director of the Company and Intec or their subsidiaries and the benefits under any directors' and officers' liability insurance policy maintained by the Company or Intec, in accordance with its terms thereof; and

(vi) payments for any accrued but unused vacation or other paid time off.

(b) "***Affiliate***" means any entity that controls, is controlled by, or is under common control with, either member of the Intec Group.

(c) "***Base Salary"*** means the salary provided for in Section 4(a) hereof or any increased salary granted to Executive pursuant to Section 4(a) hereof.

(d) "***Board"*** means the Board of Directors of Intec.

(e) "***Bonus***" means any bonus payable to the Executive pursuant to Section 4(b) hereof.

(f) "***Cause***" means:

(i) willful misconduct or gross negligence in the performance of Executive's duties, a material violation of any of the provisions of this Agreement, or a willful continued failure by the Executive to carry out the reasonable and lawful directions of the Board, provided that the Company has provided notice to the Executive of such willful misconduct or gross negligence or material violation or willful continued failure, and the Executive has failed to cure the foregoing within thirty (30) days of receipt of such notice.

(ii) a finding by a court of law or arbitrator of unlawful harassment of any employees of the Intec Group or any Affiliate;

(iii) knowingly and on Executive's own initiative causing or permitting to occur a violation of any law or regulation which subjects or may reasonably be expected to subject the Intec Group or any of its Affiliates to material liability;

(iv) a conviction of the Executive, or a plea of nolo contendere, to a felony involving moral turpitude; or

(v) fraud, embezzlement, theft or dishonesty of a material nature by the Executive against a member of the Intec Group or any Affiliate, or a willful material violation by the Executive of a policy or procedure of a member of the Intec Group or any Affiliate, resulting, in any case, in material economic harm to either member of the Intec Group or any Affiliate.

For purposes of this Section 1(f), no act, or failure to act, on the Executive's part shall be considered "willful" unless done, or omitted to be done, by the Executive not in good faith or without reasonable belief that the Executive's act, or failure to act, was in the best interest of the Company.

(g) ***"Change in Control"*** means (i) (A) a sale of all or substantially all of the assets of the Company or Intec; or (B) a sale (including an exchange) of all or substantially all of the shares of the capital stock of the Company or Intec, in either case to any person or entity that is not an Affiliate of the Intec Group, or a shareholder thereof, immediately prior to such transaction or transactions; or (ii) a merger, consolidation or like transaction of the Company or Intec into another corporation in which the holders of the outstanding share capital of the Company or Intec immediately before such consolidation or merger do not, immediately after such consolidation or merger, retain either (x) stock representing a majority of the voting power of the surviving entity, or (y) stock representing a majority of the voting power of an entity that wholly owns, directly or indirectly, the surviving entity; provided, however, that such sale, transfer or other event results in a "change in control" within the meaning of Section 409A of the Code.

(h) "***Code***" means the Internal Revenue Code of 1986, as amended.

(i) "***Competitive Activity***" means services or activity in material competition with the Intec Group in any of the States within the United States, or countries within the world, in which the Intec Group or any of its Affiliates conducts a significant level of business in which the Intec Group or any of its Affiliates engaged while the Executive was employed by the Company.

(j) "***Confidential Information***" means all trade secrets and information about the Intec Group or any of its Affiliates or its business, disclosed to the Executive or known by the Executive as a consequence of. or through the unique position of his employment with, the Company (including information conceived, originated, discovered or developed by the Executive and information acquired by the Intec Group or any of its Affiliates from others) prior to or after the date hereof, and not generally or publicly known (other than as a result of unauthorized disclosure by the Executive). Confidential Information includes, but is not limited to, inventions, ideas, designs, computer programs, circuits, schematics, formulas, algorithms, trade secrets, works of authorship, mask works, developmental or experimental work, processes, techniques, improvements, methods of manufacturing, know-how, data, financial information and forecasts, product plans, marketing plans and strategies, price lists, customer lists and contractual obligations and terms thereof, data, documentation and other information, in whatever form disclosed, relating to the Intec Group or any Affiliates, including, but not limited to, financial statements, financial projections, business plans, listings and contractual obligations and terms thereof, components of intellectual property, unique designs, methods of manufacturing or other technology of the Intec Group or any Affiliate.

(k) "***Disability***" means the Executive's inability, or failure, to perform the essential functions of his position, with or without reasonable accommodation, by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months.

(l) "***Expiration Date***" means the date on which the Term of Employment shall expire.

(m) "***Good Reason***" means

(i) the assignment to the Executive of any duties inconsistent in any material respect with the Executive's position (including status, titles and reporting requirements), authority, duties or responsibilities as contemplated by Section 2(b) of this Agreement, or any other action by the Company that results in a material diminution in such position, authority, duties or responsibilities, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by the Executive;any material failure by the Company to comply with any of the provisions of Section 4 or Section 5 of this Agreement, other than an isolated, insubstantial and inadvertent failure not occurring in bad faith and that is remedied by the Company promptly after receipt of notice thereof given by the Executive, and other than a reduction of compensation as part of an across-the-board reduction in all salaries for employees of the Intec Group; or

(ii) the Company's requiring the Executive to be based at any office or location outside of thirty-five (35) miles from San Diego. CA, except for travel reasonably required in the performance of the Executive's responsibilities.

(n) "***Intec Group***" means the Company and Intec.

(o) "***Ordinary Shares***" means the ordinary shares of Intec.

(p) "***Restricted Period***" shall be the Term of Employment and the six (6) month period immediately following termination of the Term of Employment.

(q) "***Severance Amount***" shall mean an amount equal to the sum of (i) 25% of the Executive's annual Base Salary as in effect immediately prior to the Termination Date; and (ii) an amount equal to the Executive's cost of continued health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act under the Company's group health plan (or the monthly payment provided under Section 5(b), as applicable) for twelve (12) months.

(r) "***Severance Term***" means the three (3) month period following the date on which the Term of Employment ends.

(s) "***Term of Employment***" means the period during which the Executive shall be employed by the Company pursuant to the terms of this Agreement.

(t) "***Termination Date***" means the date on which the Term of Employment ends.

2. ***Employment.***

(a) ***Employment and Term.*** The Company hereby agrees to employ the Executive and the Executive hereby agrees to serve the Intec Group during the Term of Employment on the terms and conditions set forth herein. The Executive's principal place of employment shall be in San Diego, CA, except for such travel that may be necessary to fulfill his responsibilities.

(b) ***Duties of Executive.*** During the Term of Employment, the Executive shall be employed on a part-time basis (80% position) and devote four (4) days per week serving as the Chief Medical Officer of the Company. Executive shall have such duties typically associated with such title, including, without limitation responsibility for the planning and execution of the company's clinical development activities. The Executive shall faithfully and diligently perform all services as may be assigned to him by the Chief Executive Officer (the **"CEO")** of the Company or the Board, and shall exercise such power and authority as may from time to time be delegated to him by the CEO or the Board. The Executive shall not engage in any other business or occupation during the Term of Employment that (i) directly conflicts with the interests of the Intec Group or its Affiliates, (ii) interferes with the proper and efficient performance of his duties for the Company, or (iii) interferes with the exercise of his judgment in the Intec Group's best interests, in each case as shall be determined by the CEO in its sole discretion.

3. ***Term.***

The Term of Employment under this Agreement, and the employment of the Executive hereunder, shall commence on the date hereof until terminated in accordance with Section 6 hereof.

4. ***Compensation.***

(a) ***Base Salary.*** The Executive shall receive a Base Salary at the annual rate of $320,000 during the Term of Employment, with such Base Salary payable in installments consistent with the Company's normal payroll schedule, subject to applicable withholding and other taxes. As an exempt employee, the Executive will not receive any overtime pay. The Executive's Base Salary will be reviewed annually in accordance with the established procedures of the Company.

(b) ***Bonuses.*** For each calendar year beginning on or after January 1, 2018, during which Term of Employment continues through December 31st, the Executive shall be eligible to receive a Bonus of up to 40% of Base Salary, subject to the achievement of certain goals to be set by the Board. Any Bonus under this Section 4(b) shall be payable, subject to applicable tax withholdings, as soon as administratively feasible, but in no event later than March 15 after the calendar year in which the Bonus was earned. The annual bonus opportunity shall also be reviewed annually in accordance with the compensation policies of the Company.

5. ***Expense Reimbursement and Other Benefits.***

(a) ***Reimbursement of Expenses.*** Upon the submission of proper substantiation by the Executive, and subject to such rules and guidelines as the Company may from time to time adopt with respect to the reimbursement of expenses of executive personnel, the Company shall reimburse the Executive for all reasonable expenses actually paid or incurred by the Executive during the Term of Employment in the course of and pursuant to the business of the Company. The Executive shall account to the Company in writing for all expenses for which reimbursement is sought and shall supply to the Company copies of all relevant invoices, receipts or other evidence reasonably requested by the Company.

(b) ***Compensation/Benefit Programs.*** During the Term of Employment, the Executive shall be entitled to participate in all medical, dental, hospitalization, accidental death and dismemberment, disability, travel and life insurance plans, and any and all other plans as are presently and hereinafter offered by the Company to its personnel, including savings, pension, profit-sharing and deferred compensation plans, subject to the general eligibility and participation provisions set forth in such plans.

(c) ***Stock Options.*** The Company shall grant to the Executive options to purchase up to 250,000 shares of Intec's Ordinary Shares (the **"Stock Options"),** in each case at a per share exercise price equal to the average closing sale price of Intec's Ordinary Shares on NASDAQ Capital Market over the 30 trading-day period immediately preceding the date of approval by the Board, or the fair market value (as determined in accordance with Section 409A of the Code) of an Ordinary Share of Intec, whichever amount is greater. Subject to the Term of Employment under this Agreement, and the employment of the Executive hereunder, continuing on and through each vesting date (except as provided in Section 6 below), the Stock Options will vest over three (3) years according to the following schedule: 33% of the Stock Options shall vest and become exercisable on the first anniversary of the grant date, and the remaining portion of the Stock Options shall vest and become exercisable in eight equal quarterly installments thereafter. The Stock Options shall be subject to a seven (7) year expiration from the grant date, and such other terms and conditions set forth in the stock option agreement and the provisions of Intec's equity plan pursuant to which the Stock Options grant is being made. In the event of (i) a Change in Control or (ii) the entry into a "'Material Agreement" (as shall be defined by the compensation committee of the Board and the Board) any Stock Options that have not previously vested shall become vested and exercisable immediately prior to such event. The Executive shall also be eligible for additional share option grants, or any other equity or equity related compensation plan or arrangement that may be made available to senior executives, in each case, at the discretion of the Board.

(d) ***Other Benefits.*** The Executive shall be entitled to (i) paid holidays as generally provided by Intec to its personnel, and (ii) three (3) weeks of paid vacation each calendar year during the Term of Employment, to be taken at such times as the Executive and the Company shall mutually determine, and provided that such vacation time shall not adversely affect in any material way the Executive's performance of his duties required to be rendered by the Executive under this Agreement. Any vacation time accrued but not taken by the Executive during any calendar year may not be carried forward into any succeeding calendar year. The Executive shall receive such additional benefits, if any, as the Board shall from time to time determine.

(g) ***Israeli Taxes.*** To the extent any component of the Executive's compensation under this Agreement shall be subject to withholdings, taxes or other govemmentally imposed taxes or tariffs under Israeli law ***("Israeli Taxes"),*** the Company shall pay directly to the tax counsel or other expert tax advisor(s) engaged by either the Company or Intec (with the Executive's approval, which shall not be unreasonably withheld) any fees, expenses or other costs incurred in order to provide counsel, advice and representation on the Executive's behalf with regard to liability for any such Israeli Taxes. If the Executive is subject to any inquiry (including, without limitation, an audit, examination or investigation) by an agent or agency of the Israeli government, the Company shall pay directly to the auditor(s), accountant(s), attorney(s) or other person(s) engaged by either the Company or Intec (with the Executive's approval, which shall not be unreasonably withheld) any fees, expenses or other costs incurred that relate to any such inquiry.

6. ***Termination.***

(a) ***General.*** The Term of Employment shall terminate upon the earliest to occur of (i) the Executive's death, (ii) a termination by the Company (in accordance with all applicable law, including, without limitation, the Americans with Disabilities Act) or the Executive by reason of the Executive's Disability, (iii) a termination by the Company with or without Cause, or (iv) a termination by the Executive with or without Good Reason. Upon any termination of the Executive's employment for any reason, except as may otherwise be requested by the Company in writing and agreed upon in writing by the Executive, the Executive shall resign from any and all directorships, committee memberships or any other positions the Executive holds with the Company or any of its Affiliates.

(b) ***Termination By Company for Cause.*** The Company shall at all times have the right, upon written notice to the Executive, to terminate the Term of Employment for Cause with an immediate effect (subject to the cure period, if applicable, as provided herein in this Section 6(b)). In no event shall a termination of the Executive's employment for Cause occur unless the Company gives written notice to the Executive in accordance with this Agreement stating with reasonable specificity the events or actions that constitute Cause and providing the Executive with an opportunity to cure (if curable) within a reasonable period of time, and if not cured within such period, the Executive's termination shall be effective upon the date immediately following the expiration of such period. Cause shall in no event be deemed to exist except upon a decision made by the Board, at a meeting, duly called and noticed, to which the Executive (and the Executive's counsel) shall be invited upon proper notice. For purposes of this Section 6(b), a reasonable, good faith determination of Cause by the Board (based on all relevant facts and circumstances) shall be binding and conclusive on all interested parties. In the event that the Term of Employment is terminated by the Company for Cause, the Executive shall be entitled only to the Accrued Obligations, payable as of the termination date of the Term of Employment.

(c) ***Disability.*** Either the Company (in accordance with all applicable law, including, without limitation, the Americans with Disabilities Act) or the Executive shall have the option to terminate the Term of Employment, upon written notice to the other party, at any time during which the Executive is suffering from a Disability. In the event that the Term of Employment is terminated due to the Executive's Disability, the Executive shall be entitled to (i) the Accrued Obligations, payable as of the termination date of the Term of Employment, and (ii) vesting, immediately prior to such termination, in any Stock Options that have not previously vested.

(d) ***Death.*** In the event that the Term of Employment is terminated due to the Executive's death, the Executive shall be entitled to (i) the Accrued Obligations, payable as of the termination date of the Term of Employment, and (ii) vesting, immediately prior to such termination, in any Stock Options that have not previously vested.

(e) ***Termination Without Cause.*** The Company may terminate the Term of Employment at any time without Cause, by written notice to the Executive not less than 30 days prior to the effective date of such termination. In the event that the Term of Employment is terminated by the Company without Cause (other than due to the Executive's death or Disability) the Executive shall be entitled to (i) the Accrued Obligations, payable as of the termination date of the Term of Employment, and (ii) the Severance Amount, payable in equal monthly installments during the Severance Term.

(f) ***Termination by Executive for Good Reason.*** The Executive may terminate the Term of Employment for Good Reason by providing the Company thirty (30) days' written notice setting forth in reasonable specificity the event that constitutes Good Reason, which written notice, to be effective, must be provided to the Company within sixty (60) days of the occurrence of such event. During such thirty (30) day notice period, the Company shall have a cure right (if curable), and if not cured within such period, the Executive's termination shall be effective upon the date immediately following the expiration of the thirty (30) day notice period, and the Executive shall be entitled to the same payments and benefits as provided in Section 6(e) above for a termination without Cause.

(g) ***Termination by Executive Without Good Reason.*** The Executive may terminate his employment without Good Reason by providing the Company sixty (60) days' written notice of such termination. In the event of a termination of employment by the Executive under this Section 6(g), the Executive shall be entitled only to the Accrued Obligations, payable as of the termination date of the Term of Employment. In the event of termination of the Executive's employment under this Section 6(g), the Company may, in its sole and absolute discretion, by written notice of at least five (5) business days, accelerate such date of termination and still have it treated as a termination without Good Reason.

(h) ***Change in Control of the Company.*** In the event of a Change in Control, any Stock Options granted to the Executive that have not previously vested shall become fully vested and exercisable immediately prior to such Change in Control, pursuant to Section 5(d). If the Executive's employment is terminated by the Company without Cause or by the Executive for Good Reason during the one (1) year period immediately following a Change in Control, then in lieu of any amounts otherwise payable under Section 6(e) or 6(1) hereof, the Executive shall be entitled to (i) the Accrued Obligations, payable as of the termination date of the Term of Employment and (ii) a lump-sum payment equal to the Severance Amount, payable on the first day after the general release of claims (as described in Section 6(i), below) becomes irrevocable in accordance with the provisions of such general release of claims.

(i) ***Release.*** Any payments or benefits due to Executive under this Section 6 (other than the Accrued Obligations) shall be conditioned upon the Executive's execution of a general release of claims substantially in the form attached hereto as Exhibit A (subject to such modifications as the Company or the Executive reasonably may request) that becomes irrevocable in accordance with the provisions of such general release of claims. The vesting of the Stock Options and payment of any amounts subject to the Executive's release shall be delayed until the first day after the date such release becomes irrevocable in accordance with the provisions of such general release of claims (the "Payment Commencement Date "), and any payments or benefits that are so delayed shall be paid or made effective on the Payment Commencement Date.

(j) ***Section 280G Reductions.***

(i) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (a "Payment"), would be nondeductible by the Company for Federal income tax purposes because of Section 280G of the Code, then the aggregate present value of amounts payable or distributable to or for the benefit of the Executive pursuant to this Agreement (such payments or distributions pursuant to this Agreement are hereinafter referred to as "Agreement Payments") shall be reduced to the Reduced Amount. The "Reduced Amount" shall be an amount expressed in present value which maximizes the aggregate present value of Agreement Payments without causing any Payment to be nondeductible by the Company because of Section 280G of the Code. Anything to the contrary notwithstanding, if the Reduced Amount is zero and it is determined further that any Payment which is not an Agreement Payment would nevertheless be nondeductible by the Company for Federal income tax purposes because of Section 280G of the Code, then the aggregate present value of Payments which are not Agreement Payments shall also be reduced (but not below zero) to an amount expressed in present value which maximizes the aggregate present value of Payments without causing any Payment to be nondeductible by the Company because of Section 280G of the Code. For purposes of this Section 6(k), present value shall be determined in accordance with Section 280G(d)(4) of the Code.

(ii) All determinations required to be made under this Section 6(k) shall be made by Price Waterhouse Coopers, LLC (the **"Accounting Firm"),** which shall provide detailed supporting calculations both to the Company and the Executive within twenty (20) business days of the Company's "change in control" determined in accordance with Section 280G of the Code or such other time as is requested by the Company and an opinion to the Executive that he has substantial authority not to report any excise tax on his Federal income tax return with respect to any Payments. Any such determination by the Accounting Firm shall be binding upon the Company and the Executive. The Company shall elect which and how much of the Payments shall be eliminated or reduced consistent with the requirements of this Section 6(k) and shall notify the Executive promptly of such election. If and to the extent necessary to avoid a violation of Section 409A, no amounts payable under any "nonqualified deferred compensation plan" subject to Section 409A shall be reduced until after all other Payments have been reduced. Within five business days thereafter, the Company shall pay to or distribute to or for the benefit of the Executive such amounts as are then due to the Executive under this Agreement. All fees and expenses of the Accounting Firm incurred in connection with the determinations contemplated by this Section 6(k) shall be borne by the Company.

(k) ***Cooperation.*** Following the Term of Employment, the Executive shall give his assistance and cooperation willingly, upon reasonable advance notice with due consideration for his other business or personal commitments, in any matter relating to his position with the Intec Group, or his expertise or experience as the Intec Group may reasonably request, including his attendance and truthful testimony where deemed appropriate by the Intec Group, with respect to any investigation or the Intec Group's defense or prosecution of any existing or future claims or litigations or other proceedings relating to matters in which he was involved or potentially had knowledge by virtue of his employment with the Company. In no event shall his cooperation materially interfere with his services for a subsequent employer or other similar service recipient. To the extent permitted by law, the Company agrees that (i) it shall promptly reimburse the Executive for his reasonable and documented expenses in connection with his rendering assistance and/or cooperation under this Section 6(1) upon his presentation of documentation for such expenses and (ii) the Executive shall be reasonably compensated for any continued material services as required under this Section 6(1).

(l) ***Return of Company Property.*** Following the Termination Date, the Executive or his personal representative shall return all Intec Group property in his possession, including but not limited to all computer equipment (hardware and software), telephones, facsimile machines, palm pilots and other communication devices, credit cards, office keys, security access cards, badges, identification cards and all copies (including drafts) of any documentation or information (however stored) relating to the business of the Intec Group, its customers and clients or its prospective customers and clients.

(m) ***Compliance with Section 409A.***

(i) ***General.*** It is the intention of both the Company and the Executive that the benefits and rights to which the Executive could be entitled pursuant to this Agreement comply with Section 409A of the Code and the Treasury Regulations and other guidance promulgated or issued thereunder **("Section** 409A**"),** to the extent that the requirements of Section 409A are applicable thereto, and the provisions of this Agreement shall be construed in a manner consistent with that intention. If the Executive or the Company believes, at any time, that any such benefit or right that is subject to Section 409A does not so comply, it shall promptly advise the other and shall negotiate reasonably and in good faith to amend the terms of such benefits and rights such that they comply with Section 409A (with the most limited possible economic effect on the Executive and on the Company).

(ii) ***Distributions on Account of Separation from Service.*** If and to the extent required to comply with Section 409A, no payment or benefit required to be paid under this Agreement on account of termination of the Executive's employment shall be made unless and until the Executive incurs a "separation from service" within the meaning of Section 409A.

(iii) ***6 Month Delay for Specified Employees.***

(A) If the Executive is a "specified employee", then no payment or benefit that is payable on account of the Executive's "separation from service", as that term is defined for purposes of Section 409A, shall be made before the date that is six (6) months after the Executive's "separation from service" (or, if earlier, the date of the Executive's death) if and to the extent that such payment or benefit constitutes deferred compensation (or may be nonqualified deferred compensation) under Section 409A and such deferral is required to comply with the requirements of Section 409A. Any payment or benefit delayed by reason of the prior sentence shall be paid out or provided in a single lump sum at the end of such required delay period in order to catch up to the original payment schedule.

(B) For purposes of this provision, the Executive shall be considered to be a "specified employee" if, at the time of his or her separation from service, the Executive is a "key employee", within the meaning of Section 416(i) of the Code, of the Company (or any person or entity with whom the Company would be considered a single employer under Section 414(b) or Section 414(c) of the Code) any stock in which is publicly traded on an established securities market or otherwise.

(iv) ***No Acceleration of Payments.*** Neither the Company nor the Executive, individually or in combination, may accelerate any payment or benefit that is subject to Section 409A, except in compliance with Section 409A and the provisions of this Agreement, and no amount that is subject to Section 409A shall be paid prior to the earliest date on which it may be paid without violating Section 409A.

(v) ***Treatment of Each Installment as a Separate Payment.*** For purposes of applying the provisions of Section 409A to this Agreement, each separately identified amount to which the Executive is entitled under this Agreement shall be treated as a separate payment. In addition, to the extent permissible under Section 409A, any series of installment payments under this Agreement shall be treated as a right to a series of separate payments.

(vi) ***Taxable Reimbursements and In-Kind Benefits.***

(A) Any reimbursements by the Company to the Executive of any eligible expenses under this Agreement that are not excludable from the Executive's income for Federal income tax purposes (the "**Taxable Reimbursements**") shall be made by no later than the last day of the taxable year of the Executive following the year in which the expense was incurred.

(B) The amount of any Taxable Reimbursements, and the value of any in-kind benefits to be provided to the Executive, during any taxable year of the Executive shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year of the Executive.

(C) The right to Taxable Reimbursement, or in-kind benefits, shall not be subject to liquidation or exchange for another benefit.

(vii) ***Tax Gross-Ups.*** Payment of any tax reimbursements under this Agreement must be made by no later than the end of the taxable year of the Executive following the taxable year of the Executive in which the Executive remits the related taxes.

(viii) ***No Guaranty of 409A Compliance.*** Notwithstanding the foregoing, the Company does not make any representation to the Executive that the payments or benefits provided under this Agreement are exempt from, or satisfy, the requirements of Section 409A, and the Company shall have no liability or other obligation to indemnify or hold harmless the Executive or any beneficiary of the Executive for any tax, additional tax, interest or penalties that the Executive or any beneficiary of the Executive may incur in the event that any provision of this Agreement, or any amendment or modification thereof, or any other action taken with respect thereto, is deemed to violate any of the requirements of Section 409A.

7. ***Restrictive Covenants.***

(a) ***Non-competition.*** At all times during the Restricted Period, the Executive shall not, directly or indirectly (whether as a principal, agent, partner, employee, officer, investor, owner, consultant, board member, security holder, creditor or otherwise), engage in any Competitive Activity, or have any direct or indirect interest in any sole proprietorship, corporation, company, partnership, association, venture or business or any other person or entity that directly or indirectly (whether as a principal, agent, partner, employee, officer, investor, owner, consultant, board member, security holder, creditor, or otherwise) engages in a Competitive Activity; provided that the foregoing shall not apply to the Executive's ownership of Ordinary Shares of the Company or the acquisition by the Executive, solely as an investment, of securities of any issuer that is registered under Section 12(b) or 12(g) of the Securities Exchange Act of 1934, and that are listed or admitted for trading on any United States national securities exchange or that are quoted on the Nasdaq Stock Market, or any similar system or automated dissemination of quotations of securities prices in common use, so long as the Executive does not control, acquire a controlling interest in or become a member of a group which exercises direct or indirect control of, more than five percent (5%) of any class of capital stock of such corporation.

(b) ***Nonsolicitation of Employees and Certain Other Third Parties.*** At all times during the Restricted Period, the Executive shall not. directly or indirectly, for himself or for any other person, firm, corporation, partnership, association or other entity (i) employ or attempt to employ or enter into any contractual arrangement with any employee, consultant or independent contractor performing services for the Intec Group, or any Affiliate, and/or (ii) call on, solicit, or engage in business with, any of the actual or targeted prospective customers or clients of the Intec Group or any Affiliate on behalf of any person or entity in connection with any Competitive Activity, nor shall the Executive make known the names and addresses of such actual or targeted prospective customers or clients, or any information relating in any manner to the trade or business relationships of the Intec Group or any Affiliates with such customers or clients, other than in connection with the performance of the Executive's duties under this Agreement, and/or (iii) persuade or encourage or attempt to persuade or encourage any persons or entities with whom the Intec Group or any Affiliate does business or has some business relationship to cease doing business or to terminate its business relationship with the Intec Group or any Affiliate or to engage in any Competitive Activity on its own or with any competitor of the Intec Group or any Affiliate.

(c) ***Confidential Information.*** The Executive shall not at any time divulge, communicate, use to the detriment of the Intec Group or any Affiliate or for the benefit of any other person or persons, or misuse in any way, any Confidential Information pertaining to the business of the Intec Group or any Affiliate. Any Confidential Information or data now or hereafter acquired by the Executive with respect to the business of the Intec Group or any Affiliate (which shall include, but not be limited to, information concerning the Intec Group's or any Affiliate's financial condition, prospects, technology, customers, suppliers, sources of leads and methods of doing business) shall be deemed a valuable, special and unique asset of the Intec Group and Affiliates that is received by the Executive in confidence and as a fiduciary, and the Executive shall remain a fiduciary to the Intec Group and its Affiliates with respect to all of such information. Notwithstanding the foregoing, nothing herein shall be deemed to restrict the Executive from disclosing Confidential Information as required to perform his duties under this Agreement or to the extent required by law or by a court of law or regulatory process. If any person or authority makes a demand on the Executive purporting to legally compel him to divulge any Confidential Information, the Executive immediately shall give notice of the demand to the Company so that the Company may first assess whether to challenge the demand prior to the Executive's divulging of such Confidential Information. The Executive shall not divulge such Confidential Information until the Company either has concluded not to challenge the demand, or has exhausted its challenge, including appeals, if any. Upon request by the Company, the Executive shall deliver promptly to the Company upon termination of his services for the Intec Group, or at any time thereafter as the Company may request, all memoranda, notes, records, reports, manuals, drawings, designs, computer files in any media and other documents (and all copies thereof) containing such Confidential Information.

(d) ***Ownership of Developments.*** All processes, concepts, techniques, inventions and works of authorship, including new contributions, improvements, formats, packages, programs, systems, machines, compositions of matter manufactured, developments, applications and discoveries, and all copyrights, patents, trade secrets, or other intellectual property rights associated therewith conceived, invented, made, developed or created by the Executive during the Term of Employment either during the course of performing work for the Intec Group or its Affiliates, or their clients, or which are related in any manner to the business (commercial or experimental) of the Intec Group or its Affiliates or their clients (collectively, the "Work Product") shall belong exclusively to the Intec Group and its Affiliates and shall, to the extent possible, be considered a work made by the Executive for hire for the Intec Group and its Affiliates within the meaning of Title 17 of the United States Code. To the extent the Work Product may not be considered work made by the Executive for hire for the Intec Group and its Affiliates, the Executive agrees to assign, and automatically assign at the time of creation of the Work Product, without any requirement of further consideration, any right, title, or interest the Executive may have in such Work Product. Upon the request of the Company, the Executive shall take such further actions, including execution and delivery of instruments of conveyance, as may be appropriate to give full and proper effect to such assignment. The Executive shall further: (i) promptly disclose the Work Product to the Company; (ii) assign to the Company or its assignee, without additional compensation, all patent or other rights to such Work Product for the United States and foreign countries; (iii) sign all papers necessary to carry out the foregoing; and (iv) give testimony in support of his inventions, all at the sole cost and expense of the Company.

(e) ***Books and Records.*** All books, records, and accounts relating commercially or professionally to the customers or clients of the Intec Group or its Affiliates, whether prepared by the Executive or otherwise coming into the Executive's possession, shall be the exclusive property of the Intec Group and its Affiliates and shall be returned immediately to the Company on termination of the Executive's employment hereunder or on the Company's request at any time.

(I) ***Acknowledgment by Executive.*** The Executive acknowledges and confirms that the restrictive covenants contained in this Section 7 (including without limitation the length of the term of the provisions of this Section 7) are reasonably necessary to protect the legitimate business interests of the Intec Group and its Affiliates, are not unreasonable and are not the result of duress or coercion of any kind. The Executive further acknowledges and confirms that the compensation payable to the Executive under this Agreement is in consideration for the duties and obligations of the Executive hereunder, including the restrictive covenants contained in this Section 7, and that such compensation is sufficient, fair and reasonable. The Executive acknowledges and confirms that given the position the Executive holds within the Intec Group and its Affiliates, the Company would not enter into this Agreement or otherwise employ or continue the employment of the Executive unless the Executive agrees to be bound by the restrictive covenants set forth in this Section 7. The Executive expressly agrees that upon any breach or violation of the provisions of this Section 7, the Intec Group shall be entitled, as a matter of right, in addition to any other rights or remedies it may have, to (i) injunctive relief in any court of competent jurisdiction as described in Section 7(i) hereof, and (ii) such damages as are provided at law or in equity.

(h) ***Reformation by Court.*** In the event that a court of competent jurisdiction shall determine that any provision of this Section 7 is invalid or more restrictive than permitted under the governing law of such jurisdiction, then only as to enforcement of this Section 7 within the jurisdiction of such court, such provision shall be interpreted or reformed and enforced as if it provided for the maximum restriction permitted under such governing law.

(i) ***Extension of Time.*** If the Executive is in material violation of any provision of this Section 7, then each time limitation set forth in this Section 7 shall be extended for a period of time equal to the period of time during which such violation or violations occur.

(j) ***Injunction.*** It is recognized and hereby acknowledged by the parties hereto that a material breach by the Executive of any of the covenants contained in Section 7 of this Agreement may cause irreparable harm and damage to the Intec Group, and its Affiliates, the monetary amount of which may be impossible to ascertain. As a result, the Executive recognizes and hereby acknowledges that the Intec Group and its Affiliates shall be entitled to an injunction from any court of competent jurisdiction enjoining and restraining any violation of any or all of the covenants contained in Section 7 of this Agreement by the Executive or any of his agents, either directly or indirectly, and that such right to injunction shall be cumulative and in addition to whatever other remedies the Company may lawfully possess.

8. ***Representations and Warranties of Executive.*** The Executive represents and warrants to the Company that:

(a) the Executive's employment with the Company will not in any material way conflict with or result in his breach of any agreement to which he is a party or otherwise may be bound;

(b) the Executive has not violated, and in connection with his employment with the Company will not violate, any non-solicitation, non-competition or other similar covenant or agreement of a prior employer by which he is or may be bound; and

(c) in connection with the Executive's employment with the Company, he will not use any confidential or proprietary information that he may have obtained in connection with employment with any prior employer.

9. ***Taxes.*** Anything in this Agreement to the contrary notwithstanding, all payments required to be made by the Company hereunder to the Executive or his estate or beneficiaries shall be subject to the withholding of such amounts relating to taxes as the Company may reasonably determine it should withhold pursuant to any applicable law or regulation. In lieu of withholding such amounts, in whole or in part, the Company may, in its sole discretion, accept other provisions for payment of taxes and withholding as required by law, provided it is satisfied that all requirements of law affecting its responsibilities to withhold have been satisfied.

10. ***Arbitration.***

(a) ***Exclusive Remedy.*** The parties recognize that litigation in federal or state courts or before federal or state administrative agencies of disputes arising out of the Executive's employment with the Company or out of this Agreement, or the Executive's termination of employment or termination of this Agreement, may not be in the best interests of either the Executive or the Company, and may result in unnecessary costs, delays, complexities, and uncertainty. The parties agree that any dispute between the parties arising out of or relating to the Executive's employment, or to the negotiation, execution, performance or termination of this Agreement or the Executive's employment, including, but not limited to, any claim arising out of this Agreement, claims under Title VII of the Civil Rights Act of 1964, as amended, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, Section 1981 of the Civil Rights Act of 1966, as amended, the Family Medical Leave Act, the Employee Retirement Income Security Act, and any similar federal, state or local law, statute, regulation, or any common law doctrine, whether that dispute arises during or after employment shall be resolved by arbitration in the San Diego, California area, in accordance with the National Employment Arbitration Rules of the American Arbitration Association, as modified by the provisions of this Section 10. Except as set forth below with respect to Section 7 of this Agreement, the parties each further agree that the arbitration provisions of this Agreement shall provide each party with its exclusive remedy, and each party expressly waives any right it might have to seek redress in any other forum, except as otherwise expressly provided in this Agreement. Notwithstanding anything in this Agreement to the contrary, the provisions of this Section 10 shall not apply to any injunctions that may be sought with respect to disputes arising out of or relating to Section 7 of this Agreement. The parties acknowledge and agree that their obligations under this arbitration agreement survive the expiration or termination of this Agreement and continue after the termination of the employment relationship between the Executive and the Company. **By election of arbitration as the means for Final settlement of all claims, the parties hereby waive their respective rights to, and agree not to, sue each other in any action in a Federal, State or local court with respect to such claims, hut may seek to enforce in court an arbitration award rendered pursuant to this Agreement. The parties specifically agree to waive their respective rights to a trial by jury', and further agree that no demand, request or motion will be made for trial by jury.**

(b) ***Arbitration Procedure and Arbitrator's Authority.*** In the arbitration proceeding, each party shall be entitled to engage in any type of discovery permitted by the Federal Rules of Civil Procedure, to retain its own counsel, to present evidence and cross-examine witnesses, to purchase a stenographic record of the proceedings, and to submit post-hearing briefs. In reaching his/her decision, the arbitrator shall have no authority to add to, detract from, or otherwise modify any provision of this Agreement. The arbitrator shall submit with the award a written opinion which shall include findings of fact and conclusions of law. Judgment upon the award rendered by the arbitrator may be entered in any court having competent jurisdiction.

(c) ***Effect of Arbitrator's Decision; Arbitrator's Fees.*** The decision of the arbitrator shall be final and binding between the parties as to all claims which were or could have been raised in connection with the dispute, to the full extent permitted by law. In all cases in which applicable federal law precludes a waiver of judicial remedies, the parties agree that the decision of the arbitrator shall be a condition precedent to the institution or maintenance of any legal, equitable, administrative, or other formal proceeding by the Executive in connection with the dispute, and that the decision and opinion of the arbitrator may be presented in any other forum on the merits of the dispute. If the arbitrator finds that the Executive was terminated in violation of law or this Agreement, the parties agree that the arbitrator acting hereunder shall be empowered to provide the Executive with any remedy available should the matter have been tried in a court, including equitable and/or legal remedies, compensatory damages and back pay. The arbitrator's fees and expenses and all administrative fees and expenses associated with the filing of the arbitration shall be borne by the non-prevailing party.

11. ***Section 162(m) Limits.*** Notwithstanding any other provision of this Agreement to the contrary, if and to the extent that any remuneration payable by the Company to the Executive for any year would exceed the maximum amount of remuneration that the Company may deduct for that year under Section 162(m), payment of the portion of the remuneration for that year that would not be so deductible under Section 162(m) shall, in the sole discretion of the Board, be deferred and become payable at such time or times as the Board determines that it first would be deductible by the Company under Section 162(m), with interest at the "short-term applicable rate" as such term is defined in Section 1274(d) of the Code. The limitation set forth under this Section 11 shall not apply with respect to any amounts payable to the Executive pursuant to Section 6 hereof.

12. ***Assignment.*** The Company shall have the right to assign this Agreement and its rights and obligations hereunder in whole, but not in part, to any corporation or other entity with or into which the Company may hereafter merge or consolidate or to which the Company may transfer all or substantially all of its assets, if in any such case said corporation or other entity shall by operation of law or expressly in writing assume all obligations of the Company hereunder as fully as if it had been originally made a party hereto, but may not otherwise assign this Agreement or its rights and obligations hereunder. The Executive may not assign or transfer this Agreement or any rights or obligations hereunder (other than by will or the laws of descent and distribution).

13. ***Governing Law.*** To the extent not preempted by federal law, this Agreement shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to principles of conflict of laws.

14. ***Jurisdiction and Venue.*** The parties acknowledge that a substantial portion of the negotiations, anticipated performance and execution of this Agreement occurred or shall occur in New York, New York, and that, therefore, without limiting the jurisdiction or venue of any other federal or state courts, each of the parties irrevocably and unconditionally (i) agrees that any suit, action or legal proceeding arising out of or relating to this Agreement which is expressly permitted by the terms of this Agreement to be brought in a court of law, shall be brought in the courts of record of the State of New York in Kings County or the court of the United States, Second Circuit; (ii) consents to the jurisdiction of each such court in any such suit, action or proceeding; (iii) waives any objection which it or he may have to the laying of venue of any such suit, action or proceeding in any of such courts; and (iv) agrees that service of any court papers may be effected on such party by mail, as provided in this Agreement, or in such other manner as may be provided under applicable laws or court rules in such courts.

15. ***Entire Agreement.*** This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and. upon its effectiveness, shall supersede all prior agreements, understandings and arrangements, both oral and written, between the Executive and the Company (or any of its affiliates) with respect to such subject matter. This Agreement may not be modified in any way unless by a written instrument signed by both the Company and the Executive.

16. ***Survival.*** The respective rights and obligations of the parties hereunder shall survive any termination of the Executive's employment hereunder, including without limitation, the Company's obligations under Section 6 and the Executive's obligations under Section 7 above, and the expiration of the Term of Employment, to the extent necessary to the intended preservation of such rights and obligations.

17. ***Notices.*** All notices required or permitted to be given hereunder shall be in writing and shall be personally delivered by courier, sent by registered or certified mail, return receipt requested, sent via email with receipt acknowledgment or sent by confirmed facsimile transmission addressed as set forth herein. Notices personally delivered, sent via email or by facsimile or sent by overnight courier shall be deemed given on the date of delivery, and notices mailed in accordance with the foregoing shall be deemed given upon the earlier of receipt by the addressee, as evidenced by the return receipt thereof, or three (3) days after deposit in the U.S. mail. Notice shall be sent (i) if to the Company, addressed to 12 Hartom St., Har Hotzvim. Jerusalem. Israel: Attention: Chief Financial Officer, and (ii) if to the Executive, to his address as reflected on the payroll records of the Company, or to such other address as either party shall request by notice to the other in accordance with this provision.

18. ***Benefits; Binding Effect.*** This Agreement shall be for the benefit of and binding upon the parties hereto and their respective heirs, personal representatives, legal representatives, successors and. where permitted and applicable, assigns, including, without limitation, any successor to the Company, whether by merger, consolidation, sale of stock, sale of assets or otherwise.

19. ***Right to Consult with Counsel; No Drafting Party.*** The Executive acknowledges having read and considered all of the provisions of this Agreement carefully, and having had the opportunity to consult with counsel of his own choosing, and, given this, the Executive agrees that the obligations created hereby are not unreasonable. The Executive acknowledges that he has had an opportunity to negotiate any and all of these provisions and no rule of construction shall be used that would interpret any provision in favor of or against a party on the basis of who drafted the Agreement.

20. ***Severability.*** The invalidity of any one or more of the words, phrases, sentences, clauses, provisions, sections or articles contained in this Agreement shall not affect the enforceability of the remaining portions of this Agreement or any part thereof, all of which are inserted conditionally on their being valid in law, and, in the event that any one or more of the words, phrases, sentences, clauses, provisions, sections or articles contained in this Agreement shall be declared invalid, this Agreement shall be construed as if such invalid word or words, phrase or phrases, sentence or sentences, clause or clauses, provisions or provisions, section or sections or article or articles had not been inserted. If such invalidity is caused by length of time or size of area, or both, the otherwise invalid provision will be considered to be reduced to a period or area which would cure such invalidity.

21. ***Waivers.*** The waiver by either party hereto of a breach or violation of any term or provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or violation.

22. ***Damages; Attorneys Fees.*** Nothing contained herein shall be construed to prevent the Company or the Executive from seeking and recovering from the other damages sustained by either or both of them as a result of its or his breach of any term or provision of this Agreement. In the event that either party hereto seeks to collect any damages resulting from, or the injunction of any action constituting, a breach of any of the terms or provisions of this Agreement, then the party found to be at fault shall pay all reasonable costs and attorneys' fees of the other.

23. ***Waiver of Jury Trial.*** The Executive hereby knowingly, voluntarily and intentionally waives any right that the Executive may have to a trial by jury in respect of any litigation based hereon, or arising out of, under or in connection with this Agreement and any agreement, document or instrument contemplated to be executed in connection herewith, or any course of conduct, course of dealing statements (whether verbal or written) or actions of any party hereto.

24. ***Section Headings.*** The article, section and paragraph headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

25. ***No Third Party Beneficiary.*** Nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Company, the parties hereto and their respective heirs, personal representatives, legal representatives, successors and permitted assigns, any rights or remedies under or by reason of this Agreement.

26. ***Counterparts.*** This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument and agreement.

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the date first above written.

COMPANY:

Intec Pharma Inc.

By:	/s/ Jeffrey A. Meckler	/s/ Nir Sassi
Name:	Jeffrey A. Meckler	Nir Sassi
Title:	CEO	CFO

EXECUTIVE:

/s/ R. Michael Gendreau
R. Michael Gendreau, MD

EXHIBIT A
FORM OF RELEASE

GENERAL RELEASE OF CLAIMS

1. R. Michael Gendreau ("Executive"), for himself and his family, heirs, executors, administrators, legal representatives and their respective successors and assigns, in exchange for the consideration received pursuant to Section 6 (other than the Accrued Obligations) of the Employment Agreement to which this release is attached as Exhibit A (the " Employment Aureement"). does hereby release and forever discharge Intec Pharma, Inc. (the "Company"), its subsidiaries, affiliated companies, successors and assigns, and its current or former directors, officers, employees, shareholders or agents in such capacities (collectively with the Company, the "Released Parties") from any and all actions, causes of action, suits, controversies, claims and demands whatsoever, for or by reason of any matter, cause or thing whatsoever, whether known or unknown including, but not limited to, all claims under any applicable laws arising under or in connection with Executive's employment or termination thereof, whether for tort, breach of express or implied employment contract, wrongful discharge, intentional infliction of emotional distress, or defamation or injuries incurred on the job or incurred as a result of loss of employment. Executive acknowledges that the Company encouraged him to consult with an attorney of his choosing, and through this General Release of Claims encourages him to consult with his attorney with respect to possible claims under the Age Discrimination in Employment Act ("ADEA") and that he understands that the ADEA is a Federal statute that, among other things, prohibits discrimination on the basis of age in employment and employee benefits and benefit plans. Without limiting the generality of the release provided above, Executive expressly waives any and all claims under ADEA that he may have as of the date hereof. Executive further understands that by signing this General Release of Claims he is in fact waiving, releasing and forever giving up any claim under the ADEA as well as all other laws within the scope of this paragraph 1 that may have existed on or prior to the date hereof. Notwithstanding anything in this paragraph 1 to the contrary, this General Release of Claims shall not apply to (i) any rights to receive any payments or benefits pursuant to Section 6 of the Employment Agreement, (ii) any rights or claims that may arise as a result of events occurring after the date this General Release of Claims is executed, (iii) any indemnification rights Executive may have as a former officer or director of the Company or its subsidiaries or affiliated companies, (iv) any claims for benefits under any directors' and officers' liability policy maintained by the Company or its subsidiaries or affiliated companies in accordance with the terms of such policy, and (v) any rights as a holder of equity securities of the Company.

2. Executive represents that he has not filed against the Released Parties any complaints, charges, or lawsuits arising out of his employment, or any other matter arising on or prior to the date of this General Release of Claims, and covenants and agrees that he will never individually or with any person file, or commence the filing of, any charges, lawsuits, complaints or proceedings with any governmental agency, or against the Released Parties with respect to any of the matters released by Executive pursuant to paragraph 1 hereof (a "Proceeding"); provided. however. Executive shall not have relinquished his right to commence a Proceeding to challenge whether Executive knowingly and voluntarily waived his rights under ADEA.

3. Executive hereby acknowledges that the Company has informed him that he has up to twenty-one (21) days to sign this General Release of Claims and he may knowingly and voluntarily waive that twenty-one (21) day period by signing this General Release of Claims earlier. Executive also understands that he shall have seven (7) days following the date on which he signs this General Release of Claims within which to revoke it by providing a written notice of his revocation to the Company.

4. Executive acknowledges that this General Release of Claims will be governed by and construed and enforced in accordance with the internal laws of the State of New York applicable to contracts made and to be performed entirely within such State.

5. Executive acknowledges that he has read this General Release of Claims, that he has been advised that he should consult with an attorney before he executes this general release of claims, and that he understands all of its terms and executes it voluntarily and with full knowledge of its significance and the consequences thereof.

6. This General Release of Claims shall take effect on the eighth day following Executive's execution of this General Release of Claims unless Executive's written revocation is delivered to the Company within seven (7) days after such execution.

7. Notwithstanding any of the foregoing provisions of this General Release of Claims, in the event that the period within which the Executive had the right to execute or revoke execution of this Release extends from one tax year of the Executive to the subsequent tax year of the Executive, such execution or revocation shall be deemed to be made in the subsequent tax year of the Executive, in compliance with Section 409A of the Internal Revenue Code of 1986, as amended.

February 1, 2018

Exhibit 10.26

PROCESS DEVELOPMENT AGREEMENT
ACCORDION PILL™ CARBIDOPA LEVODOPA

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

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PROCESS DEVELOPMENT AGREEMENT

THIS AGREEMENT, made and effective as of this 17thday of December, 2018 ("Effective Date") by and between LTS LOHMANN Therapie-Systeme AG, company organized and existing under the laws of Germany, having its executive offices and principal place of business at Lohmannstraße 2, 56626 Andernach, Germany (hereinafter called "LTS") and INTEC PHARMA Ltd., a corporation organized and existing under the laws of the State of Israel, having its executive offices and principal place of business at 12 Hartom Street, P.O. Box 45219, Jerusalem, Israel (hereinafter called "INTEC" and as further defined, below).

Individually referred to as a "Party" and jointly referred to as the "Parties".

WITNESSETH

WHEREAS INTEC has developed or owns rights to a certain delivery technology called "Accordion Pill" which is based on patents under an exclusive license to INTEC and additional proprietary intellectual property and confidential know-how of INTEC;

WHEREAS LTS has expertise in the formulation and manufacturing process of transdermal therapeutic systems and oral thin films and the commercial manufacture of such formulations which is based on patents and additional proprietary intellectual property and confidential know-how of LTS;

WHEREAS, LTS and INTEC entered into a Term Sheet dated March 11, 2018 regarding scaling up of the manufacturing process for the Product using the Accordion Pill technology containing the ingredients Carbidopa/Levodopa (the "Term Sheet");

WHEREAS, INTEC intends to distribute the Product by itself or through its licensees, successors or assigns as hereinafter defined;

WHEREAS, INTEC wishes LTS to perform the scale-up, process development and establishes the commercial manufacturing of the Product;

NOW THEREFORE, in consideration of the premises and mutual covenants and conditions set forth herein, the Parties agree as follows:

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

ARTICLE I DEFINITIONS

GENERAL

When used in this Agreement, each of the following terms shall have the meaning set forth in this Article I.

Wherever used in this Agreement

(a) words of any gender include each other gender;

(b) words using the singular or plural number also include the plural or singular number, respectively;

(c) the terms "hereof", "herein", "hereunder", "hereby" and derivative or similar words refer to this entire Agreement;

(d) the terms "Article" or "Section" refer to the specified Article or Section of this Agreement;

(e) The titles of the Articles and Sections of this Agreement are for general information and reference only, and this Agreement shall not be construed by reference to the titles.

1.01 "ACCORDION PILL"

The term "Accordion Pill" shall mean a gastro-retentive oral drug delivery dosage form, comprising a multi-layered drug delivery system composed of a drug-containing polymeric matrix, the system is folded with multiple undulating pleats, and the folded system is within a capsule.

1.02 "ACCORDION PILL PRODUCTION LINE"

The term "Accordion Pill Production Line" shall mean [***]

1.03 "ACTIVE PHARMACEUTICAL INGREDIENT/ API"

"Active Pharmaceutical Ingredient" or "API" shall mean Carbidopa and Levodopa with specifications as set forth Annex 5 ("API Specifications").

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

1.04 "AFFILIATE"

"Affiliate" shall mean any entity which controls, is controlled by, or is under common control with a Party. For purposes of this definition, a Party shall be deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting equity of such other entity (or other comparable ownership interest or voting power in an entity other than a corporation) or if it has management control of the other entity.

1.05 "AGREEMENT"

"Agreement" shall mean this Process Development Agreement and the annexes thereto.

1.06 "BUSINESS DAY"

"Business Day" shall mean any day (other than Saturdays, Sundays and Public Holidays) on which LTS is opened for business in Andernach, Germany.

1.07 "CLINICAL SAMPLES"

"Clinical Samples" shall mean samples and placebos of the Product supplied to INTEC for purposes of evaluation by INTEC in a clinical study.

1.08 "CMC PART"

"CMC Part" shall mean the Chemistry, Manufacturing and Controls part of regulatory submissions for the product (drug master file or equivalent in other territories).

1.09 "COMMERCIALLY REASONABLE EFFORTS"

"Commercially Reasonable Efforts" shall mean [***].

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

1.10 "COMPONENTS"

"Components" shall mean, collectively, all raw materials, excipients and materials required to manufacture and package for performing the Development Activities other than API.

1.11 "CONTROL"

"Control" (including any variations such as "Controlled" and "Controlling"), in the context of intellectual property or other rights, shall mean rights sufficient to enable a person to grant another person ownership, access, a license or sublicense (as applicable) to such intellectual property or other rights, subject to any applicable terms and conditions, without

(a) requiring the consent of third party or

(b) violating the terms of an agreement with a third party.

1.12 "DEFECTIVE PRODUCT"

"Defective Product" shall mean Product and/or Clinical Samples that do not comply with the Specifications or, in the case of Clinical Samples, not manufactured according to cGMP.

1.13 "DEVELOPMENT ACTIVITIES"

"Development Activities" shall mean the activities as set forth in the Development Plan or additional activities that the Parties may agree upon in connection with the development of the manufacturing process for the Product (including, but not limited to, qualification and validation of the manufacturing process).

1.14 "DEVELOPMENT PLAN"

"Development Plan" shall mean the plan, which is attached hereto as Annex 1 setting forth the activities to be performed hereunder and the prospective timelines for such activities starting with the execution of the Agreement.

1.14 "INTEC"

"INTEC" shall mean INTEC PHARMA, Ltd. and its Affiliates, successors and assigns.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

1.15 "INTEC TECHNOLOGY"

"Intec Technology" shall mean the delivery technology called "Accordion Pill" which is based on patents under an exclusive license to INTEC and additional proprietary Intellectual Property and confidential know-how of INTEC.

1.16 "INTELLECTUAL PROPERTY"

"Intellectual Property" shall mean any and all rights in and/or to (a) patents; (b) inventions, discoveries, utility models and improvements (whether or not capable of protection by patent or registration); (c) copyright and related rights; (d) design rights; (e) trademarks and service marks; (f) business or trade names, domain names; (g) database rights; (h) confidential information, know-how, trade secrets; and (i) other intellectual property rights; in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

1.17 "LTS TECHNOLOGY"

"LTS Technology" shall mean LTS' expertise in the formulation and manufacturing process of transdermal therapeutic systems and oral thin films and the commercial manufacture of such formulations which is based on patents and additional proprietary Intellectual Property and confidential know-how of LTS.

1.18 "MANUFACTURING AGREEMENT"

"Manufacturing Agreement" shall mean the manufacturing and supply agreement to be negotiated between the Parties for the manufacture and supply of the Product as set forth in Article 2.02 of this Agreement.

1.19 "PRODUCT"

The term "Product" shall mean an Accordion Pill containing the API according to the Product properties set forth in the Specifications.

1.20 "PROJECT"

"Project" shall mean cooperation of the Parties under this Agreement with the objective to perform the Development Activities.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

1.21 "SPECIFICATIONS"

"Specifications" shall mean the written specifications to be developed by the Parties for the raw materials of Product and for the manufacturing and quality control of the Product and/or Clinical Samples, including any and all additions and amendments to the same made in writing by the Parties during the course of the Project.

ARTICLE II COOPERATION; SCOPE OF WORK

2.01 The Parties shall duly and exclusively cooperate during the course of the Project.

2.02 In case that the respective first regulatory market authorisation grants the market authorisation for the Product, the Parties agree that LTS shall exclusively manufacture the Product for INTEC and/or its licensees, successors or assigns for as long as the Parties' relationship has not been terminated in accordance with the terms hereof or of the Manufacturing Agreement to be negotiated and entered into by the Parties (subject to the execution of the Manufacturing Agreement, and the standard termination provisions included therein) and INTEC and/or its licensees shall collaborate exclusively in the scaling-up of Product with LTS and LTS shall supply all of INTEC's and/or its licensees requirements of Product.

2.03 LTS shall be responsible for the Development Activities. INTEC shall be responsible for all clinical trials and any other activities required for the registration and commercialization of the Product which are not part of the Development Activities.

2.04 All Development Activities are subject to the Parties providing the necessary manufacturing equipment as set forth in Article III, including but not limited to the Accordion Pill Production Line and LTS Equipment as set forth in **Annex 2** attached hereto which may be amicably amended by the Parties from time to time based on the Project progress.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

ARTICLE III EQUIPMENT

3.01 The Accordion Pill Production Line shall be owned by INTEC and placed in LTS' facility during the entire term of the Agreement. In addition, LTS shall not [***] which is considered as Confidential Information (as defined in the CDA set forth in Annex 3), [***]. To the extent required, INTEC and LTS shall execute all necessary agreements and documents to in order to reflect INTEC's ownership rights hereunder.

3.02 The Accordion Pill Production Line shall be operated and maintained by LTS as follows:

(a) INTEC shall be responsible for and carry out the acceptance procedure with the supplier of the Accordion Pill Production Line upon the completion of its installation at LTS' facility with assistance, as required, and prior consultation with LTS personnel. INTEC shall handle any warranty claims against the supplier of the Accordion Pill Production Line and shall be responsible for providing a working Accordion Pill Production Line to use for the Development Activities.

(b) [***] during the term of the Agreement and shall be responsible for the proper operation and maintenance of the Accordion Pill Production Line in compliance with the manufacturer's and INTEC's specifications for the Accordion Pill Production Line.

(c) For any maintenance and/or repair works - including, but not limited to, wear parts - on the Accordion Pill Production Line LTS believes to be necessary LTS shall be required to execute such work on behalf of INTEC including, but not limited to, the mandating of external service providers. Any costs incurred to such works shall be borne by LTS up to an [***]. Any additional costs for such works carried out by LTS or any third party on behalf of INTEC [***] shall be borne by INTEC subject to INTEC's prior approval which shall not be unreasonably withheld.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

(d) LTS shall be entitled to make minor adjustments on the Accordion Pill Production Line at its own discretion that lead to an enhancement of performance and/or quality. LTS shall inform INTEC about any planned material improvement as soon as feasible and shall obtain INTEC's approval prior to implementation which shall not be unreasonable withheld.

(e) In case of emergency or any accident LTS shall be entitled to initiate any necessary actions on behalf of INTEC.

(f) For any of the activities LTS carries out on behalf of INTEC under this Section 3.02 LTS shall only be liable for any damages resulting from such initiated actions, but LTS shall in no event be liable for any lost profits as set forth in Section 11.06.

3.03 LTS and INTEC shall make the actual investments into the necessary production equipment as set forth in **Annex 2** ("LTS Equipment") which may be amicably amended by the Parties from time to time based on the Project progress as follows:

(a) INTEC shall bear the total investment sum incurred by LTS for the LTS Equipment ("Intec Share") that is necessary according to the decision of the technical working group for and solely related to the Project.

(b) LTS shall reimburse INTEC for the Intec Share by reducing the commercial Product price by [***] % [***] per unit until the total amount of the Intec Share is reimbursed. In the event that INTEC provides notice to LTS that INTEC has decided not to continue with the Project or with the commercialisation of the Product, LTS shall be entitled in its sole discretion to either (i) retain the LTS Equipment or parts thereof by reimbursing to INTEC the actually incurred Intec Share for the LTS Equipment or parts thereof minus LTS' investment under the LTS Share above the first [***] of such investment, and in any event LTS may not take more than € 2 million (two million Euro) of deduction or (ii) transfer the LTS Equipment or parts thereof to INTEC at INTEC's costs by INTEC reimbursing to LTS LTS' investment under the LTS Share above the first [***] of such investment, and in any event in an amount not more than € 2 million (two million Euro) in total reimbursement by INTEC.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

(c) The LTS Equipment shall be owned by LTS and LTS shall be responsible for the maintenance, repair and improvements of the LTS Equipment.

(d) In addition, LTS shall upgrade the space dedicated to INTEC's Product manufacturing and maintaining that and its Andernach facility to GMP standard and to expand its facility in order to establish the production of the Product. Any necessary investments related to such upgrade shall be borne by LTS up to an amount [***] and any investment amount exceeding [***] ("LTS Share"). The amount of the actual gap in the LTS Share as set forth above, not to exceed € 1 million (one million Euro), shall be borne by INTEC and such contribution to the investment shall be due upon the announcement of the results of the phase III clinical study by INTEC or October 31, 2019 whatever occurs earlier. LTS shall be entitled to invoice the amount to INTEC with payment due within 30 (thirty) days of receipt of LTS' invoice.

3.04 The LTS Equipment shall be purchased by LTS on behalf of INTEC on INTEC's costs by LTS providing a purchase order to INTEC for INTEC's approval which shall not be unreasonably withheld.

3.05 LTS shall invoice the costs for such purchases of equipment to INTEC in the first week of each month according to the payment schedule set forth in **Annex 2** which may be amicably amended by the Parties from time to time based on the Project progress and according to the payment terms set forth in Section 7.02.

3.06 LTS shall solely use the LTS Equipment to manufacture the Product for INTEC hereunder until (a) the [***] of the launch date in the first country or (b) INTEC fails to place binding orders in the annual amount of [***] units commencing on the [***] anniversary of the commercial launch date, whichever occurs earlier. Upon occurrence of Section 3.06 (a) or (b) as set forth above LTS shall be entitled to use the LTS Equipment for any product other than Product, provided such use does not negatively impact INTEC's production of Product. However, in case that Section 3.06 (b) occurs and the LTS Equipment has not been fully reimbursed by LTS according to Section 3.03 (b) the Parties shall discuss reasonable mechanism to allow INTEC to recoup the Intec Share.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

ARTICLE IV CONTRIBUTION OF LTS

4.01 LTS CONTRIBUTION

LTS shall use its Commercially Reasonable Efforts to perform the Development Activities. LTS shall document the Development Activities. LTS shall purchase, qualify, test, inspect and approve all Components for the Development Activities at its costs.

4.02 CHANGES TO THE DEVELOPMENT PLAN AND ADDITIONAL LTS ACTIVITIES

Any changes to the Development Plan, additional LTS activities or changes to such additional activities shall only become valid upon the prior written agreement of the Parties.

4.03 ESTIMATED TIMELINES AND COSTS

LTS shall use its Commercially Reasonable Efforts to perform the Development Activities within the timelines set forth in the Development Plan. The assessment of employee-hours as set forth in the Development Plan is based on LTS' best estimates and is subject to variance. LTS shall advise INTEC monthly on each Development Activity as listed in the Development Plan, the aggregate hours expended for the work performed in that month together with a forecast of hours to be expended in the following month including a forecast for the completion of each remaining Development Activity. In the event LTS determines or forecasts that the employee-hours required to complete each element of the Development Plan will exceed the amount as set forth in the Development Plan by more than [***], LTS shall provide a basis for the variance and INTEC shall have 10 (ten) Business days to challenge the variance costs. No response by INTEC to LTS' provided variance shall be deemed as acceptance by INTEC thereof. In the event the Parties do not resolve the variance with two (2) months after LTS' receipt of INTEC challenge, the Parties shall submit the variance to the Parties' steering committee (to be established) for resolution. Employee-hours charged by LTS under this Agreement shall not include time expended by [***] of the employees working on the Project.

In case of agreement of additional activities by the Parties, the foregoing shall also apply to these additional activities accordingly.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

4.04 LTS' SUPPORT OF REGISTRATION

LTS shall provide to INTEC in a timely manner the information required for preparing the CMC Part of INTEC's regulatory filings for the Product in the USA and as contemplated in the Development Plan.

In the event INTEC wishes additional support from LTS for the registration of the Product any such activities shall be subject to the terms and conditions of this Agreement and a written agreement defining LTS' compensation for such support.

Any man-hours resulting from such additional support shall not be taken into consideration for determining (according to Section 4.03) whether the employee-hours set forth in the Development Plan would be exceeded or not.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

4.05 AUDIT AT LTS

LTS will permit an authorized representative of INTEC and/or its Affiliates upon written reasonable advance notice to conduct a quality audit at LTS' facility at reasonable times under such conditions as LTS may reasonably require in order to protect the confidentiality of its own and its other customer's proprietary and confidential information.

4.06 QUALITY AGREEMENT

The pharmaceutical aspects of the manufacturing of Clinical Samples and the division of responsibilities between the Parties in relation to the manufacturing and release of the Clinical Samples, including but not limited to the obligations of each Party with respect to the raw materials, shall be regulated in a separate quality agreement ("Quality Agreement") between the Parties.

ARTICLE V CONTRIBUTIONS OF INTEC

5.01 API SUPPLY

INTEC shall deliver or have delivered to [***] such quantities of API at such times as LTS reasonably requests for the Development Activities at no cost for LTS. All API supplied hereunder shall be utilized by LTS solely for conducting the Development Activities and any unused quantities shall be either returned to INTEC or destroyed at INTEC's cost and risk subject to INTEC's sole discretion.

(a) INTEC's Compliance with API Specifications

INTEC represents and warrants that API delivered under this Agreement conforms to the API Specifications as set forth in Annex 5 and that it has been manufactured according to cGMP and all other applicable statutes, laws and regulations and is suitable and ready to be used for the Development Activities or the manufacture of Clinical Samples. Upon the successful transfer and validation of the methods LTS shall [***] all such API supplies intended for GMP-use according to the API Specifications set forth in Annex 5. In case that the API does not conform with the API Specifications INTEC shall promptly replace and deliver the necessary quantities of API to LTS. LTS shall bear the liability for conducting such testing of the API solely in the event of LTS' willful misconduct and/or gross negligence. LTS shall bear the costs of replacement of such wrongly tested API used for Development Activities. In any case, LTS shall bear the expenses for investigating the root cause; all other liability shall be excluded.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

(b) Audit at Supplier of API

If it is required by law, INTEC shall enable authorized representatives of LTS and/or its Affiliates upon written reasonable advance notice to inspect at reasonable times the manufacturing process and storage of the API supplies, under such conditions as INTEC or any supplier of the API may reasonably require in order to protect the confidentiality of its and its other customer's proprietary and confidential information.

(c) During the course of the execution of this Agreement, INTEC and LTS shall cooperate on the execution of an analytical methods transfer for those analytical methods required for the testing and release of incoming API so that LTS may assume responsibility for API testing and release upon the implementation of the Manufacturing Agreement.

5.02 DATA TRANSFER

INTEC shall transfer to LTS all technical documents, data, know-how and other information necessary to scale-up and establish the manufacturing process to qualify, test manufacture and supply the Product to INTEC (including the Product formulation, Specification, analytical methods and manufacturing instructions) and make available to LTS INTEC's qualified personnel for both on-site and off-site support of the scale-up at LTS' facility with respect to qualification and validation and Product manufacturing. All data obtained by both parties during the development at LTS shall be shared with both parties according to the Development Plan.

5.03 EVALUATING RESULTS

INTEC shall duly evaluate the results in order to promote the Project.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

5.04 CLINICAL TRIALS

INTEC shall be responsible for planning and conducting all clinical trials of the Product. INTEC shall be the sole owner of all clinical data and all results of the clinical trials. INTEC agrees to share the top line results with LTS of any relevant clinical trials relating to the Product.

5.05 REGISTRATION OF PRODUCTS

INTEC shall (i) be responsible for preparing the applicable regulatory documents and filings for registration and approval of Product, (ii) use only such documents created by LTS under the Development Activities approved for such filing purpose and (iii) inform LTS of such filing and/or approvals in due time.

ARTICLE VI TECHNICAL WORKING GROUP

6.01 Both parties have established a joint technical working group with named representatives (project leaders) to discuss adjusting the Development Activities and Development Plan, and determine and follow-up regulatory, analytical and process related needs (e.g. for IND, NDA purposes). In case additional development activities not included in the Development Plan are requested, such activities shall be agreed upon in writing by the joint technical working group regarding related costs and time-frame

ARTICLE VII COMPENSATION

7.01 INTEC FUNDING OF DEVELOPMENT ACTIVITIES

INTEC shall compensate LTS for all employee-hours, actually incurred by LTS during its Development Activities spent in performing its tasks according to the Development Plan. The total budget (which includes all materials and labour) is attached hereto together with the Development Plan in **Annex 1**.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

7.02 PAYMENT TERMS

(a) INTEC shall compensate LTS for its Development Activities, which shall include services performed by third parties for any Development Activity, under the Development Plan which shall not exceed the total budget referred to in the Development Plan in **Annex 1** and any additional services by LTS as mutually agreed upon at the following rate:

[***]

LTS shall provide a monthly invoice setting forth the hours charged for LTS labor, materials and charges for third-party services including VAT if applicable for each Development Activity identified in the Development Plan in Annex 1.

[***]

(b) LTS shall provide an invoice at the end of each month.

(c) LTS will verify and document the time devoted by LTS' employees to the Project, and will submit an accounting monthly to INTEC. LTS will allocate employee-hours and production machine time consistently with its historical allocation practice and will provide INTEC with a sufficiently detailed explanation of such practice, upon request, so as to allow an independent certified public accountant or chartered accountant reasonably acceptable to INTEC to audit same.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

7.03 PAYMENT TERMS

(a) Maturity

INTEC shall pay LTS the compensation provided for in Section 0 within [***] days upon receipt of the invoice from LTS. Payments shall be made in EURO (€).

(b) Overdue payments

Overdue payments shall accrue interest at the rate of [***] on the first Business Day that any payments becomes overdue, until made.

(c) No Setoff

INTEC shall not be entitled to exercise any right of setoff, net-out or deduction, take any credit, or assert any other defense arising out of any transaction unless and until INTEC has obtained a final and non-appealable judgment against LTS in the amount asserted by INTEC.

7.04 EXPENSES

Each Party shall bear all of the expenses of its own participation or related to its contribution or the performance of its obligations under this Agreement unless provided for in this Agreement. In the event of unforeseen or extraordinary expenses LTS shall be entitled to request an equitable allocation.

ARTICLE VIII CONFIDENTIALITY

8.01 The confidentiality agreement concluded between the Parties effective from May 13, 2016 (the "CDA", attached hereto as **Annex 3**), shall govern the exchange of information pursuant hereto, it being clarified that INTEC's Technology shall be deemed INTEC's Confidential Information thereunder. The term of the confidentiality agreement is hereby amended such that it will continue throughout the term of this Agreement and the Parties' obligations thereunder shall survive the termination hereof until 31 December 2029, provided however that expiration of such contractual restriction shall not derogate from INTEC's rights under its Patents and shall not in any manner be interpreted as a grant of right or license to Manufacture other Accordion Pills than Product. The terms of this Agreement shall be treated as Confidential Information as defined under the confidentiality agreement.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

ARTICLE IX INTELLECTUAL PROPERTY

9.01 INTEC shall own all Intellectual Property generated during such Project which directly relates to the Intec Technology and/or medical use/s thereof, including INTEC's Intellectual Property covering the manufacturing process of the Accordion Pill, and any improvements thereto.

9.02 LTS shall own all Intellectual Property directly related to the LTS Technology.

9.03 (i) Any Intellectual Property generated during such Project which directly relates to the preparation of thin films which are introduced into (i.e. manufacturing process taking place outside of) the Accordion Pill Production Line, or any similar machine being used in the Project, and (ii) any other results and Intellectual Property generated during such Project which are not included in 9.01 or 9.02 and relate to the manufacturing processes, including web converting methods, which are of general applicability and may be used to produce products other than the Accordion Pill, shall be jointly owned by both Parties. Each Party can use this joint Intellectual Property on a royalty free basis and without the need for the other Party's prior consent (the "License").

9.04 In case of LTS, such joint Intellectual Property may be used by LTS outside of this collaboration for any products except for Product or other Accordion Pills as long as the Parties exclusively cooperate with regard to the manufacturing of the Product or while LTS remains subject to the restrictions set forth in Section 10.1 hereunder.

9.05 For avoidance of doubt, such License does not grant the right to use either Party's solely owned Intellectual Property and confidential know-how, including the Intellectual Property set forth in Sections 9.01 and 9.02 for any other projects with third parties.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

ARTICLE X FUTURE RIGHTS

10.01 LTS shall not have the right to manufacture the Product or any of its components (including, for clarity, any other Accordion Pill) to any third party without the prior written consent from INTEC until the later of: (i) [***] or (ii) for as long as [***] continues, provided however that expiration of such contractual restriction shall not derogate from INTEC's rights under its Intellectual Property and shall not in any manner be interpreted as a grant of right or license to manufacture Products or Accordion Pills.

ARTICLE XI LIABILITY AND INDEMNIFICATION

11.01 SUPPLY OF SAMPLES

All deliveries of samples and Clinical Samples of Product shall be made [***].

11.02 REPLACEMENT

LTS will replace Defective Product at [***]. Such replacement shall be subject to INTEC (i) providing sufficient evidence of appropriate and correct storage at all times after Product has been delivered by LTS (ii) providing notice specifying the nature of the defect and the Product lot number of claimed Defective Product in the time period set forth hereunder but not later than [***] after shipment. Should INTEC reject any Defective Product, INTEC shall deliver to LTS written notice of rejection within [***] after receipt by INTEC of the applicable shipment or, in case of hidden defects within [***] after INTEC has taken notice of the defect. LTS shall have the right to examine any claimed Defective Product before any such claim is honoured.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

11.03 PRODUCT LIABILITY

11.03.1 In addition, LTS shall hold INTEC harmless [***] from any claim, cost, expense and damage arising out of the use of Defective Product ("Claims") supplied by LTS to INTEC for clinical trials to the extent that:

(i) INTEC (and/or its designated clinical research organization) acts in accordance with applicable laws and standards, such as GCP and the Helsinki Declaration;

(ii) the aforementioned claim, expense, damage or injury is not caused by the API supplied by INTEC to LTS for the manufacture of Product and/or Clinical Samples according to Section 5.01.

A certificate of LTS' current product liability insurance is attached hereto as **Annex 4**. LTS shall employ its Commercially Reasonable Efforts to maintain an insurance coverage similar to the coverage set forth in **Annex 4**.

11.03.2 INTEC shall bear all of the risk, cost and expenses related to the use of Product (incl. Clinical Samples) and shall be fully liable and shall indemnify and hold harmless LTS from any damage, claims, costs and expenses (including reasonable attorney's fees) arising out of claims resulting from damage or injury to itself and its employees and any third party, for which LTS is not liable according to this Section 0.

11.03.3 The restrictions on LTS' liability shall not apply in the event of LTS' willful misconduct.

11.04 VOLUNTEER INSURANCE

INTEC shall maintain adequate clinical trial insurance coverage of at least an amount as required by applicable laws and as reasonable and customary in the pharmaceutical industry considering the nature and extent of the clinical trials in question for any clinical trial conducted by INTEC with the Product.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

11.05 ACKNOWLEDGEMENT

INTEC acknowledges that the development of the manufacturing process by LTS is dependent on the quality of INTEC's design of Product.

11.06 NO INDIRECT, PUNITIVE OR EXEMPLARY DAMAGES

NEITHER PARTY SHALL BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, LOST PROFITS AND/OR PUNITIVE DAMAGES, PROVIDED HOWEVER, THAT THIS SHALL NOT LIMIT THE INDEMNIFICATION OBLIGATIONS FOR THIRD PARTY CLAIMS AS SET FORTH IN ARTICLE XI. THIS EXCLUSION OF LIABILITY DOES NOT APPLY IF SUCH AGREEMENT WOULD BE INVALIDATED BY STRINGENT LAW AS IT MAY BE THE CASE OF INTENTIONAL MISCONDUCT OR WILLFUL DEFAULT.

11.07 NO WARRANTY

EACH OF THE PARTIES ACKNOWLEDGES THAT THE WORK TO BE PERFORMED HEREUNDER IS DEVELOPMENTAL AND THAT NOTHING IN THIS AGREEMENT MAY OR SHALL BE CONSTRUED AS A GUARANTEE, REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED THAT THE DEVELOPMENT ACTIVITIES WILL BE SUCCESSFULLY PERFORMED,ACHIEVED WITHIN A CERTAIN PERIOD OF TIME, FIT FOR A PARTICULAR USE, ARE FEASIBLE OF BEING MANUFACTURED, FREE FROM ANY THIRD PARTY'S INTELLECTUAL PROPERTY RIGHTS, PROTECTED BY PATENTS OF THE PARTIES OR MARKETABLE, NOR THAT INVENTIONS ARE PATENTABLE.

ARTICLE XII TERM AND TERMINATION

12.01 TERM

This Agreement shall remain in effect until terminated in accordance with this Article XII or upon termination of the Manufacturing Agreement.

12.02 Either Party hereto shall have the right in its discretion to terminate this Agreement at once by written notice to the other Party in the event that the other Party by voluntary or involuntary action goes into liquidation or receivership; or dissolves or files a petition for bankruptcy or reorganization or for suspension of payments or is adjudicated a bankrupt, becomes insolvent or assigns or makes any composition of its assets for the benefit of creditors; or

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

12.03 If either Party shall be in default of any of its material obligations under this Agreement, the non-defaulting Party shall give the defaulting Party written notice of such default, upon which the defaulting Party shall have ninety (90) days to cure such default and/or establish that no default has occurred and/or in the event such default is incapable of cure by employing Commercially Reasonable Efforts within such ninety (90) days period to commence appropriate action to cure such default by employing Commercially Reasonable Efforts. In the event that a default remains uncured and/or the defaulting Party has not established that a default has not occurred and/or in case the default was incapable of cure within such ninety (90) days by using Commercially Reasonable Efforts the defaulting Party did not commence appropriate action to cure such default by employing Commercially Reasonable Efforts after ninety (90) days have elapsed, the non-defaulting Party may declare this Agreement terminated by written notice to the defaulting Party.

12.04 INTEC shall have the right to terminate this Agreement by three (3) months written notice in case of a change of control of LTS subject to the following provisions:

(i) INTEC shall without undue delay and in no event later than twenty (20) Business Days after having been informed by LTS of an existing or upcoming event of change of control with respect to LTS notify LTS of its intention to terminate the Agreement.

(aa) If prior to or during a period of twenty (20) Business Days following receipt by LTS of INTEC's notification pursuant to sub clause (i) or any other term agreed by the Parties in writing ("Grace Period"), LTS delivers to INTEC a written undertaking of the new shareholder stating that even after the change of control LTS commits itself to fulfill its obligations under the Agreement then INTEC shall not exercise the termination right under this Section 12.05.

(bb) If the event that LTS does not deliver to INTEC the shareholder undertaking within the Grace Period then INTEC shall be free to exercise the termination right under this Section 12.05. The termination right must be exercised within twenty (20) Business Days after the lapse of the Grace Period.

(ii) Unless otherwise agreed between the Parties in writing, any failure by INTEC to comply with any notification requirement within the notice period set forth in this Section 12.05 shall operate as a waiver by INTEC of its termination right hereunder.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

12.05 INTEC shall have the right to terminate this Agreement or to revoke INTEC's obligation to engage LTS on an exclusive basis, by [***] written notice in case INTEC consummates a change of control or if INTEC sells or licenses the Product to a third party in the framework of a Commercial License (as defined below) and such third party (licensee or acquirer) decides to not have the Product manufactured by LTS (or not to have it manufactured exclusively by LTS), provided that the effective date of termination or the end of exclusive basis in such event may not be prior to [***] from the Product's commercial launch.

"Commercial License" means a license permitting licensee to market and sell the Product in consideration for defined license fees and compensation (i.e. excluding licenses granted in connection with feasibility, evaluation, collaboration, contracting or similar agreements). For clarity, if the relevant agreement between the parties includes a preliminary option, e.g. feasibility or similar phase, the Commercial License will be deemed executed for the purpose hereof only upon the entering into effect of the Commercial License within such agreement, i.e. the permission to market and sell as defined above. INTEC shall notify LTS in writing within twenty (20) Business days about the execution of or the entering into effect of the change of control or the Commercial License whatever the case may be.

The termination right (as opposed to the right to revoke the exclusivity) must be exercised within six (6) months following the consummation of a charge of control or the execution of or the entering into effect of the Commercial License (whatever the case may be).

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

12.06 SURVIVING RIGHTS

Neither cancellation nor termination of this Agreement nor the execution of a Manufacturing Agreement shall relieve the Parties of their obligations as to Confidentiality (Article VIII), Intellectual Property (Art. IX) and Liability and Indemnification (Art. XI).

ARTICLE XIII MISCELLANEOUS PROVISIONS

13.01 NO WAIVER

No failure or delay by either Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise or any other right, power or privilege.

13.02 ASSIGNMENT

This Agreement shall not be assignable by either Party hereto, in whole or in part, in fact or by operation of law, without the prior written consent of the other Party, provided that each Party may assign its rights to an acquirer acquiring all or substantially all of its assets or all of the Product assets, provided that such acquirer shall agree in writing to be bound to the other Party by all of the terms of this Agreement.

13.03 INVOLVEMENT OF THIRD PARTIES BY LTS

13.03.1 LTS may have certain of its tasks or duties performed by one of its Affiliates, or, after written authorization of INTEC by a third party under obligation of confidentiality, if same is necessary for the timely performance of the Development Activities, however, LTS shall remain solely responsible for the performance of the Development Activities in accordance with the terms hereof. LTS warrants that any tasks performed by an Affiliate shall fully comply with any applicable regulation relating to the manufacture of the Product and that such performance by the Affiliate shall in no way delay or interfere with any applicable regulatory filing or approval required for the Product unless otherwise agreed upon between the Parties. If LTS chooses to have certain of its tasks or duties performed by one of its Affiliates or a third party according to the foregoing or if the Parties determine that the Product shall be manufactured in the facilities of LTS' Affiliates, then all licenses and rights in favor of LTS hereunder shall be deemed to be granted to such LTS' Affiliate or such third party for the period during which it is performing LTS' tasks or duties or is manufacturing the Product.

13.03.2 With the written authorization of INTEC, which shall not be unreasonable withheld, LTS may assign all of its rights, obligations and interests to a third party under obligations of confidentiality.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

13.04 INVOLVEMENT OF THIRD PARTIES BY INTEC

INTEC may have certain of its tasks or duties performed by a third party

(a) upon prior written authorization of LTS which shall not be unreasonably withheld, and

(b) under an obligation of confidentiality no less stringent than provided for in this Agreement or in case such third party carries out its services on LTS' premises under the obligation to execute a confidentiality agreement directly with LTS.

13.05 NO AGENCY

Nothing in this Agreement shall be construed as an authorization for a Party to act as an agent for another.

13.06 FORCE MAJEURE

Neither Party shall be held responsible or shall be considered in default or liable to the other Party for, nor shall this Agreement be terminated as a result of any delay or failure to perform any of its obligations hereunder, if such delay or failure results from circumstances beyond the control of such Party, including requisition by any authority, the effect of any statute, ordinance or governmental order or regulation, war, rebellion, terrorist action, insurrection, civil commotion, riot, strike, lockout, labor disturbance, epidemic, disease, act of God, civil commotion, explosion, fire, earthquake, storm, accident, failure of public utilities, common carriers or suppliers or the like, or any other circumstances, whether or not similar to the above causes and whether or not foreseeable. The Parties shall use Commercially Reasonable Efforts to remove any such cause and shall resume performance under this Agreement as soon as feasible whenever such cause is removed; provided, however, that the foregoing shall not be construed to require either Party to settle any dispute with any third party, to commence, continue or settle any litigation, or to incur any unusual or extraordinary expense.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

13.07 CHOICE OF LAW AND JURISDICTION

This Agreement shall be exclusively governed by the laws of Switzerland. The Parties shall make all reasonable efforts to amicably resolve any disputes which may arise out of or relating to the application of this Agreement. In the event that the Parties fail to so resolve any dispute, then the dispute shall be finally settled by binding arbitration before a panel of three arbitrators und the rules of Conciliation and Arbitration of the International Chamber of Commerce (ICC). Any arbitration pursuant to this Agreement shall be conducted in the English language and shall be held Zurich, Switzerland. The decisions of the arbitrators shall be rendered to the Parties in writing, and shall be final and binding. The costs and expenses of the arbitrators shall be borne equally by the parties, but each Party shall bear its own expenses incurred in the proceedings. The arbitrators shall have no authority to award punitive damages.

13.08 NO JURY TRIAL

THE UNDERSIGNED PARTIES ACKNOWLEDGE THAT THE RIGHT TO TRIAL BY JURY IS A CONSTITUTIONAL ONE, BUT THAT IT MAY BE WAIVED AND AFTER CONSULTING WITH COUNSEL, EITHER PARTY MAY KNOWINGLY AND VOLUNTARILY WAIVE ANY RIGHT TO TRIAL BY JURY IN THE EVENT OF LITIGATION REGARDING THE PERFORMANCE OR ENFORCEMENT OF, OR IN ANY WAY RELATED TO, THIS AGREEMENT AND ANY AGREEMENT CONNECTED THERETO.

13.09 NOTICES

Any notice required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given for all purposes if mailed by first class certified or registered mail, or commercial delivery service, postage prepaid. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described above.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

13.10 OFFICIAL LANGUAGE

English shall be the language employed in all amendments to this Agreement, further agreements relating to the subject matter and all correspondence and other communication and documentation by the technical working group.

13.11 SEVERABILITY

The provisions of this Agreement shall be deemed severable. Therefore, if any part of this Agreement is rendered void, invalid or unenforceable, such rendering shall not affect the validity or enforceability of the remainder of this Agreement and shall be replaced by provisions that are economically similar; provided that if the part or parts which are void, invalid or unenforceable as aforesaid shall substantially impair the value of the whole Agreement to either Party, that Party may cancel and terminate this Agreement by giving written notice to the other Party.

13.12 AMENDMENT

This Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by both Parties.

13.13 ENTIRE AGREEMENT

This Agreement, including the Appendices attached hereto, constitutes and contains the complete, final and exclusive undertaking and agreement of LTS and INTEC hereto, and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements whether oral or written, between the Parties regarding the subject matter hereof.

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement.

LTS LOHMANN Therapie-Systeme AG	INTEC PHARMA Ltd.
/s/ Klaudia Haczkiewicz /s/ Tim Ohnemueller	/s/ Walt A. Linscott
(Signature)	(Signature)
Head of Business Development General Counsel	Walt A. Linscott, Chief Business Officer
(Name, Title)	(Name, Title)
Andernach, December 21, 2018	Jerusalem, December 21, 2019
(Place, Date)	(Place, Date)

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

List of Annexes

ANNEX 1 Development Plan

ANNEX 2 LTS Equipment and Payment Schedule

ANNEX 3 Confidentiality Agreement May 13, 2016 as amended

ANNEX 4 Certificate of LTS Product Liability Insurance

ANNEX 5 API Specifications

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

Annex 1

[***]

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

Annex 2

[***]

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

Annex 3

[***]

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

Annex 4

[***]

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

Annex 5

[***]

[***] = Information that has been omitted and submitted separately to the Securities and Exchange Commission and for which confidential treatment has been requested.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-227027, No. 333-222217, No. 333-209700 and No. 333-212801) of Intec Pharma Ltd. of our report dated February 26, 2019 relating to the financial statements, which appears in this Form 10-K.

Tel-Aviv, Israel
February 27, 2019

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

Exhibit 31.1

CERTIFICATIONS

I, Jeffrey A. Meckler, certify that:

1. I have reviewed this Annual Report on Form 10-K for the period ended December 31, 2018 of Intec Pharma Ltd. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant'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 registrant 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 registrant, 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant'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 registrant's internal control over financial reporting.

Date: February 27, 2019

/s/ Jeffrey A. Meckler
Jeffrey A. Meckler
Chief Executive Officer and Vice Chairman

Exhibit 31.2

CERTIFICATIONS

I, Nir Sassi, certify that:

1. I have reviewed this Annual Report on Form 10-K for the period ended December 31, 2018 of Intec Pharma Ltd. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant'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 registrant 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 registrant, 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant'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 registrant's internal control over financial reporting.

Date: February 27, 2019

/s/ Nir Sassi
Nir Sassi
Chief Financial Officer

Exhibit 32.1

Intec Pharma Ltd.

Certification Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Intec Pharma Ltd. (the "Company") on Form 10-K for the period ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey A. Meckler, Chief Executive Officer and Vice Chairman of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(a) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(b) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Jeffrey A. Meckler
Jeffrey A. Meckler
Chief Executive Officer and Vice Chairman

Date: February 27, 2019

Exhibit 32.2

Intec Pharma Ltd.

Certification Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Intec Pharma Ltd. (the "Company") on Form 10-K for the period ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nir Sassi, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(a) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(b) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Nir Sassi
Nir Sassi
Chief Financial Officer

Date: February 27, 2019