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, 2019

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	NTEC	The Nasdaq Capital Market
(Title of each class)	Trading Symbol(s)	(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 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, 2019, was $121,348,153.

The number of shares of Registrant's ordinary shares outstanding as of February 29, 2020: 52,973,580.

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;
- our ability to obtain additional financing;
- because of our limited operating history, we may not be able to successfully operate our business or execute our business plan;
- our ability to enter into collaborative, licensing, and other commercial relationships and on terms commercially reasonable to us;
- 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 any future clinical trial, 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;

- 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; and

- our ability to remain listed on the Nasdaq Capital Market.

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.

Public health epidemics or outbreaks could adversely impact our business. In late 2019, a novel strain of COVID-19, also known as coronavirus, was reported in Wuhan, China. While initially the outbreak was largely concentrated in China, it has now spread to several other countries and infections have been reported globally. The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, and the actions that may be required to contain the coronavirus or treat its impact. In particular, the continued spread of the coronavirus globally, could adversely impact our operations and workforce which in turn could have an adverse impact on our business and financial results.

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, except as required by law. In evaluating forward-looking statements, you should consider these risks and uncertainties and not place undue reliance on our forward-looking statements.

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. in August 2015, we raised gross proceeds of approximately $34.0 million before deducting underwriting discounts and commissions and other offering expenses and since then we have raised approximately $104 million in gross proceeds in public offerings in the U.S.

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 have been 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 stages of development. 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.

In July 2019, we announced top-line results from our pivotal Phase III clinical for AP-CD/LD for the treatment of advanced Parkinson's disease known as the ACCORDANCE study in which the ACCORDANCE study did not meet its target endpoints. While AP-CD/LD provided treatment for Parkinson's disease symptoms, it did not demonstrate statistically superiority over immediate release CD/LD on the primary endpoint of OFF time reduction under the conditions established in the protocol. Treatment-emergent adverse effects observed with AP-CD/LD were generally consistent with the known safety profile of CD/LD formulations and no new safety issues were observed throughout the double-blinded study, during the gastroscopy safety sub-study or the 12-month open-label extension study. From our review of the data, we have observed a meaningful reduction in OFF time in certain subsets of patients. We have completed the analysis of the full data set and we are currently seeking to partner AP-CD/LD as the basis for the strategy for AP-CD/LD moving forward.

Previously, we 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 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 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, or the Production Line, was delivered to LTS in Andernach, Germany and recently we completed the qualification studies for the commercial scale manufacture of the Accordion Pill and we have initiated the validation and stability studies which are expected to serve as the clinical material for the next Phase 3 clinical trial plan.

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 demonstrated 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 and the results of the study demonstrate that the custom designed AP delivery system in the AP-THC PK study did not meet our expectations. We are continuing to advance the AP-Cannabinoids clinical development program and we are seeking to launch a PK study with the optimized AP-THC in 2020.

While the ACCORDANCE results were not what we expected, we continue to believe in the potential of the Accordion Pill platform. 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 recently completed the human PK study that was initiated during the first quarter of 2019 and the study demonstrated that the AP met the technical requirements set forth by Novartis. In December 2019, Novartis, following an internal and revised commercial strategic assessment, advised us that this program no longer meets Novartis' mid to long-term strategic goals. Novartis paid Intec Pharma $1.5 million on conclusion of the program. We restructured our clinical manufacturing planned to support this program in order to reduce costs. We are looking to identify additional compounds in the Novartis portfolio that can benefit from the unique characteristics of the AP platform.

In May 2019, we reported entering into a research collaboration agreement with Merck for the development of a custom-designed AP for one of Merck's proprietary compounds that met the required *in vitro* specifications. We aim to initiate an in-vivo study by the middle of 2020.

We continue to advance discussions with other potential pharmaceutical partners for the development of new custom-designed APs. We believe the data from our ACCORDANCE trial enhances those discussions as it validates the AP platform and provides long-term safety data.

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.

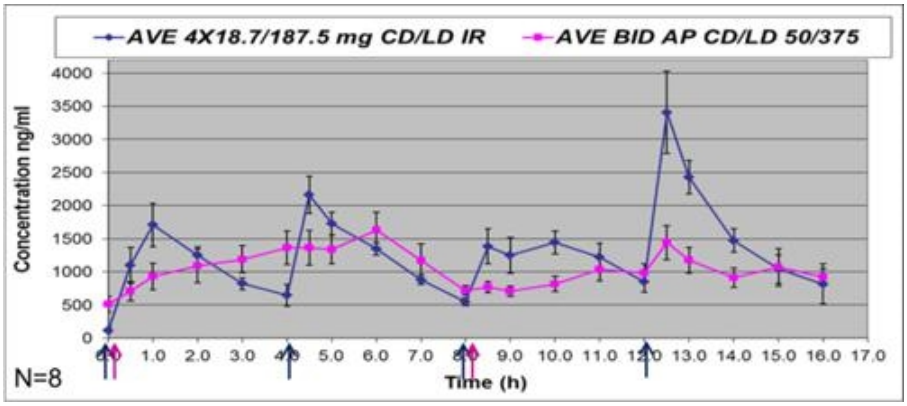
Our anticipated ability to submit NDAs pursuant to Section 505(b)(2) for our existing pipeline and future products increases the likelihood of accelerating the time to commercialization of our products and decreasing costs when compared to those typically associated with new chemical entities, or NCEs.

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:

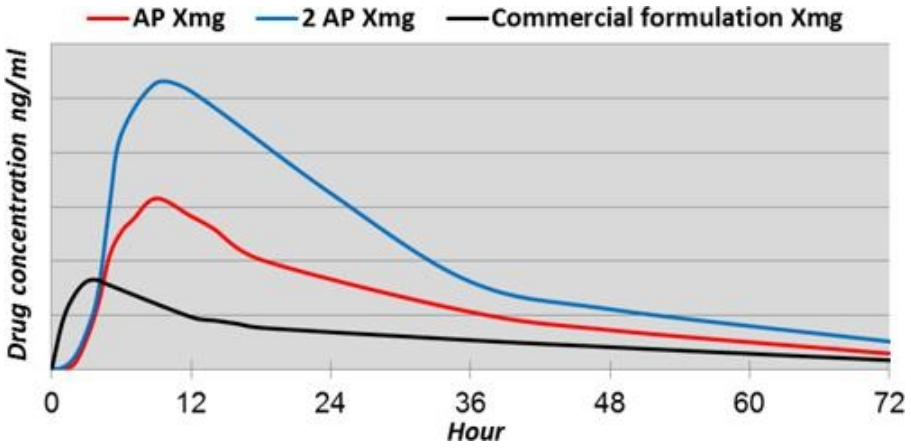
AP-CD/LD Phase II clinical trial — more stable Levodopa levels with statistically significant reduced peak-to-trough fluctuations



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.

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

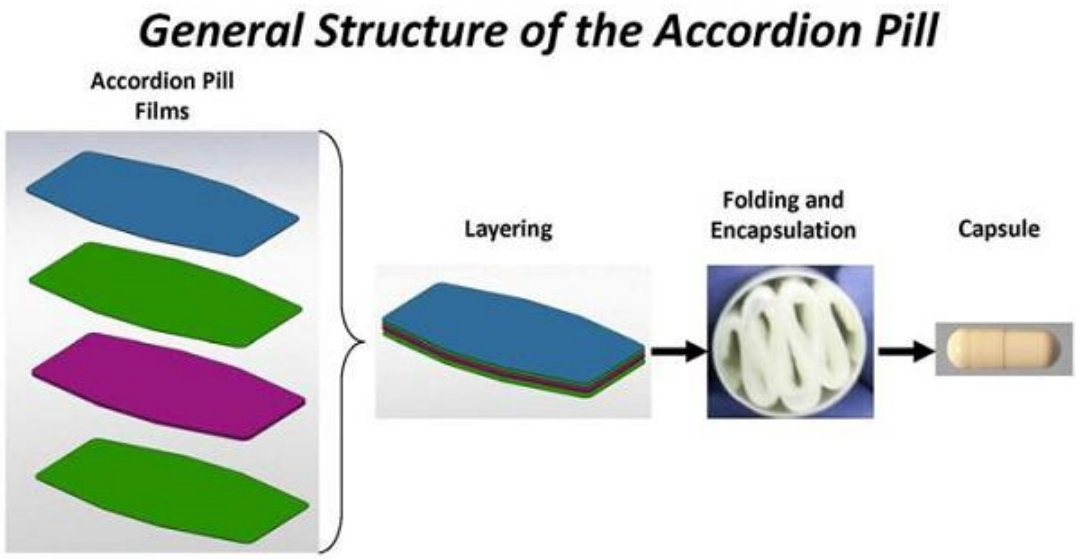


The results of our clinical trial have demonstrated approximately a 100% increase in bioavailability in 12 healthy volunteers with our Accordion Pill technology, as compared to the commercial formulation of the drug. Furthermore, the results demonstrated that the increase in bioavailability obtained 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 stages of development.

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. In July 2019, we announced top-line results from our pivotal Phase III clinical for AP-CD/LD for the treatment of advanced Parkinson's disease known as the ACCORDANCE study in which the ACCORDANCE study did not meet its target endpoints. While AP-CD/LD provided treatment for Parkinson's disease symptoms, it did not demonstrate statistically superiority over immediate release CD/LD on the primary endpoint of OFF time reduction under the conditions established in the protocol. Treatment-emergent adverse effects observed with AP-CD/LD were generally consistent with the known safety profile of CD/LD formulations and no new safety issues were observed throughout the double-blinded study, during the gastroscopy safety sub-study or the 12-month open-label extension study. From our review of the data, we have observed a meaningful reduction in OFF time in certain subsets of patients. We have completed the analysis of the full data set and we are currently seeking to partner AP-CD/LD as the basis for the strategy for AP-CD/LD moving forward.

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 demonstrated 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 and the results of the study demonstrate that the custom designed AP delivery system in the AP-THC PK study did not meet our expectations. We are continuing to advance the AP-Cannabinoids clinical development program and we are seeking to launch a PK study with the optimized AP-THC in 2020.

In May 2019, we reported entering into a research collaboration agreement with Merck for the development of a custom-designed AP for one of Merck's proprietary compounds that met the required *in vitro* specifications. We aim to initiate an in-vivo study by the middle of 2020.

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., depending on cash resources available to us at the time. 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 development. Specific elements of our current strategy include the following:

- ***Continue to advance our current pipeline by developing or co-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. We are advancing both our co-development program with Merck and our in-house AP-Cannabinoids clinical development program while seeking to partner AP-CD/LD for the treatment of advanced Parkinson's disease.

- ***Seek attractive partnership opportunities***. With respect to AP-CD/LD, while the ACCORDANCE results were not what we expected, we continue to believe in the potential of the Accordion Pill platform and we are currently seeking to partner AP-CD/LD as the basis for the strategy for AP-CD/LD moving forward. We believe that our business development efforts are significantly enhanced by our large safety database, ACCORDANCE results that validate the platform, our ability to build customized Accordion Pills that meet specified PK parameters and our large scale commercial manufacturing capabilities. More generally, 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. 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 benefit from our partners' marketing capabilities, while also enabling us to treat a more significant number of patients.

- ***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.

- ***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 or co-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.

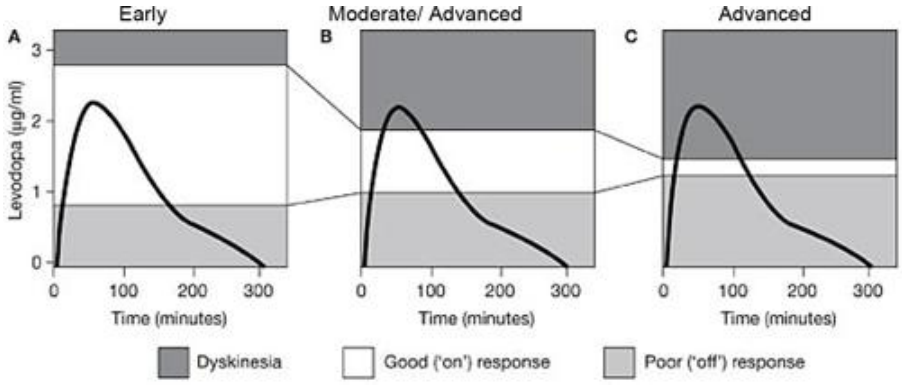
As the disease progresses, it becomes increasingly difficult to control the symptoms adequately by Levodopa treatment, and patients develop motor complications, for the following reasons:

- 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 which was completed and its top-line results were announced in July 2019.

AP-CD/LD – Clinical Trials

Phase III ACCORDANCE Study

The Phase III ACCORDANCE clinical trial of AP-CD/LD was a multi-center, global, randomized, double-blind, double-dummy, active-controlled, parallel-group study in adult subjects with advanced PD. The study was 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.

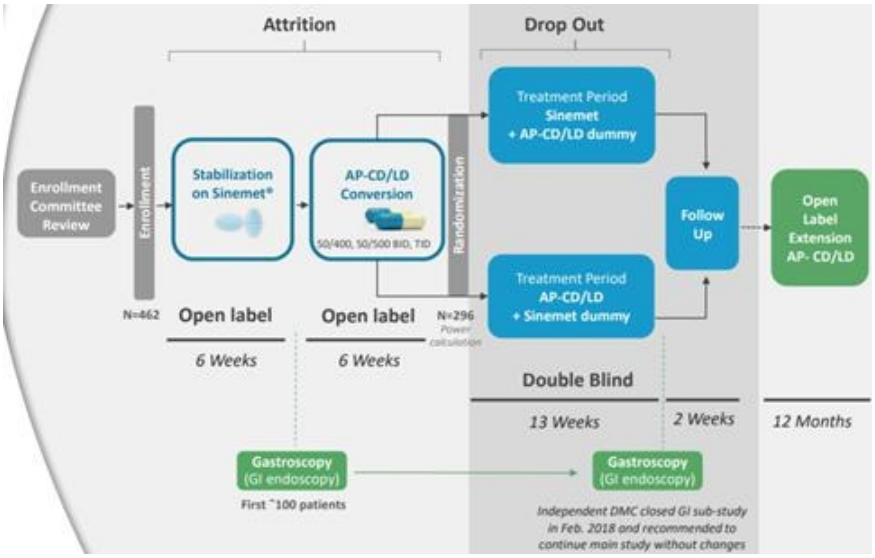
The study enrolled a total of 462 patients into the Sinemet titration period. After the multiple titration and optimization steps, 320 patients were then randomized into the 13-week double-blinded portion of the study. The study was conducted at approximately 90 clinical sites throughout the U.S., Europe 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 who completed the 13-week randomized period were eligible to continue in an Open Label Extension study, or the OLE study, in which they received treatment with AP-CD/LD for up to an additional 12 months.

The following is an illustration of the study design:

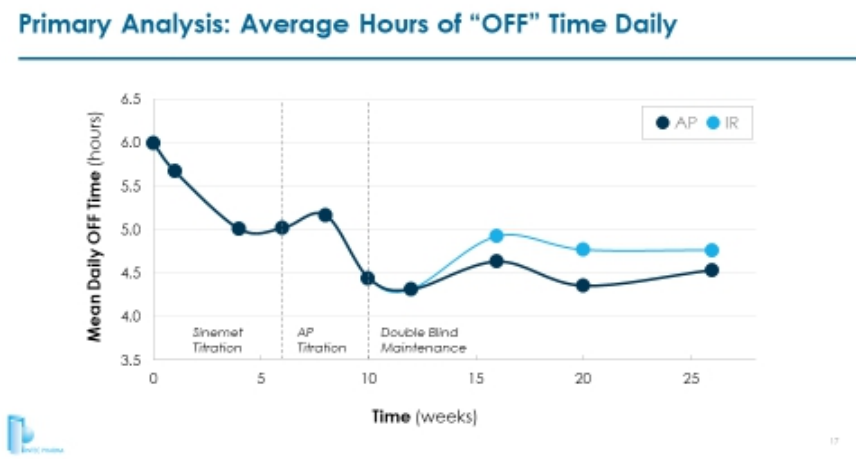


The primary efficacy endpoint of the study was the change from baseline to endpoint in the percentage of daily off time during waking hours based on Hauser home diaries. The study was 90% powered to be statistically significant for a one-hour difference in off time between Sinemet and AP-CD/LD.

Secondary endpoints included 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.

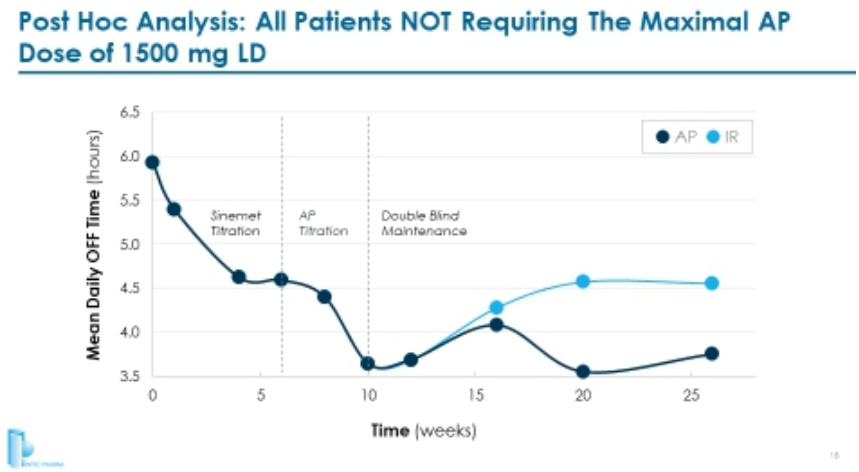
In July 2019, we announced top-line results from our pivotal Phase III clinical for AP-CD/LD for the treatment of advanced Parkinson’s disease known as the ACCORDANCE study in which the ACCORDANCE study did not achieve its primary objective. The ACCORDANCE study featured two open-label titration steps where patients were first optimized on immediate release CD/LD, and then optimized on the AP-CD/LD formulation. Patients entered the study with an average OFF time of 6.0 hours per 16-hour day. After the initial open-label titration, the average OFF time was reduced to 5.02 hours. Double blinded treatment for 13 weeks with either immediate release or AP CD/LD led to further improvements in OFF time, with the final OFF time for the IR treated group at 4.76 hours and the OFF time for the AP group at 4.53 hours. Therefore, while AP-CD/LD provided treatment for Parkinson’s disease symptoms comparable to the immediate release preparation, it did not achieve the primary objective of demonstrating statistically superiority over immediate release CD/LD under the conditions established in the protocol.

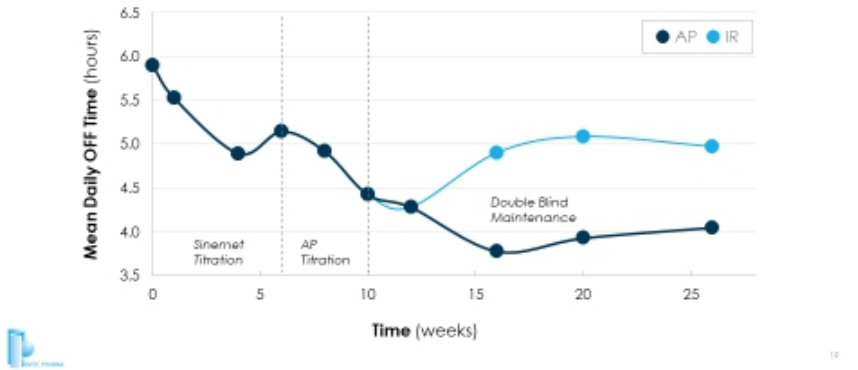
The following figure displays the average hours of “off” time of the AP-CD/LD treated group and the IR treated group:



From our review of the data, we observed a meaningful reduction in OFF time in certain subsets of patients and from a safety perspective, treatment-emergent adverse effects observed with AP-CD/LD were generally consistent with the known safety profile of CD/LD formulations and no new safety issues were observed throughout the double-blinded study, during the gastroscopy safety sub-study or the 12-month open-label extension study. We believe that both dosing was suboptimal and titration targets in the protocol were suboptimal.

The following figures display the post hoc analysis of a subset of patients that did not require the maximal AP dose of 1500 mg LD and who received 1.6 to 2.0 dose ratio of AP LD to IR LD.





We have completed the analysis of the full data set and we are currently seeking to partner AP-CD/LD as the basis for the strategy for AP-CD/LD moving forward.

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

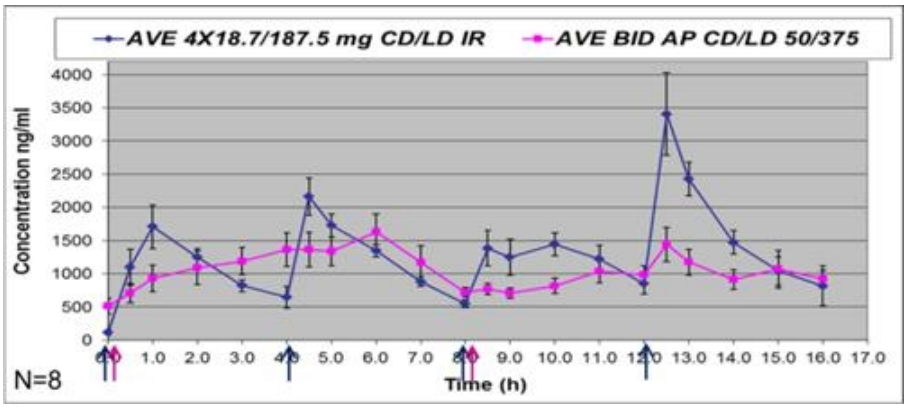
Group 1 of our Phase II clinical trial with AP-CD/LD was conducted with 12 male and female patients with non-fluctuating Parkinson's disease. The crossover design included the following treatment arms: (i) AP-CD/LD 50/250 mg administered b.i.d and (ii) immediate release CD/LD 25/250 mg administered by 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):

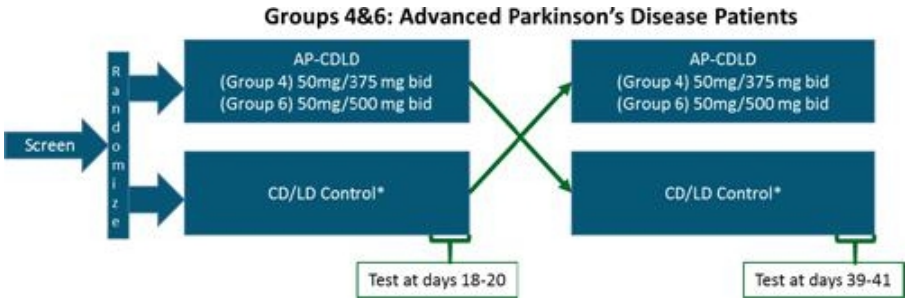
AP-CD/LD Phase II clinical trial — more stable Levodopa levels with statistically significant reduced peak-to-trough fluctuations



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

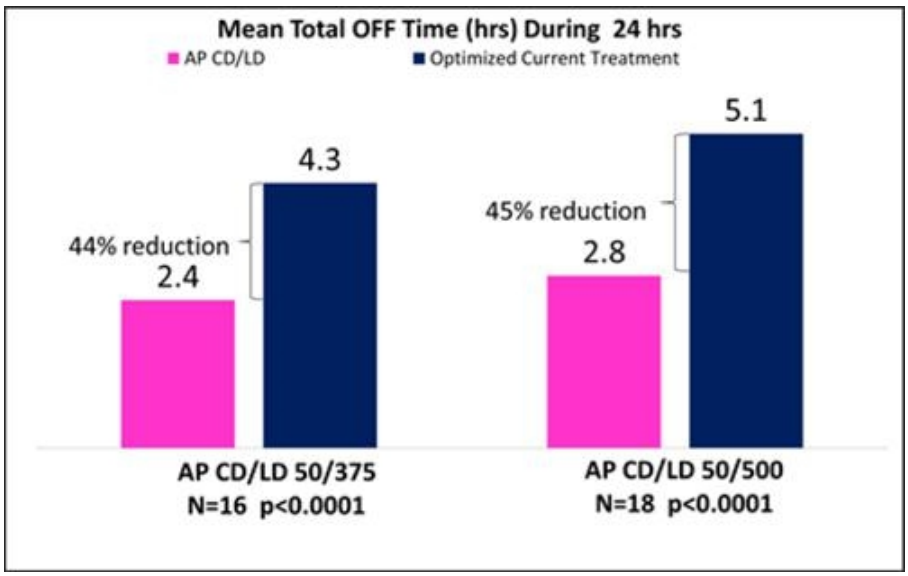
Groups 3, 4 and 6 of our Phase II clinical trial examined the pharmacodynamic effects of AP-CD/LD. Each group assessed the effects in patients with advanced Parkinson's disease; ten, 16 and 18 patients completed the trials per protocol in Groups 3, 4 and 6, respectively. Groups 3 and 4 tested AP-CD/LD 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.

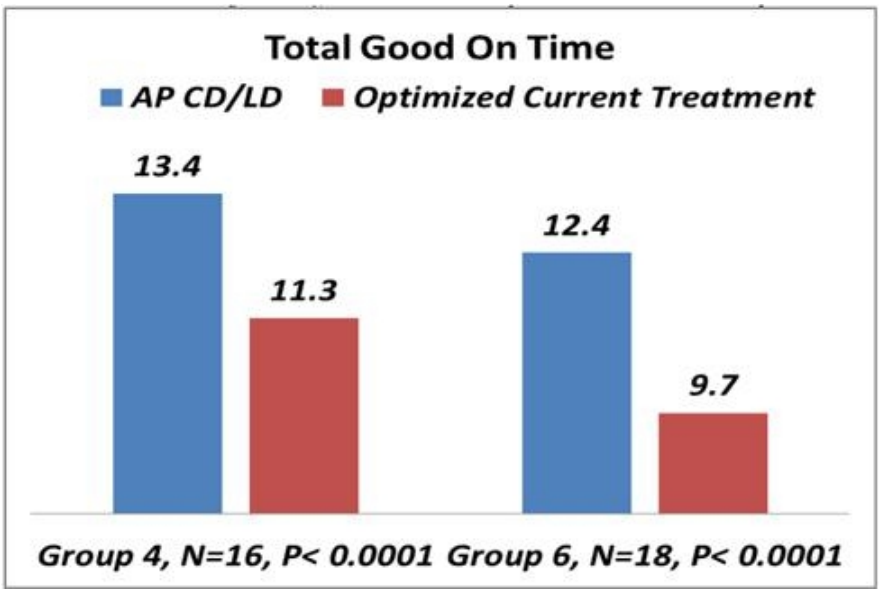
The figure below reflects the mean total off time in hours over a 24 hour period during days 18 through 20 of Groups 4 and 6. The average total off time was reduced by 1.9 hours and 2.3 hours with AP-CD/LD 50/375 mg (Group 4) and 50/500 mg (Group 6), respectively. This reduction is statistically significant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

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



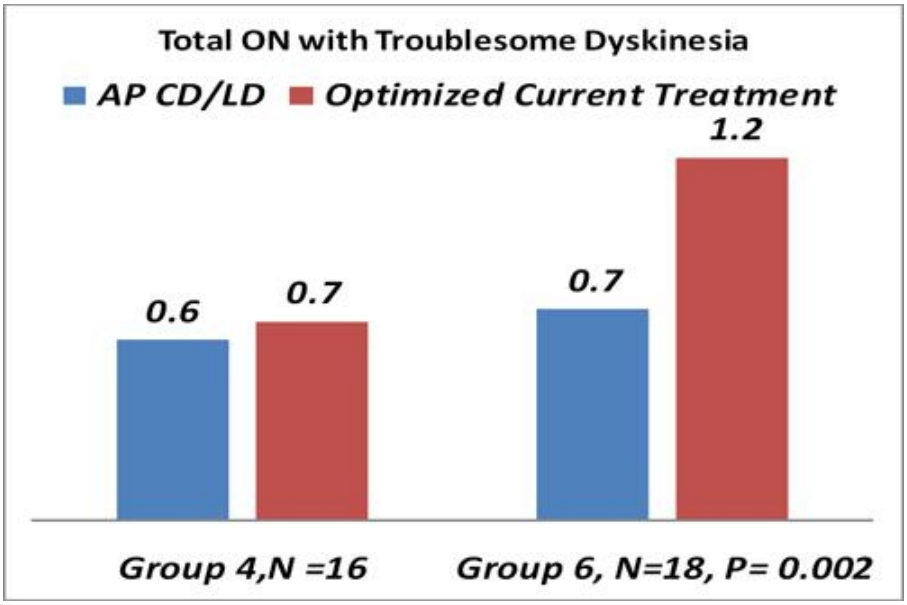
The figure below reflects the mean total “good” on time (on time without troublesome dyskinesia) in hours over a 24 hour period during days 18 through 20 of Groups 4 and 6. The average total “good” on time was increased by 2.1 hours and 2.7 hours with AP-CD/LD 50/375 mg (Group 4) and 50/500 mg (Group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

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



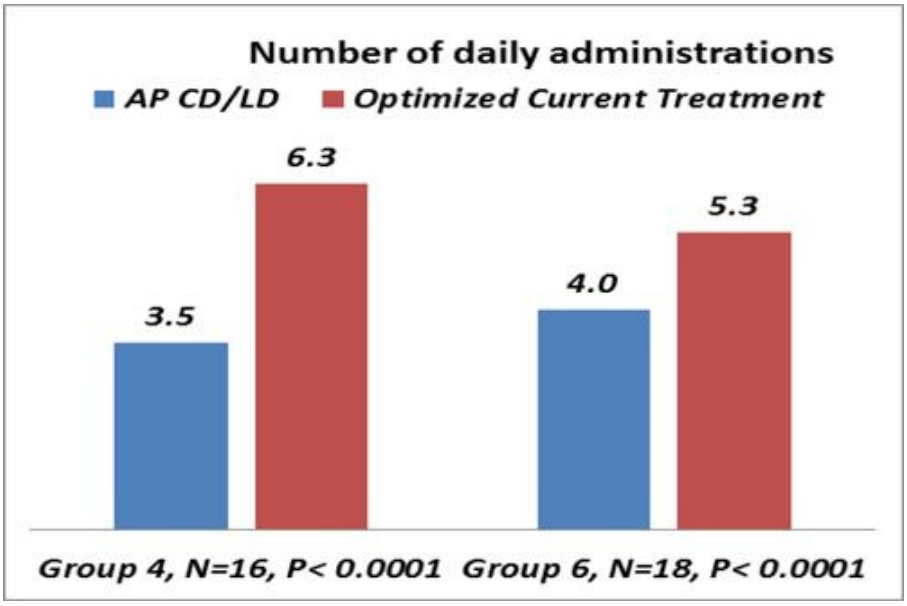
The figure below reflects the mean total on time with troublesome dyskinesia in hours over a 24 hour period during days 18 through 20 of Groups 4 and 6. On time with troublesome dyskinesia was not changed and decreased by 0.5 hours (p = 0.002) with AP-CD/LD 50/375 mg (Group 4) and 50/500 mg (Group 6), 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 five Phase I clinical trials - four 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 fourth PK trial was conducted in order 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 [(Cmax-Cmin)/Cavg] 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 t.i.d. 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 pre-specified 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**

The GR Phase I clinical trial was an 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.

In the Phase III clinical trial, treatment-emergent adverse effects observed with AP-CD/LD were generally consistent with the known safety profile of CD/LD formulations and no new safety issues were observed throughout the double-blinded study, during the gastroscopy safety sub-study or the 12-month open-label extension study.

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. In December 2018, we initiated a PK study of AP-THC. The study was 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 the results of the study demonstrated that the custom designed AP delivery system in the AP-THC PK study did not meet our expectations. We are continuing to advance the AP-Cannabinoids clinical development program and we are seeking to launch a PK study with the optimized AP-THC in 2020.

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. On December 11, 2019, we announced the termination of the Feasibility and Option agreement with Novartis for the development of a custom-designed Accordion Pill® (AP) for a proprietary Novartis compound, despite the AP having met the technical and PK clinical specifications set forth by Novartis. Novartis, following an internal and revised commercial strategic assessment, advised us that this program no longer meets Novartis' mid to long-term strategic goals. Novartis paid us $1.5 million USD on conclusion of the program.

In May 2019, we reported entering into a research collaboration agreement with Merck for the development of a custom-designed AP for one of Merck's proprietary compounds that met the required *in vitro* specifications. We aim to initiate an in-vivo study by mid-2020.

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 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.

Manufacturing

Our production and packaging facility is 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.

Our fully automated assembly line enables us to manufacture approximately two to three million capsules annually. With respect to any 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 amounted to approximately $6.8 million and was fully paid as of December 31, 2019; 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. 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. In October 2019, we completed the qualification studies for the commercial scale manufacture of the Accordion Pill, and initiated the validation and stability studies which are expected to serve as the clinical material for the next Phase 3 clinical trial plan.

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. 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 and manufacturing 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, Lyndra Therapeutics, 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.

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. Our initial approach with the AP-CD/LD program did not meet a statistically significant endpoint against Sinemet, a combination of Levodopa and Carbidopa, which is sold by Merck, as well as generic Sinemet, which is sold by various generic manufacturers. Further clinical work will be required to develop the AP-CD/LD if it is going to be competitive against existing treatments for Parkinson's. We are seeking a partner to undertake this clinical work. 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 the 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. In August 2019, the company announced that it was advancing ND0612 into a Phase III trial.

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 and ending in spring 2025. During the theoretical pilot program, which it is expected will focus on very expensive drugs reimbursed by the Medicare Part B program, CMS would monitor and evaluate the impact of the model on beneficiary access to drugs, program costs, and the quality of care for beneficiaries. Despite extensive media coverage of the roll out of this announcement as well as the announcement by the Democratic majority in the U.S. House of Representatives of alternative legislative proposals, no specific rule has been forthcoming during the intervening time since the original announcement in 2018.

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. This Trump Administration initiative has been withdrawn for now.

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 candidate 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.

- In the European Union, the General Data Protection Regulation, or GDPR, —Regulation EU 2016/679— was adopted in May 2016 and became applicable on May 25, 2018, or GDPR. The GDPR further harmonizes data protection requirements across the European Union member states by establishing new and expanded operational requirements for entities that collect, process or use personal data generated in the European Union, including consent requirements for disclosing the way personal information will be used, information retention requirements, and notification requirements in the event of a data breach.

- The California Consumer Privacy Act of 2018, or CCPA, effective as of January 1, 2020, that gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation.

- In addition, failure to comply with the Israeli Privacy Protection Law 1981, and its regulations as well as the guidelines of the Israeli Privacy Protection Authority, may expose us to administrative fines, civil claims (including class actions) and in certain cases criminal liability. Current pending legislation may result in a change of the current enforcement measures and sanctions.

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 January 29, 2020, we own or exclusively license six families of patents to use within our field of business (families IN-1, IN-3, IN-7, IN-11, IN-21 and IN-23). Four of the patent families (IN-1, IN-3, IN-7 and IN-11) have granted patents registered in various countries, as detailed below. With the exception of the first family of patents (IN-1) four families (IN-3, IN-7, IN-11 and IN-23) have active pending application under examination. The sixth patent family (IN-23) currently comprises of recently filed pending provisional US patent application, dated January 2, 2020. The deadline for filing priority PCT or national applications is January 2, 2021. 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 2041. 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 November 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 five granted patents in the U.S. and an additional pending patent application in connection with IN-3, as well as granted patents in Israel (four 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. Application in Europe (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) and 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.

IN-23

This patent family is directed to a novel Accordion Pill, with a new platform for delivering active pharmaceutical agents.

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. The ACCORDION PILL trademark/service mark is also registered in the United States and 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 a coverage limit of $20.0 million 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 24.0 million for fixed cost. In addition, we maintain the following insurance: employer liability with coverage of NIS 20.0 million and third-party liability with coverage of NIS 20.0 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, 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 (or any other interest rate that the IIA may choose to apply in the future) 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, 2019, we received from IIA approximately NIS 42.3 million (approximately $11.3 million). We did not apply for any grants from the IIA for the years ended December 31, 2019, 2018 and 2017. For more information see note 6c in our consolidated financial statements for the year ended December 31, 2019.

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.

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, 2019, we had 49 employees, 38 of whom are full-time employees, five of whom were employed in management, eight of whom were employed in finance and administration, 29 of whom were employed in research and development and operations, one of whom were employed in clinical trials and regulatory affairs and 6 of whom were employed in quality assurance. As of December 31, 2019, all of these employees are located in Israel or the United States, where our U.S. subsidiary employs four 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. 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 may increase substantially in the foreseeable future if we:

- initiate, either alone or with a partner, further 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, 2018 and 2019, we had net losses of $43.5 million and $47.6 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 do not advance to further clinical trials, 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 negative outcome of the ACCORDANCE study, the discontinuation of the Novartis program, and the general uncertainty regarding our development programs and 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 2019 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, 2019 and included an explanatory paragraph stating that the Company has suffered recurring losses from operations and negative cash outflows from operating activities. As a result, there is substantial doubt about our ability to continue as a going concern. 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 and for working capital and for general corporate purposes. In addition, we may choose to expand our current research and development focus, or other clinical operations. The negative outcome of the ACCORDANCE study, the discontinuation of the Novartis program, and the general uncertainty regarding our development programs has adversely affected our ability to obtain funding and there is no assurance that we will be successful in obtaining the level of financing needed for our activities. As of December 31, 2019, we had cash and cash equivalents of $9.3 million and marketable securities of $770,000.

On December 2, 2019, we entered into an ordinary shares purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, an Illinois limited liability company, or Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of our ordinary shares over the 30-month term of the Purchase Agreement. See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Aspire Capital Financing Arrangement”.

In addition, on March 1, 2019, we entered into a Sales Agreement with Cowen and Company, LLC, or Cowen, which provides that, upon the terms and subject to the conditions and limitations in the Sales Agreement, we may elect from time to time, to offer and sell ordinary shares through an "at-the-market" equity offering program through Cowen acting as sales agent. The issuance and sale of ordinary shares by us under the program will be made pursuant to our effective "shelf" registration statement on Form S-3 (Registration Statement No. 333-230016) filed with the SEC on March 1, 2019, and declared effective on March 28, 2019. We may sell up to approximately $72.4 million of ordinary shares under the Sales Agreement, subject to the Baby Shelf Rule described below. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Aspire Capital Financing Arrangement".

The extent to which we utilize the Purchase Agreement with Aspire Capital or Sales Agreement with Cowen as a source of funding will depend on a number of factors, including the prevailing market price of our ordinary shares, the volume of trading in our ordinary shares and the extent to which we are able to secure funds from other sources. The number of ordinary shares that we may sell to Aspire Capital under the Purchase Agreement on any given day and during the term of the agreement is limited. Additionally, we and Aspire Capital may not effect any sales of ordinary shares under the Purchase Agreement and during the continuance of an event of default or on any trading day that the closing sale price of our ordinary shares is less than $0.25 per share. As a result of certain lock-up provisions in our recent underwritten public offering, we may not effect any sales under the Purchase Agreement or Sales Agreement until after April 30, 2020 unless we receive prior written approval from the underwriter in the offering.

In addition, our future capital requirements may be substantial and will depend on many factors including:

- our ability to enter into collaborative, licensing, and other commercial relationships;
- adhering to patient recruitment in any clinical trials;
- 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.

Under General Instruction I.B.6 to Form S-3, or the Baby Shelf Rule, the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Company. As of March 5, 2020, our public float was approximately $15.2 million, based on 52,552,032 ordinary shares held by non-affiliates and a price of $0.29 per share, which was the last reported sale price of our common stock on the Nasdaq Capital Market on March 5, 2020. We therefore are limited by the Baby Shelf Rule as of the filing of this Annual Report on Form 10-K, until such time as our public float exceeds $75 million. If we are required to file a new registration statement on another form, we may incur additional costs and be subject to delays due to review by the SEC Staff.

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.

We may not be able to raise additional funds unless we increase our authorized share capital.

As of February 29, 2020, we have 100,000,000 authorized ordinary shares, out of which 52,973,580 ordinary shares are issued and outstanding, 21,714,809 are reserved for future issuance under outstanding options and warrants and under our 2015 Option and 2005 Plan. Any additional equity financing in order to fund our operations may require us to increase our authorized share capital prior to initiating any such financing transaction. Increasing our share capital is subject to the approval of our shareholders. In the event we fail to obtain the approval of our shareholders to such increase in our authorized share capital, our ability to raise sufficient funds, if at all, might be adversely effected.

We have incurred and could incur further impairment charges of our long-lived assets that could negatively affect our results of operations.

We periodically evaluate whether events and circumstances have occurred that require an impairment assessment. In July 2019, we announced top-line results from our ACCORDANCE study which did not meet its target endpoints. We determined that the clinical trial results constituted a triggering event that required us to undertake an impairment test and as a result we recorded an impairment charge of approximately $13.7 million with respect to our production line equipment and related assets for commercial scale manufacturing of AP-CD/LD. In the third quarter ended September 30, 2019, we recorded for the first time an impairment charge of approximately $9.8 million which was updated in the fourth quarter by approximately $3.9 million following a new impairment assessment performed at December 31, 2019 following changes in management assumptions. We could incur further impairment charges if we determine that the carrying value of our production line equipment and related assets is reduced. In addition, any changes in the actual market conditions versus the assumptions used in the model to determine impairment charges could result in further impairment charges in the future. In the event that we determine that our long-lived assets are impaired, we may be required to record a non-cash charge that could adversely affect our results of operations.

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. Due to the negative outcome of the ACCORDANCE study, the discontinuation of the Novartis program, and the general uncertainty regarding our development programs, we do not anticipate commercializing any products or technologies in the near future. 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.

We seek to partner with third-party collaborators with respect to the development and commercialization of AP-CD/LD and for new custom-designed APs, and we may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all.

Our business strategy relies on partnering with pharmaceutical companies to complement our internal development efforts. In July 2019, we announced top-line results from our ACCORDANCE study in which the ACCORDANCE study did not meet its target endpoints. We have completed the analysis of the full data set and we are currently seeking to partner AP-CD/LD as the basis for the strategy for AP-CD/LD moving forward. In addition, we entered into a research collaboration agreement with Merck for the development of a custom-designed AP for one of Merck's proprietary compound and are seeking partners for the development of new custom-designed APs. We will be competing with many other companies as we seek partners for AP-CD/LD and for any new custom-designed APs and we may not be able to compete successfully against those companies. If we are not able to enter into collaboration arrangements for AP-CD/LD or for any new custom-designed APs, we may be required to undertake and fund further development, clinical trials, manufacturing and commercialization activities solely at our own expense and risk. If we are unable to finance and/or successfully execute those expensive activities, or we delay such activities due to capital availability, our business could be materially and adversely affected, and potential future product launch could be materially delayed, be less successful, or we may be forced to discontinue clinical development of these product candidates. Furthermore, if we are unable to enter into a commercial agreement for the development and commercialization of the custom-designed AP for Merck's proprietary compound, then this could have a material adverse effect on our business, financial condition or results of operations.

The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- a collaboration partner may shift its priorities and resources away from our product candidates due to a change in business strategies, or a merger, acquisition, sale or downsizing;
- a collaboration partner may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaboration partner may cease development in therapeutic areas which are the subject of our strategic collaboration;
- a collaboration partner may not devote sufficient capital or resources towards our product candidates;
- a collaboration partner may change the success criteria for a drug candidate thereby delaying or ceasing development of such candidate;
- a significant delay in initiation of certain development activities by a collaboration partner will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaboration partner could develop a product that competes, either directly or indirectly, with our drug candidate;
- a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;

- a collaboration partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;

- a partner may exercise a contractual right to terminate a strategic alliance;

- a dispute may arise between us and a partner concerning the research, development or commercialization of a drug candidate resulting in a delay in milestones, royalty payments or termination of an alliance and possibly resulting in costly litigation or arbitration which may divert management attention and resources; and

- a partner may use our products or technology in such a way as to invite litigation from a third party.

Any collaborative partners we enter into agreements with in the future may shift their priorities and resources away from our product candidates or seek to renegotiate or terminate their relationships with us. For example, in December 2019, we discontinued the development of a custom designed AP for a Novartis proprietary compound following an internal and revised commercial strategic assessment, in which Novartis advised us that this program no longer meets Novartis' mid to long-term strategic goals. If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

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 development of different formulations or new chemical entities may remove any competitive advantage a product formulated with the Accordion Pill platform technology may present. Other companies are engaged in research and development of gastric retention technologies that may become competitive to or even superior to the capabilities of the 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 have reduced the size of our organization, and we may encounter difficulties in managing our business as a result of this reduction, or the attrition that may occur following this reduction, which could disrupt our operations. In addition, we may not achieve anticipated benefits and savings from the reduction.

Following the negative outcome of the ACCORDANCE study, we reduced the size of our headcount by approximately 50%, designed to focus our cash resources mainly on research and development and business development activities. The restructuring, and the attrition thereafter, resulted in the loss of longer-term employees, the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. The restructuring and possible additional cost containment measures may yield unintended consequences, such as attrition beyond our intended reduction in headcount and reduced employee morale. In addition, the restructuring may result in employees who were not affected by the reduction in headcount seeking alternate employment, which would result in us seeking contract support at unplanned additional expense. In addition, we may not achieve anticipated benefits from the restructuring. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, loss of business opportunities, loss of employees and reduced productivity among remaining employees. We may also determine to take additional measures to reduce costs, which could result in further disruptions to our operations and present additional challenges to the effective management of our company. If our management is unable to effectively manage this transition and restructuring and additional cost containment measures, our expenses may be more than expected, and we may not be able to implement our business strategy.

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, emergence of a pandemic, or other widespread health emergencies (or concerns over the possibility of such an emergency, including for example, the recent coronavirus outbreak), 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.

We or the third parties upon whom we depend may be adversely affected by natural disasters and/or health epidemics, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, health epidemic or other event occurred that prevented us from using all or a significant portion of our office, manufacturing and/or lab spaces, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, CROs, clinical sites, third parties ongoing activities and schedules or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our plans and business for a substantial period of time.

Our business could be adversely impacted by the effects of the coronavirus outbreak originating in China, or by other epidemics. Although we do not currently source directly a material portion of our AP-CD/LD components directly from China, our supply chain for certain and critical components is worldwide and accordingly could be subject to disruption. In addition, such an event may cause other parties to slow down their activities and schedules and therefore influence our timelines. A health epidemic or other outbreak, including the current coronavirus outbreak, may materially and adversely affect our business, financial condition and results of operations.

The disaster recovery and business continuity plan we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

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

Our product candidates are at various stages of 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. For example, the negative outcome of our ACCORDANCE study had a material adverse effect on our business, operating results and financial condition. 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. All 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.

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.

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. 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. For example, our Phase III ACCORDANCE study failed to meet its target endpoints despite positive Phase II data. 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. For example, our Phase III ACCORDANCE study failed to meet its target endpoints despite positive Phase II data. Also, interim results during a clinical trial do not necessarily predict final results. We along with 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 future 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 clinical trials, we may be incorrect and we may not have the resources or facilities to manufacture our product candidates for clinical trials.

With respect to any 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 able to 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 and business interruption insurance coverage of up to NIS 24.0 million for damage to our property and the disruption of our business from fire and other casualties, 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 providing 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 2018 calendar year was published on June 30, 2019. Failure to submit required information may result in civil monetary penalties 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 intentions. 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, but in 2019, the Fifth Circuit Court of Appeals subsequently upheld the lower court decision which was then appealed to the United States Supreme Court. The U.S. Supreme Court declined to hear the appeal on an expedited basis and so no decision will be forthcoming until the next Supreme Court term in late 2020 or early 2021. 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 any product containing these substances 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 pain indications, 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 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 and ending in spring 2025. During the theoretical pilot program, which it is expected will focus on very expensive drugs reimbursed by the Medicare Part B program, CMS would monitor and evaluate the impact of the model on beneficiary access to drugs, program costs, and the quality of care for beneficiaries. Despite extensive media coverage of the roll out of this announcement as well as the announcement by the Democratic majority in the U.S. House of Representatives of alternative legislative proposals, no specific rule has been forthcoming during the intervening time since the original announcement in 2018.

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. This Trump Administration initiative has been withdrawn for now.

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. Our business license is valid until December 31, 2023 and 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 parties re-examination 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 November 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 of our or of 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 parties 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, suppliers or partners;
- 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;

- political and economic instability, war or acts of terrorism or natural disasters, emergence of a pandemic, or other widespread health emergencies (or concerns over the possibility of such an emergency, including for example, the recent coronavirus outbreak); 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 business interest income plus 30% of adjusted taxable income (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, 2019, and December 31, 2020, 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, 2019, we believe that we were a PFIC. We also expect to be classified as a PFIC for 2020. 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 2020 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 applications 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 52,973,580 ordinary shares outstanding as of February 29, 2020. All of our ordinary shares outstanding as of December 31, 2019 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 29, 2020, up to 16,250,000 ordinary shares are issuable upon exercise of outstanding registered warrants. Furthermore, as of February 29, 2020, up to 5,484,808 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 under the 2005 and 2015 Plans.

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.

Raising additional capital would cause dilution to our existing shareholders, and may restrict our operations or require us to relinquish rights.

We may seek additional capital through a combination of private and public equity offerings, "at-the-market" issuances, equity-linked and structured transactions, debt (straight, convertible, or otherwise) financings, collaborations and licensing arrangements. Under our existing equity line with Aspire Capital, we may generally sell, from time to time, up to $10 million of additional ordinary shares and under our "at the market" equity offering program, we may sell, from time to time, up to approximately $72.4 million of additional ordinary shares, subject to limitations under the Baby Shelf Rule. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licenses on terms that are not favorable to us. Depending upon market liquidity at the time, additional sales of shares registered at any given time could cause the trading price of our ordinary shares to 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. We currently do not meet Nasdaq's bid price rule and if we do not cure the bid price rule deficiency or do not meet other continued listing requirements, our ordinary shares could be delisted. See "Item 1A. Risk Factors — Risks Related to Ownership of Our Ordinary Shares — If we fail to comply with the continued listing requirements of the Nasdaq Capital Market, our ordinary shares may be delisted and the price of our ordinary shares and our ability to access the capital markets could be negatively impacted." 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.

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.

If we fail to comply with the continued listing requirements of the Nasdaq Capital Market, our ordinary shares may be delisted and the price of our ordinary shares and our ability to access the capital markets could be negatively impacted.

On September 3, 2019, we were notified by Nasdaq that we were not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. The notification provided that we had 180 calendar days, or until March 2, 2020, to regain compliance with Nasdaq Listing Rule 5550(a)(2). On March 3, 2020, we were notified by Nasdaq that we are eligible for an additional 180 calendar day period, or until August 31, 2020, to regain compliance. To regain compliance, the bid price of our ordinary shares must have a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days. Failure to meet applicable Nasdaq continued listing standards could result in a delisting of our ordinary shares. A delisting of our ordinary shares from Nasdaq could materially reduce the liquidity of our ordinary shares and result in a corresponding material reduction in the price of our ordinary shares. In addition, delisting could harm our ability to raise capital on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

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.

The legislative power of the State resides in the Knesset, a unicameral parliament that consists of 120 members elected by nationwide voting under a system of proportional representation. Israel's most recent general elections were held on April 9, 2019, September 17, 2019 and March 2, 2020, following which a process of composing and approving a new government has commenced. This uncertainty surrounding future elections and/or the results of such elections in Israel may continue and the political situation in Israel may further deteriorate. Actual or perceived political instability in Israel or any negative changes in the political environment, may individually or in the aggregate adversely affect the Israeli economy and, in turn, our business, financial condition, results of operations and prospects.

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 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 (or any other interest rate that the IIA may choose to apply in the future) 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 the IIA funded program 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, 2019, we received approximately NIS 42.3 million of such grants. We did not apply for any grants from the IIA for the years ended December 31, 2019, 2018 and 2017. For more information see note 6c in our consolidated financial statements for the year ended December 31, 2019. 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 1,060 square meters, which includes production, packaging, warehousing and laboratory facilities.

The manufacturing facility is 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 1,960 square meters, from an unaffiliated third party, pursuant to a lease agreement which, as amended, expires June 30, 2021. We also lease one standard size office in New York City for our U.S. subsidiary, Intec Pharma Inc and leased three standard size offices in Modi'in. The lease in Modi'in ended on February 29, 2020. Pursuant to the leases our annual rental costs for 2019 were approximately $720,000 (excluding VAT). Our expected rental costs for 2020 are approximately $580,000 (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. Except as set forth below, 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.

On December 19, 2019, Zvi Joseph and Giora Carni, former officers and directors of the Company, filed a complaint with the Jerusalem District Labor Court alleging breach of contract related to the purported vesting of certain options issued to the plaintiffs and further alleging payments due for unredeemed vacation days. The plaintiffs are seeking pecuniary damages of NIS 2,443,098 (approximately $700,000) plus interest and linkage to the Israeli Consumer Price Index. In addition, the plaintiffs have filed motions to obtain liens on our assets to secure any future recovery. These motions were withdrawn pursuant to the Court's recommendation at the conclusion of a pretrial hearing held on February 9, 2020. We together with our legal advisors believe that we have good defense arguments to the claims against us and filed a statement of defense to the complaint on March 8, 2020 in which we rejected all of the plaintiffs' claims. Accordingly, we assessed the likelihood of damages and concluded that no provisions are needed to be recorded within the financial statements regarding this matter.

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 29, 2020, 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 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.

In July 2019, we announced top-line results from our pivotal Phase III clinical for AP-CD/LD for the treatment of advanced Parkinson's disease known as the ACCORDANCE study in which the ACCORDANCE study did not meet its target endpoints. While AP-CD/LD provided treatment for Parkinson's disease symptoms, it did not demonstrate statistically superiority over immediate release CD/LD on the primary endpoint of OFF time reduction under the conditions established in the protocol. Treatment-emergent adverse effects observed with AP-CD/LD were generally consistent with the known safety profile of CD/LD formulations and no new safety issues were observed throughout the double-blinded study, during the gastroscopy safety sub-study or the 12-month open-label extension study. From our review of the data, we have observed a meaningful reduction in OFF time in certain subsets of patients. We have completed the analysis of the full data set and we are currently seeking to partner AP-CD/LD as the basis for the strategy for AP-CD/LD moving forward.

Previously, we 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 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 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 Production Line was delivered to LTS in Andernach, Germany and recently we completed the qualification studies for the commercial scale manufacture of the Accordion Pill and we have initiated the validation and stability studies which are expected to serve as the clinical material for the next Phase 3 clinical trial plan.

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 demonstrated 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 and the results of the study demonstrate that the custom designed AP delivery system in the AP-THC PK study did not meet our expectations. We are continuing to advance the AP-Cannabinoids clinical development program and we are seeking to launch a PK study with the optimized AP-THC in 2020.

While the ACCORDANCE results were not what we expected, we continue to believe in the potential of the Accordion Pill platform. 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 recently completed the human PK study that was initiated during the first quarter of 2019 and the study demonstrated that the AP met the technical requirements set forth by Novartis. In December 2019, Novartis, following an internal and revised commercial strategic assessment, advised us that this program no longer meets Novartis' mid to long-term strategic goals. Novartis paid Intec Pharma $1.5 million on conclusion of the program. We restructured our clinical manufacturing planned to support this program in order to reduce costs. We are looking to identify additional compounds in the Novartis portfolio that can benefit from the unique characteristics of the AP platform.

In May 2019, we reported entering into a research collaboration agreement with Merck for the development of a custom-designed AP for one of Merck's proprietary compounds that met the required *in vitro* specifications. We aim to initiate an in-vivo study by mid-2020.

We continue to advance discussions with other potential pharmaceutical partners for the development of new custom-designed APs. We believe the data from our ACCORDANCE trial enhances those discussions as it validates the AP platform and provides long-term safety data.

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

On September 3, 2019, we were notified by Nasdaq that we were not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. The notification provided that we had 180 calendar days, or until March 2, 2020, to regain compliance with Nasdaq Listing Rule 5550(a)(2). On March 3, 2020, we were notified by Nasdaq that we are eligible for an additional 180 calendar day period, or until August 31, 2020, to regain compliance. To regain compliance, the bid price of our ordinary shares must have a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days. Failure to meet applicable Nasdaq continued listing standards could result in a delisting of our ordinary shares. A delisting of our ordinary shares from Nasdaq could materially reduce the liquidity of our ordinary shares and result in a corresponding material reduction in the price of our ordinary shares. In addition, delisting could harm our ability to raise capital on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

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, 2019, we had an accumulated deficit of $189.4 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, 2019, our net loss was approximately $47.6 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 $204.9 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, follow-on public offerings on the Nasdaq Capital Market in August 2017, April 2018 and February 2020 and through our at-the-market equity offering program. As of December 31, 2019, we had approximately $10.1 million of cash, cash equivalents and marketable securities.

On December 2, 2019, we entered into the Purchase Agreement with Aspire Capital, pursuant to which, upon the terms and conditions set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of our ordinary shares over the 30-month term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 612,520 of our ordinary shares, or the Commitment Shares. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Aspire Capital Financing Arrangement".

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 years ended December 31, 2018 and 2019 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 2018 and 2019 were insignificant. Although we reduced the size of our headcount by approximately 50%, we expect our research and development expense to remain our primary expense in the near future as we continue to develop our products. However, the reduction in headcount may yield unintended consequences, such as attrition beyond our intended reduction in headcount and reduced employee morale. In addition, this may result in employees who were not affected by the reduction in headcount seeking alternate employment, which would result in us seeking contract support at unplanned additional expense. Increases or decreases in research and development expenditures are primarily attributable to the number and/or duration of the clinical studies that we will 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 2019, the standard corporate tax rate in Israel was 23%, and during 2017 it was 24%. During 2018 and 2019, the U.S. statutory tax rate was 21%.

We have not yet generated taxable income in Israel. We have historically incurred operating losses resulting in carry forward tax losses totaling approximately $158.5 million as of December 31, 2019. 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 2019 and 2018, we incurred tax expenses of approximately $638,000 and approximately $103,000, 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	
	2019	2018
	(dollars in thousands)	
Research and development expenses, net	$ (26,659)	$ (35,402)
General and administrative expenses	(8,287)	(7,926)
Impairment of long-lived assets	(13,663)	-
Other Income	1,500	-
Operating loss	(47,109)	(43,328)
Financial income (expenses), net	_148	(112)
Loss before income tax	(46,961)	(43,440)
Income tax	(638)	(103)
Net loss	$ (47,599)	$ (43,543)

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

Research and Development Expenses, Net

Our research and development expenses, net, for the year ended December 31, 2019 amounted to approximately $26.7 million, a decrease of $8.7 million, or approximately 24.6%, compared to approximately $35.4 million for the year ended December 31, 2018. The decrease was primarily due to a decrease in expenses related to our ACCORDANCE study and OLE study, both of which were completed during 2019.

General and Administrative Expenses

Our general and administrative expenses for the year ended December 31, 2019 amounted to approximately $8.3 million, an increase of $400,000, or approximately 5.1%, compared to approximately $7.9 million for the year ended December 31, 2018. The increase was primarily related to the increase in insurance expenses. This increase was offset by a decrease in professional services.

Impairment of long-lived assets

For the year ended December 31, 2019, we recorded an impairment charge of approximately $13.7 million of our Production Line and Equipment, net, from the liability described in note 6e(2) to the consolidated financial statements for the year ended December 31, 2019, together “AP-CD/LD Assets, net”, which represents the excess carrying value compared to the fair value of the AP-CD/LD Assets, net. In the third quarter ended September 30, 2019 we recorded for the first time an impairment charge of approximately $9.8 million which was updated in the fourth quarter by approximately $3.9 million following a new impairment assessment performed at December 31, 2019 following changes in management assumptions. For more information, see note 6e(3) in our consolidated financial statements for the year ended December 31, 2019.

Other Income

For the year ended December 31, 2019, we recorded an amount of $1.5 million in other income on conclusion of the program with Novartis. For more information, see note 6b(1) in our consolidated financial statements for the year ended December 31, 2019.

Operating Loss

Because of the foregoing, for the year ended December 31, 2019 our operating loss was approximately $47.1 million, an increase of $3.8 million, or approximately 8.8%, compared to our operating loss for the year ended December 31, 2018 of approximately $43.3 million. The increase was mainly due to the impairment of our long-lived assets offset by the other income associated with the conclusion of the Novartis program and the decrease in research and development expenses, as detailed above.

Financial Income (expenses), Net

For the year ended December 31, 2019, we had financial income from interest on cash and cash equivalents in the amount of approximately $333,000 and financial income from change in fair value of marketable securities in the amount of approximately $13,000, offset by financial expenses from foreign currency exchange expenses in the amount of approximately $183,000 and bank fees.

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.

Income tax

During 2019 and 2018, we have not generated taxable income in Israel. However, in 2019 and 2018 we incurred tax expenses in our U.S. subsidiary in the amount of approximately $638,000 and approximately $103,000, respectively.

Net Loss

Because of the foregoing, for the year ended December 31, 2019 our net loss was approximately $47.6 million, an increase of $4.1 million, or approximately 9.4%, compared to our loss and comprehensive loss for the year ended December 31, 2018 of approximately $43.5 million. The increase was mainly due to the impairment of our long-lived assets and an increase in general and administrative expenses as detailed above offset by the other income associated with the conclusion of the Novartis program and the decrease in research and development 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, 2019, we had cash and cash equivalents and marketable securities of approximately $10.1 million. As of December 31, 2018, we had cash and cash equivalents and marketable securities of approximately $40.6 million.

Net cash used in operating activities was approximately $29.0 million for the year ended December 31, 2019 compared with net cash used in operating activities of approximately $39.1 million for the year ended December 31, 2018. This decrease resulted primarily from a decrease in our research and development activities in the amount of approximately $8.7 million and changes in operating asset and liability items of approximately $1.2 million.

We had negative cash flow from investing activities of approximately $3.2 million for the year ended December 31, 2019 compared with negative cash flow from investing activities of approximately $9.3 million for the year ended December 31, 2018. This decrease resulted primarily from a decrease of approximately $2.1 million in investment in other assets related to the establishment of the commercial scale production capabilities for AP-CD/LD at LTS and a decrease in purchase of property and equipment in the amount of approximately $3.8 million.

Net cash provided by financing activities was approximately $2.4 million for the year ended December 31, 2019 compared with net cash provided in financing activities of approximately $35.1 million for the year ended December 31, 2018. The principal source of the cash provided by financing activities during 2019, was the funds received from the sale of ordinary shares through our "at-the-market" equity offering program that resulted in net proceeds of approximately $2.1 million. 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.

At-the-Market Equity Offering Program

On March 1, 2019, we entered into a Sales Agreement with Cowen, which provides that, upon the terms and subject to the conditions and limitations in the Sales Agreement, we may elect from time to time, to offer and sell ordinary shares through an "at-the-market" equity offering program through Cowen acting as sales agent. The issuance and sale of ordinary shares by us under the program will be made pursuant to our effective "shelf" registration statement on Form S-3 (Registration Statement No. 333-230016) filed with the SEC on March 1, 2019, and declared effective on March 28, 2019. As of March 12, 2020, we have sold 2,775,883 ordinary shares for gross proceeds of $2.6 million under the offering program. As a result of certain lock-up provisions in our recent underwritten public offering, we may not effect any sales under the Sales Agreement until after April 30, 2020 unless we receive prior written approval from the underwriter in the offering. Subsequent to April 30, 2020, we may sell up to approximately $72.4 million of ordinary shares under the Sales Agreement, subject to limitations under the Baby Shelf Rule.

Aspire Capital Financing Arrangement

On December 2, 2019, we entered the Purchase Agreement with Aspire Capital, pursuant to which provides that, upon the terms and conditions set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of our ordinary shares over the 30-month term of the Purchase Agreement. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital, or the Registration Rights Agreement, in which we agreed to file with the SEC one or more registration statements, as necessary, and to the extent permissible and subject to certain exceptions, to register for sale under the Securities Act for the sale of our ordinary shares that have been and may be issued to Aspire Capital under the Purchase Agreement.

We filed with the SEC a prospectus supplement to our effective shelf registration statement on Form S-3 (File No. 333-230016) registering all of the ordinary shares that may be offered to Aspire Capital from time to time. Under the Purchase Agreement, on any trading day selected by us, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice, each, a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 200,000 of our ordinary shares in an amount no greater than $500,000 per business day, up to $10.0 million of our ordinary shares in the aggregate at a per share price, or the Purchase Price, equal to the lesser of:

- the lowest sale price of our ordinary shares on the purchase date; or
- the arithmetic average of the three (3) lowest closing sale prices for our ordinary shares during the ten (10) consecutive trading days ending on the trading day immediately preceding the purchase date.

We and Aspire Capital also may mutually agree to increase the dollar amount to greater than $500,000 and the number of ordinary shares that may be sold to as much as an additional 2,000,000 ordinary shares per business day, respectively.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital in an amount equal to at least 200,000 ordinary shares, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice, each, a VWAP Purchase Notice, directing Aspire Capital to purchase an amount of ordinary shares equal to up to 30% of the aggregate of our ordinary shares traded on our principal market on the next trading day, or the VWAP Purchase Date, subject to a maximum number of 250,000 ordinary shares. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for our ordinary shares traded on our principal market on the VWAP Purchase Date.

The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, share split, or other similar transaction occurring during the period(s) used to compute the Purchase Price. We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

As a result of certain lock-up provisions in our recent underwritten public offering, we may not effect any sales under the Purchase Agreement until after April 30, 2020 unless we receive prior written approval from the underwriter in the offering. The Purchase Agreement provides that we and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our ordinary shares is less than $0.25. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of sales of our ordinary shares to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as directed by us in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future funding, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital the Commitment Shares. The Purchase Agreement may be terminated by us at any time, at its discretion, without any cost to us. Aspire Capital has agreed that neither we nor any of our agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of our ordinary shares during any time prior to the termination of the Purchase Agreement. Any proceeds from us received under the Purchase Agreement are expected to be used to fund our research and development activities, for working capital and for general corporate purposes.

The Purchase Agreement provides that the number of ordinary shares that may be sold pursuant to the Purchase Agreement will be limited to 7,002,394 ordinary shares, or the Exchange Cap, which represents 19.99% of our outstanding ordinary shares on December 2, 2019, unless shareholder approval or an exception pursuant to the rules of the Nasdaq Capital Market is obtained to issue more than 19.99%. This limitation will not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all ordinary shares issued under the Purchase Agreement is equal to or greater than $0.48978, which is the price equal to the closing sale price of our ordinary shares immediately preceding the execution of the Purchase Agreement. We are not required or permitted to issue any ordinary shares under the Purchase Agreement if such issuance would breach its obligations under the rules or regulations of the Nasdaq Capital Market or other applicable law (including, without limitation, the Israeli Companies Law – 1999, as amended, or the Israeli Companies Law). We may, in our sole discretion, determine whether to obtain shareholder approval to issue more than 19.99% of our outstanding ordinary shares hereunder if such issuance would require shareholder approval under the rules or regulations of the Nasdaq Capital Market or the Israeli Companies Law.

Current Outlook

We believe 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. Currently we will not have adequate cash to fund our ongoing activities beyond the second quarter of 2021. As a result, there is substantial doubt about our ability to continue as a going concern. We expect to satisfy our future cash needs through 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 and February 2020. 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, 2019.

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, 2019 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)	$ 1,424	$ 599	$ 825	—	—

(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.

Long-Lived Assets

We evaluate our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Estimates of future cash flows and timing of events for evaluating long-lived assets for impairment are based upon management's assumptions and market conditions. If any of our long-lived assets are considered to be impaired, the amount of impairment to be recognized is the excess of the carrying amount of the assets over its fair value.

As of December 31, 2019, we incurred an asset impairment of approximately $13.7 million as a result of the top-line results from our pivotal Phase III clinical for AP-CD/LD for the treatment of advanced Parkinson's which did not meet its target endpoints. The impairment charge was the result of both internal and external factors and the fair value was determined using the discounted cash flow method (level 3) which utilized significant estimates and assumptions surrounding the amount and timing of the projected net cash flows, which includes the probability of out-licensing the AP-CD/LD program to a third-party, the probability of obtaining FDA approval, the expected impact of competition, the discount rate, which seeks to reflect the various risks inherent in the projected cash flows and the tax rate.

We believe the assumptions used in our impairment assessment are reasonable, any changes in the actual market conditions versus the assumptions used in the model could result in a change in estimated future cash flows, which may result in an additional impairment charge on AP-CD/LD Assets, net, in the future.

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 (i.e., December 31, 2020), 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, 2019 and 2018, and the related consolidated statements of operations, changes in shareholder's equity and cash flows for each of the two years in the period ended December 31, 2019**,** 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019 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 audits 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 audits 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
March 13, 2020

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

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel,
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INTEC PHARMA LTD.
CONSOLIDATED BALANCE SHEETS

	December 31	
	2019	2018
	U.S. dollars in thousands	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 9,292	$ 39,246
Investment in marketable securities (Note 3)	770	1,333
Prepaid expenses and other receivables (Note 8a)	3,683	2,986
TOTAL CURRENT ASSETS	13,745	43,565
NON-CURRENT ASSETS:		
Property and equipment, net (Note 4)	2,575	12,233
Operating lease right-of-use assets (Note 6d)	1,243	-
Other assets (Note 6e(2))	3,717	5,431
Deferred tax assets (Note 9)	-	281
TOTAL NON-CURRENT ASSETS	7,535	17,945
TOTAL ASSETS	$ 21,280	$ 61,510
Liabilities and shareholders' equity		
CURRENT LIABILITIES -		
Accounts payable and accruals:		
Trade	$ 3,507	$ 2,849
Other (Note 8b)	4,835	4,807
TOTAL CURRENT LIABILITIES	8,342	7,656
LONG-TERM LIABILITIES -		
Operating lease liabilities (Note 6d)	799	-
Other liabilities (Note 9)	604	309
TOTAL LONG-TERM LIABILITIES -	1,403	309
TOTAL LIABILITIES	9,745	7,965
COMMITMENTS AND CONTINGENT LIABILITIES (Note 6)		
SHAREHOLDERS' EQUITY:		
Ordinary shares, with no par value - authorized: 100,000,000 as of December 31, 2019 and December 31, 2018, respectively; issued and outstanding: 35,892,209 and 33,232,988 Ordinary Shares as of December 31, 2019 and December 31, 2018, respectively	727	727
Additional paid-in capital	200,231	194,642
Accumulated deficit	(189,423)	(141,824)
TOTAL SHAREHOLDERS' EQUITY	11,535	53,545
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 21,280	$ 61,510

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

INTEC PHARMA LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31	
	2019	2018
	U.S. dollars in thousands	
OPERATING EXPENSES:		
RESEARCH AND DEVELOPMENT EXPENSES, net	$ (26,659)	$ (35,402)
GENERAL AND ADMINISTRATIVE EXPENSES	(8,287)	(7,926)
IMPAIRMENT OF LONG-LIVED ASSETS	(13,663)	-
OTHER INCOME	1,500	-
OPERATING LOSS	(47,109)	(43,328)
FINANCIAL INCOME (EXPENSES), net (Note 8c)	148	(112)
LOSS BEFORE INCOME TAX	(46,961)	(43,440)
INCOME TAX (Note 9)	(638)	(103)
NET LOSS	$ (47,599)	$ (43,543)
	$	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	$ (1.41)	$ (1.40)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE IN THOUSANDS	33,776	31,193

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, 2018	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 7c)	7,218	-	30	-	30
Share-based compensation (Note 7c)	-	-	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
CHANGES DURING 2019:					
Issuance of ordinary shares, net of issuance costs (Note 7b)	1,944,512	-	2,086	-	2,086
Issuance of ordinary shares per equity line agreement (Note 7b)	612,520	-	-	-	-
Exercise of options by employees (Note 7c)	102,189	-	282	-	282
Share-based compensation (Note 7c)	-		3,221		3,221
Net loss	-	-	-	(47,599)	(47,599)
BALANCE AT DECEMBER 31, 2019	35,892,209	$ 727	$ 200,231	$ (189,423)	11,535

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

INTEC PHARMA LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31	
	2019	2018
	U.S. dollars in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (47,599)	$ (43,543)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	854	859
Impairment of long-lived assets	13,663	-
Exchange differences on cash and cash equivalents	67	829
Change in right of use asset	967	-
Change in lease liabilities	(713)	-
Losses (gains) on marketable securities	(13)	194
Share-based compensation	3,221	3,227
Changes in operating asset and liabilities:		
Increase in prepaid expenses and other receivables	(747)	(1,861)
Increase (decrease) in deferred tax assets	281	(281)
Increase in accounts payable and accruals	679	1,191
Increase in other liabilities	295	309
Net cash used in operating activities	(29,045)	(39,076)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(921)	(4,667)
Investment in other assets	(2,865)	(4,932)
Proceeds from disposal of marketable securities, net	576	298
Net cash used in investing activities	(3,210)	(9,301)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of ordinary shares, net of issuance costs	2,086	35,029
Proceeds from exercise of options by employees	282	30
Net cash provided by financing activities	2,368	35,059
DECREASE IN CASH AND CASH EQUIVALENTS	(29,887)	(13,318)
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR	39,246	53,393
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(67)	(829)
CASH AND CASH EQUIVALENTS AT END OF THE YEAR	$ 9,292	$ 39,246
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING ACTIVITIES:		
Liability with respect to property and equipment (see note 6e(1))	-	170
Liability with respect to other assets (see note 6e(2))	-	499
SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION:		
Taxes paid	75	96
Interest received	327	734

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").

   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", together with Intec - "the Company"). 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) The Company engages in research and development activities and has not yet generated revenues from operations. On July 22, 2019, the Company announced top-line results according to which its Phase III clinical trial for AP-CD/LD did not achieve its primary and secondary endpoints. As these results are considered a triggering event, the Company performed an impairment test on certain of its long-lived assets which resulted in an impairment charge of approximately $13.7 million. For more details see note 6e(3). Accordingly, there is no assurance that the Company's operations will generate positive cash flows. As of December 31, 2019, the cumulative losses of the Company were approximately $189.4 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 believes that, as of the date of the issuance of these consolidated financial statements, it will not have adequate cash to fund its ongoing activities beyond the second quarter of 2021 based on its current operating plan. Its ability to execute its operating plan beyond the second quarter of 2021 is dependent on its ability to obtain additional capital principally through entering into collaborations, strategic alliances, or license agreements with third parties and/or raising capital from the public and/or private investors and/or institutional investors. The negative outcome of the Phase III clinical trial that was announced on July 22, 2019 and uncertainty regarding the Company's development programs is expected to adversely affect its ability to obtain funding and there is no assurance that it will be successful in obtaining the level of financing needed for its activities. The Company has taken measures to reduce its costs, including reducing headcount, and is continuingly evaluating measures to reduce additional costs to preserve existing capital. If the Company is unsuccessful in securing sufficient financing, it may need to curtail or cease operations. As a result of these uncertainties, there is substantial doubt about the Company's ability to continue as a going concern.

   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 September 3, 2019, the Company was notified by NASDAQ that it was not in compliance with the minimum bid price requirements for continued listing on the Nasdaq Capital Market. The notification provided that the Company had 180 calendar days, or until March 2, 2020, to regain compliance. On March 3, 2020, the Company was notified that it is eligible for an additional 180 calendar day period, or until August 31, 2020, to regain compliance. Failure to meet these requirements could result in a delisting of the Company's ordinary shares which could negatively impact the Company's ability to raise capital.

4) On March 1, 2019, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen"). As of the date of the issuance of these consolidated financial statements, the Company sold 2,775,883 ordinary shares under the Sales Agreement raising a total of approximately $2.5 million (net of issuance expenses of approximately $127 thousand) and the Company may continue to sell up to approximately $72.4 million of ordinary shares under the Sales Agreement, subject to limitations under the Baby Shelf Rule. For more details see notes 7b(2) and 10a.

In addition, on February 3, 2020 the Company completed an underwritten public offering and raised a total of approximately $5.7 million (net of underwriting discounts, commissions and other offering expenses in the amount of approximately $800 thousand). For more details see note 10b.

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').

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 impairment assessment on certain long-lived assets and 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. 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 recorded at fair value with changes recorded in the statement of operations as "financial income**,** net", as the Company chooses 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's long-lived assets include property, equipment and long-term other assets. The Company evaluates its long-lived assets for impairment in accordance with ASC 360, whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. When necessary, the Company calculates the undiscounted value of the projected cash flows associated with the asset, or asset group, and compares this estimated amount to the carrying amount. If any of its long-lived assets are considered to be impaired, the amount of impairment to be recognized is the excess of the carrying amount of the assets over its fair value. Estimates of future cash flows and timing of events for evaluating long-lived assets for impairment are based upon management's assumptions and market conditions. Changes in assumptions or market conditions could result in a change in estimated future cash flows and the likelihood of materially different reported results.

As further discussed in note 6e(3), during the year ended December 31, 2019, the Company recorded an impairment loss in the amount of $13.7 million related to certain of its long-lived assets. The impairment charge is recorded as an operating expense.

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.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

As of December 31, 2018, the Company adopted ASU 2018-07, Compensation-Stock Compensation, which establishes that the measurement of equity-classified nonemployee awards will be fixed at the grant date. The adoption of ASU 2018-07 did not have an impact on the consolidated statements of operations.

The Company has elected to recognize forfeitures as they occur.

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, 2019 and 2018, include participation in research and development expenses in the amount of approximately $1.1 million and approximately $829 thousand, respectively.

Clinical trial expenses are charged to research and development expense as incurred. The Company accrues 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 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,	
	2019	**2018**
Outstanding stock options	4,325,105	3,301,669

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.

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.

o. Leases

The Company is a lessee in several noncancelable operating leases primarily for office and operational spaces and vehicles. The Company currently has no finance leases.

Commencing January 1, 2019, the Company accounts for leases in accordance with ASC Topic 842, “Leases”. The Company determines if an arrangement is a lease at inception. Right-of-use, or ROU, assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term as of the commencement date. Operating lease ROU assets are presented as operating lease right of use assets on the consolidated balance sheets.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

The current portion of operating lease liabilities is included in other current liabilities and the long-term portion is presented separately as operating lease liabilities on the consolidated balance sheets.

Lease expense is recognized on a straight-line basis for operating leases. The Company's leases may include variable payments based on measures that include changes in price index. Change to index based variable lease payments is expensed in the period of the change. Variable lease payments are presented as operating expense on the consolidated statements of operations in the same line item as expense arising from fixed lease payments.

The Company elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. Instead, the Company will continue to recognize the lease payments for those leases in profit or loss on a straight-line basis over the lease term.

The Company's lease terms may include options of the Company as the lessee to extend the lease. The lease extensions are included in the measurement of the right of use asset and lease liability if it is reasonably certain that it will exercise that option.

Because the Company's leases do not provide an implicit rate of return, an incremental borrowing rate is used based on the information available at the commencement date in determining the present value of lease payments on an individual lease basis. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms.

The Company has lease agreements with lease and non-lease components and has elected the practical expedient to combine lease and non-lease components for all underlying classes of assets All fixed payments of non-lease components will be included in the measurement of lease payments, the ROU asset, and the lease liability for all leases entered into on or after January 1, 2019. All variable payments for non-lease components and executory costs will be recognized and disclosed as variable lease payments.

We applied the modified retrospective transition method and elected the transition option to use the effective date of January 1, 2019 as the date of initial application ("Transition Date"). Consequently, the disclosures required under Topic 842 are not provided for dates and periods before January 1, 2019.

Topic 842 provides for a number of optional practical expedients in transition. The Company elected the 'package of practical expedients', which permits not to reassess under Topic 842 its prior conclusions about lease identification, lease classification, and initial direct costs.
Topic 842 had a material impact on our consolidated balance sheets but did not have an impact on our consolidated statements of operations. The most significant impact was the recognition of $2.2 million in ROU assets and $2.2 million in lease liabilities.

ROU assets for operating leases are periodically reviewed for impairment losses under ASC 360-10, "Property, Plant, and Equipment", to determine whether a ROU asset is impaired, and if so, the amount of the impairment loss to recognize.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

p. Newly issued accounting pronouncements

1) In February 2016, the FASB established ASC Topic 842, "Leases" (Topic 842), by issuing ASU No. 2016-02, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations.

   The Company adopted the new standard on January 1, 2019 using the modified retrospective transition method and has not restated comparative periods.

   The new standard also provides practical expedients for an entity's ongoing accounting. Beginning in 2019, the Company changed its disclosed lease recognition policies and practices, as well as to other related financial statement disclosures due to the adoption of this standard. See Note 6d.

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, adopted as of January 1, 2019, had no impact on the Company's consolidated financial statements.

New accounting pronouncements effective in future periods

Financial Instruments - Credit Losses

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326)-Measurement of Credit Losses on Financial Instruments. This guidance replaces the current incurred loss impairment methodology. Under the new guidance, on initial recognition and at each reporting period, an entity is required to recognize an allowance that reflects its current estimate of credit losses expected to be incurred over the life of the financial instrument based on historical experience, current conditions and reasonable and supportable forecasts. In November 2019, the FASB issued ASU No. 2019-10, Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates ("ASU 2019-10"). The purpose of this amendment is to create a two-tier rollout of major updates, staggering the effective dates between larger public companies and all other entities. This granted certain classes of companies, including Smaller Reporting Companies ("SRCs"), additional time to implement major FASB standards, including ASU 2016-13. Larger public companies will have an effective date for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. All other entities are permitted to defer adoption of ASU 2016-13, and its related amendments, until the earlier of fiscal periods beginning after December 15, 2022. Under the current SEC definitions, the Company meets the definition of an SRC as of the ASU 2019-10 issuance date and is adopting the deferral period for ASU 2016-13. The guidance requires a modified retrospective transition approach through a cumulative-effect adjustment to retained earnings as of the beginning of the period of adoption. The Company is currently evaluating the impact of the adoption of ASU 2016-13 on its consolidated financial statements, but does not believe the adoption of this standard will 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 recorded as fair value with changes recorded in the statement of operations as "financial income, net", as the Company chose to apply the fair value option. These assets are categorized as Level 1.

As of December 31, 2019, and 2018, the amount of the marketable securities is approximately $770 thousand and $1.3 million, respectively.

The gain, net from changes in marketable securities amounted to approximately $13 thousand in 2019 and the loss, net from changes in fair value through profit or loss amounted to approximately $194 thousand in 2018.

NOTE 4 - PROPERTY AND EQUIPMENT, NET:

	December 31	
	2019	**2018**
	U.S. dollars in thousands	
Cost:		
Computers and communications equipment	$ 248	$ 237
Production and laboratory equipment	7,286	7,280
Office furniture and equipment	208	203
Leasehold improvements	2,029	2,029
Large-scale automated production line, see note 6e(1) and 6e(3)	-	8,826
	9,771	18,575
Less:		
Accumulated depreciation	(7,196)	(6,342)
Property and equipment, net	$ 2,575	$ 12,233

Depreciation expense totaled approximately $854 thousand, and approximately $859 thousand for the years ended December 31, 2019 and 2018, respectively. During the year ended December 31, 2019 the Company had impairment of large-scale automated production line in the amount of $9.6 million. For more details, see note 6e(1) and 6e(3).

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.

Contribution plan expenses totaled approximately $610 thousand and approximately $615 thousand for the years ended December 31, 2019 and 2018, respectively.

The Company expects contribution plan expenses in 2020 to amount to approximately $400 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.

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 these consolidated 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.

NOTE 6 - COMMITMENTS AND CONTINGENT LIABILITIES (continued):

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; or (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.

1) In January 2018, the Company entered into a feasibility and option agreement with Novartis Pharmaceuticals ("Novartis") 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. In December 2019, the Company received notice from Novartis for the termination of the agreement, since this program no longer meets Novartis' mid to long-term strategic goals. Novartis agreed to pay to the Company $1.5 million on conclusion of the program. The Company recorded this amount in the statements of operations as 'Other income', which was paid in February 2020.

2) In May 2019, the Company entered into a research collaboration agreement with Merck Sharp & Dohme ("Merck") for the development of a custom-designed Accordion Pill for one of Merck's proprietary compounds. Under the agreement, the Company's activities will be funded by Merck subject to the achievement of agreed milestones.

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.

NOTE 6 - COMMITMENTS AND CONTINGENT LIABILITIES (continued):

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, 2019, 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, 2019 and 2018.

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") which was included in the initial recognition of lease assets and liabilities as of January 1, 2019. In January 2018, the Company amended the lease agreement and added additional operational spaces and on December 31, 2019, the Company has returned these spaces to the lessor. Accordingly, as of December 31, 2019, the lease asset and operating lease liability in respect of this lease agreement have been relatively reduced. 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 $147 thousand as of December 31, 2019.

   The Company also leases office space in New York City and as of the date of the issuance of these consolidated financial statements, the office space lease agreement in Modi'in was ended.

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.

   Lease expense for the year ended December 31, 2019 was comprised of the following:

	Year ended December 31, 2019
	U.S. dollars in thousands
Operating lease expense	743
Short-term lease expense	102
Variable lease expense	2
	847

NOTE 6 - COMMITMENTS AND CONTINGENT LIABILITIES (continued):

Supplemental information related to leases are as follows:

	December 31, 2019 U.S. dollars in thousands
Operating lease right-of-use assets	1,243
Current Operating lease liabilities	544
Non-current operating lease liabilities	799

Other information:

Operating cash flows from operating leases (cash paid in thousands)	743
Weighted Average Remaining Lease Term (years)	2.43
Weighted Average Discount Rate of operating leases	5.45%

Maturities of lease liabilities are as follows:

Year	Amount U.S. dollars in thousands
2020	599
2021	550
2022	274
Total lease payments	1,423
Less imputed interest	(80)
Total	1,343

3) ASC 840 Disclosures-

The Company elected the modified retrospective transition method and included the following tables previously disclosed. The lease expenses for 2018 amounted to approximately $680 thousand.

Future contractual obligations under the abovementioned operating lease agreements (not including the Extension Option) as of December 31, 2018 are as follows:

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

NOTE 6 - COMMITMENTS AND CONTINGENT LIABILITIES (continued):

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

1) 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 total cost of the Production Line amounted to approximately €8.2 million (approximately $9.6 million). As of December 31, 2019, the Company paid in full all the consideration. As of the date of the issuance of these consolidated financial statements, the installation process and qualification studies of the Production Line at the commercial site at Lohmann Therapie-Systeme AG ("LTS") was completed and the Company has initiated the validation and stability studies. For more details regarding the Manufacturing Services with LTS, see note 6e(2) below. For the year ended December 31, 2019 the Company recorded a full impairment charge of the Production Line, for more details see note 6e(3).

2) LTS Process Development Agreement

In December 2018, the Company entered into a Process Development Agreement for Manufacturing Services with LTS for the manufacture of AP-CD/LD (the "Agreement"). Under the Agreement, the Company will bear the costs incurred by LTS to acquire the production equipment for AP-CD/LD ("Equipment") which amounted to approximately €6.8 million (approximately $7.8 million), and this 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, 2019, the Company paid in full all the consideration.

The Company has recognized the Equipment as non-current other assets. As of December 31, 2019, the fair value of the Equipment is approximately $3.7 million. For the year ended December 31, 2019, the Company recorded an impairment charge of the Equipment in the amount of approximately $4.1 million. For more details, see note 6e(3) below.

The Agreement contains several termination rights which are expected to be included in a definitive manufacturing and supply agreement. As of December 31, 2019, the Company recognized a liability that was recorded against research and development expenses, net in the amount of €2.0 million (approximately $2.2 million) for LTS's facility upgrading costs. This liability will be paid to LTS only if the Company decides not to continue with the project or commercialization of AP-CD/LD. The liability that was recorded as of December 31, 2018, was approximately €1.65 million (approximately $1.9 million).

3) Impairment Assessment

On July 22, 2019, the Company announced top-line results from its pivotal Phase III clinical for AP-CD/LD for the treatment of advanced Parkinson's which did not meet its target endpoints. The Company determined that the Phase III clinical trial results constituted a triggering event that required the Company to evaluate its Production Line and Equipment net from the liability described in note 6e(2), together "AP-CD/LD Assets, net" for impairment test.

For the year ended December 31, 2019, the Company recorded an impairment charge of approximately $13.7 million of its AP-CD/LD Assets, net which represents excess carrying value compared to the fair value of the AP-CD/LD Assets, net.

NOTE 6 - COMMITMENTS AND CONTINGENT LIABILITIES (continued):

The following table illustrates the effect of the impairment assessment on the AP-CD/LD Assets, net, as of December 31, 2019:

	Cost/ Liability	Impairment Charge	Fair Value
	U.S. dollars in thousands		
Production Line	$ 9,568	$ (9,568)	$ -
Equipment	7,812	(4,095)	3,717
Liability for LTS's facility upgrading costs	(2,244)	-	(2,244)
AP-CD/LD Assets, net	$ 15,136	$ (13,663)	$ 1,473

No impairment of long-lived assets was recorded for the year ended December 31, 2018.

The fair value was determined using the discounted cash flow method (level 3) which utilized significant estimates and assumptions surrounding the amount and timing of the projected net cash flows, which includes the probability of out-licensing the AP-CD/LD program to a third-party, the probability of obtaining FDA approval, the expected impact of competition, the discount rate, which seeks to reflect the various risks inherent in the projected cash flows, and the tax rate.

While management believes the assumptions used in their impairment assessment are reasonable, any changes in the actual market conditions versus the assumptions used in the model could result in a change in estimated future cash flows, which may result in an additional impairment charge on AP-CD/LD Assets, net in the future.

f. Lawsuit

In December, 2019, two former directors and officers (the "plaintiffs") filed a statement of claim with the Jerusalem District Labor Court alleging breach of contract related to a purported vesting of certain options issued to the plaintiffs pursuant to the execution of the LTS Agreement and further alleging payments due for unredeemed vacation days.

NOTE 6 - COMMITMENTS AND CONTINGENT LIABILITIES (continued):

The plaintiffs are seeking pecuniary damages of NIS 2.4 million (approximately $700 thousand) plus interest and linkage to the Israeli CPI. In addition, the plaintiffs have filed motions to obtain liens on the Company's assets to secure any future recovery. That motion was withdrawn pursuant to the court's recommendation at the conclusion of a hearing held on February 9, 2020.

The Company records a provision in its financial statements to the extent that it concludes that a contingent liability is probable and the amount thereof is estimable.

The Company together with its legal advisors believe that it has good defense arguments to the claims against it and filed a statement of defense to the complaint on March 8, 2020 in which it rejected all of the plaintiffs' claims. Accordingly, management assessed the likelihood of damages and concluded that no provisions are needed to be recorded within the financial statements regarding the matter disclosed in this note.

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 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.

2) On March 1, 2019, the Company entered into a Sales Agreement with Cowen which provides that, upon the terms and subject to the conditions and limitations in the Sales Agreement, the Company may elect from time to time, to offer and sell ordinary shares through an "at-the-market" equity offering program having an aggregate offering price of up to $75.0 million through Cowen acting as sales agent. The issuance and sale of ordinary shares by the Company under the program is being made pursuant to the Company's effective "shelf" registration statement on Form S-3 filed with the SEC on March 1, 2019 and declared effective on March 28, 2019. During September and December 2019, the Company sold 1,944,512 ordinary shares under the Sales Agreement at an average price of $1.13 per share for aggregate net proceeds of approximately $2.1 million, net of issuance expenses of approximately $112 thousand.

3) On December 2, 2019, the Company entered into an ordinary shares purchase agreement (the "Purchase Agreement") with Aspire Capital Fund, LLC (Aspire Capital) which provides that, upon the terms and subject to the conditions and limitations in the Purchase agreement, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of the Company's ordinary shares over the 30-month term of the Purchase Agreement. The Company will control the timing and amount of sales of the Company's ordinary shares to Aspire Capital. In consideration for entering into the Purchase Agreement, the Company issued to Aspire Capital 612,520 ordinary shares.

NOTE 7 - SHARE CAPITAL (continued):

c. Share-based compensation:

1) 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, June 2018 and December 2019, an increase of 2,100,000, 1,000,000 and 1,000,000 ordinary shares, respectively, was approved by the Company's shareholders at a general meeting of shareholders.

As of December 31, 2019, 1,459,238 shares remain available for grant under the Plan.

The 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.

2) On August 22, 2019, the Company reduced the exercise price of 1,263,655 options previously granted to employees (excluding executive officers and directors) to $0.44 (determined based on the close price of the Company's ordinary shares on Nasdaq on August 21, 2019). The total incremental fair value of these options amounted to $253 thousand and was determined based on the Black-Scholes pricing options model using the following assumptions: risk free interest rate of 1.5%, expected volatility of 99% - 122%, expected term of 2.6-4.4 years and dividend yield of 0%. The incremental fair value of the fully vested options as of August 22, 2019 in the amount of $62 thousand was recognized immediately. The remaining incremental fair value will be recognized over the remaining vesting period and until January 2022.

NOTE 7 - SHARE CAPITAL (continued):

3) During the years ended December 31, 2019 and December 31, 2018, the Company granted options to employees and directors as follows:

	Year ended December 31, 2019			
	Number of options granted	**Exercise price range**	**Vesting period**	**Expiration**
Employees*	1,465,000	$0.9-$7.64	3 years	7 years
Directors	140,000	$0.62-$4.86	3 years	7 years

	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

* As part of the reduction in exercise price of the options described in note 7c(2), the option exercise price was adjusted to $0.44.

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	
	2019	**2018**
Weighted average fair value	$ 2.76	$ 2.37

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

	Year ended December 31	
	2019	**2018**
Value of ordinary share	$0.51-$7.46	$4.20-$6.45
Dividend yield	0%	0%
Expected volatility	53.32%-100.04%	45.87%-46.47%
Risk-free interest rate	1.65%-2.57%	2.25%-2.73%
Expected term	5 years	5 years

The following table summarizes the number of options outstanding with exercise price in NIS for the years ended December 31, 2019 and December 31, 2018, and related information:

	Employees and directors		Consultants	
	Number of options	**NIS (1)**	**Number of options**	**NIS (1)**
Outstanding at January 1, 2018	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
Exercised	(16)	0.5	(2,530)	0.5
Forfeited	(85,909)	23.25	-	-
Expired	(126,852)	21.89	(5,505)	0.5
Outstanding at December 31, 2019	82,675	40.60	-	-

NOTE 7 - SHARE CAPITAL (continued):

The following table summarizes the number of options outstanding with exercise price in USD for the years ended December 31, 2019 and December 31, 2018, and related information:

	Employees and directors	
	Number of options	USD[2]
Outstanding at January 1, 2018	1,872,683	5.74
Granted	1,295,000	6.01
Exercised	(7,218)	4.14
Forfeited	(22,282)	6.64
Expired	-	-
Outstanding at December 31, 2018	3,138,183	5.85
Granted	1,605,000	[3] 3.45
Exercised	(99,643)	[3] 2.83
Forfeited	(450,745)	[3] 4.00
Expired	(269,900)	7.00
Outstanding at December 31, 2019	3,922,895	[3] 4.13

(1) Weighted average price in NIS per share.
(2) Weighted average price in USD per share.
(3) After giving effect to the reduction in exercise price of the options described in note 7c(2).

The following table summarizes information concerning outstanding and exercisable options with exercise prices in NIS as of December 31, 2019:

	December 31, 2019			
	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
32.47-39.55	45,000	0.89	45,000	0.89
48.91	32,253	0.28	32,253	0.28
52.35	5,422	0.17	5,422	0.17
	82,675		82,675	

NOTE 7 - SHARE CAPITAL (continued):

The following table summarizes information concerning outstanding and exercisable options with exercise prices in USD as of December 31, 2019:

	December 31, 2019			
	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
0.447-0.9	1,355,451	5.65	402,398	4.50
3.526	224,478	6.38	224,478	6.38
4.14-4.47	505,466	5.93	230,540	5.60
5.19-5.46	435,000	5.85	310,001	5.95
6-6.7	697,500	6.37	466,665	6.23
7.628-7.64	505,000	6.11	-	-
8.56	200,000	7.91	133,334	7.91
	3,922,895		1,767,416	

The aggregate intrinsic value of the total outstanding and exercisable options as of December 31, 2019, is $50 thousand and $21 thousand respectively.

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

	Year ended December 31	
	2019	2018
	U.S. dollars in thousands	
Research and development expenses, net	$ 1,634	$ 1,732
General and administrative expenses	1,587	1,495
	$ 3,221	$ 3,227

NOTE 8 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

Balance sheets:

	December 31	
	2019	2018
	U.S. dollars in thousands	
a. Prepaid expenses and other receivables:		
Institutions	$ 1,836	$ 1,683
Termination fee, Novartis (see note 6b(1))	1,500	-
Prepaid expenses	194	227
Advances to suppliers	3	728
Interest receivable	3	118
Other receivables	147	230
	$ 3,683	$ 2,986
b. Accounts payable and accruals - other:		
Expenses payable	2,838	3,400
Salary and related expenses, including social security and other taxes	1,277	1,078
Current operating lease liabilities (see note 6d)	544	-
Accrual for vacation days and recreation pay for employees	154	309
Other	22	20
	$ 4,835	$ 4,807

Statements of operations:

c. Financial income (expenses), net:

	Year ended December 31	
	2019	2018
	U.S. dollars in thousands	
Financial income:		
Interest on cash and cash equivalents	$ 330	$ 852
Gains from changes in fair value of marketable securities	13	-
	$ 343	$ 852
Financial expenses -		
Loss from changes in exchange rates	$ (180)	$ (747)
Losses from changes in fair value of marketable securities	-	(194)
Bank fees	(15)	(23)
	$ (195)	$ (964)
Financial income (expenses), net	$ 148	$ (112)

NOTE 9 - TAXES ON INCOME:

a. Tax rates

1) Income from Israel is taxed according to the Israeli tax laws. Capital gains are taxed at the standard corporate tax rate.

   Israeli tax rate relevant to the Company is 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 2019 and 2018 were 21%. The relevant state tax rate for 2019 and 2018 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, 2019, 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 2015.

d. Losses for tax purposes carried forward to future years

As of December 31, 2019, Intec had approximately $144.9 million of net carry forward tax losses which are available to reduce future taxable income with no limited period of use.

e. Subsidiary tax expenses

During 2019 and 2018, the Subsidiary incurred a tax expense in the amount of approximately $638 thousand and approximately $103 thousand, respectively. In 2019, the Company has provided full valuation allowance with respect to the subsidiary's share-based compensation expenses and accordingly recorded in 2019 tax expenses of $562 thousand.

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

f. Deferred income taxes:

	December 31	
	2019	2018
	U.S. dollars in thousands	
In respect of:		
Net operating loss carry forward	$ 33,316	$ 24,739
Research and Development expenses	6,209	6,705
Impairment of long-lived assets	3,143	-
Issuance costs	216	734
Other	1,138	787
Less—valuation allowance	(44,022)	(32,684)
Net deferred tax assets	$ -	$ 281

The change in valuation allowance for the years ended December 31, 2019 and 2018 were as follows:

	December 31	
	2019	2018
	U.S. dollars in thousands	
Balance at the beginning of the year	$ 32,684	$ 22,774
Changes during the year	11,338	9,910
Balance at the end of the year	$ 44,022	$ 32,684

g. Loss before income tax

The components of loss before income tax are as follows:

	December 31	
	2019	2018
	U.S. dollars in thousands	
Income (loss) before income tax:		
Intec	$ (47,331)	$ (43,943)
Subsidiary	370	503
	$ (46,961)	$ (43,440)

h. Current taxes on income

The main reconciling item between the statutory tax rates of the Company and the effective rate is the share-based compensation and the provision for valuation allowance in respect of tax benefits from carryforward tax losses and issuance costs due to the uncertainty of the realization of such tax benefits.

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	
	2019	2018
	U.S. dollars in thousands	
Balance at the beginning of the year	$ 309	$ -
Increase in uncertain tax positions for the current year	295	309
Balance at the end of the year	$ 604	$ 309

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

NOTE 10 - EVENTS SUBSEQUENT TO DECEMBER 31, 2019:

a. During January 2020, the Company sold 831,371 ordinary shares under the Sales Agreement at an average price of $0.525 per share for aggregate net proceeds of approximately $421 thousand, net of issuance expenses of approximately $15 thousand.

b. In February 2020, the Company completed an underwritten public offering, pursuant to which the Company issued 15,280,000 ordinary shares, pre-funded warrants to purchase 970,000 ordinary shares and warrants to purchase 16,250,000 ordinary shares. Each pre-funded warrant was exercisable at an exercise price of $0.0001 per share. All the pre-funded warrants were exercised following the closing of the offering. Each ordinary share and warrant or pre-funded warrant and warrant were sold together at a combined price of $0.40. Each warrant shall be exercisable at an exercise price of $0.40 per share and has a term of five years from the date of issuance. The total net proceeds were approximately $5.7 million, after deducting underwriting discounts, commissions and other offering expenses in the amount of $800 thousand.

c. On February 17, 2020, the board of directors approved a grant of options to purchase an aggregate of 645,000 ordinary shares to the Company's executive officers and employees. Each option shall be exercisable at an exercise price of $0.4287 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 $127 thousand. 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, 2019. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of December 31, 2019 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, 2019. 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, 2019, 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 quarter ended December 31, 2019 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 29, 2020.

Name	Age	Position
Executive Officers		
Jeffrey A. Meckler	53	Chief Executive Officer, Vice Chairman of the Board of Directors
Dr. Nadav Navon	51	Chief Operating Officer
Walt A. Linscott, Esq.	59	Chief Business Officer
Nir Sassi	44	Chief Financial Officer
Dr. R. Michael Gendreau	64	Chief Medical Officer
Non-Executive Directors		
Dr. John W. Kozarich (3)	70	Chairman of the Board of Directors
Hila Karah (1)(2)(3)	51	Director
Anthony J. Maddaluna (2)(3)	67	Director
William B. Hayes (1)	54	Director
Dr. Roger J. Pomerantz (1)(2)	62	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.

Information about 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.

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.

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. Since October 2019, Mr. Hayes has served on the board of Builders FirstSource, a supplier and manufacturer of building materials (Nasdaq: BLDR), and currently chairs its audit committee. Previously, 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 six 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, Hila Karah and Roger Pomerantz. 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 Brad Hayes 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. 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

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.

Delinquent Section 16(a) Reports

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. Based solely upon a review of copies of Section 16(a) reports and representations received by us from reporting persons, a Form 3 was filed late by Dexcel Pharma Technologies Ltd. and Dan Oren.

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 2019, 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 2019 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, 2019 and 2018.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards (1) ($)	Non-equity Incentive Plan Compensation	All Other Compensation ($)	Total ($)
Jeffrey Meckler, CEO	2019	540,000	199,800	-	519,803	-	47,096(4)	1,306,699
	2018	500,000(2)	213,750	-	658,229	-	48,000(4)	1,419,979
Walt A. Linscott, Esq.,	2019	340,000	170,000	-	329,024	-	47,050(5)	886,074
Chief Business Officer	2018	300,000	130,613	-	254,884	-	48,000(5)	733,497
Dr. Michael Gendreau,	2019	336,000	106,982	-	443,492	-	16,166(5)	902,640
Chief Medical Officer	2018	350,483(3)	111,008	-	408,265	-	12,081(5)	881,837
Nadav Navon,	2019	235,094	57,523	-	309,239	-	102,319(6)	704,175
Chief Operating Officer	2018	210,329	52,273	-	290,011	-	93,166(6)	645,779
Nir Sassi,	2019	186,687	57,361	-	304,363	-	94,065(7)	642,476
Chief Financial Officer	2018	165,534	42,774	-	181,239	-	85,648(7)	475,195

(1) Represents the share-based compensation expenses recorded in our consolidated financial statements for the year ended December 31, 2019 and 2018, 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) The salary for Mr. Jeffrey Meckler in 2018 includes $112,532 of director fees.

(3) The salary for Dr. Michael Gendreau in 2018 includes $57,150 of consulting fees.

(4) For 2019 and 2018, referenced amount is for employer contribution to 401K plan and for life insurance and other medical premiums.

(5) For 2019 and 2018, referenced amount is for life insurance and other medical premiums.

(6) For 2019, the bulk of such compensation consisted of $20,494 of automobile expenses, $35,568 of deposits to severance funds, $15,214 of gross-up of related tax, $10,419 of social security payments, and deposits of $17,568 to an education fund. 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.

(7) For 2019, the bulk of the other compensation consisted of $21,804 of automobile expenses, $28,206 deposits to severance funds, $16,943 of gross-up of related tax, $10,419 of social security payments and deposits of $13,945 to an education fund. 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.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning outstanding option awards as of December 31, 2019, 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)	80,000	40,000	5.32	04/10/2027
	05/01/17(2)	65,000	-	5.32	05/01/2027
	12/11/17(3)	253,333	126,667	6.70	12/11/2027
	06/28/18(4)	50,000	50,000	4.44	06/28/2025
	04/04/19(5)	-	125,000	7.64	04/04/2026
Walt A. Linscott, Esq., Chief Business Officer	10/23/17(6)	40,000	20,000	8.56	10/23/2027
	12/11/17 (7)	93,333	46,667	8.56	12/11/2027
	01/22/19(8)	-	90,000	7.628	01/22/2026
	09/13/19(9)	-	200,000	0.90	09/13/2026
Dr. Michael Gendreau, Chief Medical Officer	02/01/18(10)	145,833	104,167	6.10	02/01/2025
	01/22/19(11)	-	110,000	7.628	01/22/2026

(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 April 4, 2019, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending April 4, 2022.

(6) 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.

(7) 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.

(8) The options vest over a period of three years from January 22, 2019, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending January 22, 2022.

(9) The options vest over a period of three years from September 13, 2019, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending September 13, 2022.

(10) 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.

(11) The options vest over a period of three years from January 22, 2019, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending January 22, 2022.

Employment Agreements of 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.

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, which has been revised on April 4, 2019, he is currently entitled to receive a base salary at the annual rate of $540,000. 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. In addition, subject to Mr. Meckler's continued employment by us, 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 the board of directors) an aggregate of 605,000 options granted to Mr. Meckler that have not previously vested will become vested and exercisable immediately prior to such event.

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 February 17, 2020, our board of directors, upon recommendation of the compensation committee, approved subject to shareholder approval which is pending, a grant of 125,000 options to Mr. Meckler, 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 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 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. In addition, subject to Mr. Linscott's continued employment by us, 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 the board of directors) 490,000 options granted to Mr. Linscott that have not previously vested will become vested and exercisable immediately prior to such event.

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 February 17, 2020, our board of directors, upon recommendation of the compensation committee, approved the grant to Mr. Linscott of 90,000 options to purchase ordinary shares pursuant to the 2015 Plan. The foregoing options have an exercise price of $0.4287 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 currently entitled to receive a base salary at the annual rate of $150,000 and he is employed on a part-time basis (40% position). 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. In addition, subject to Dr. Gendreau's continued employment by us, 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 the board of directors) 340,000 options granted to Dr. Gendreau under his employment agreement that have not previously vested will become vested and exercisable immediately prior to such event.

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 February 17, 2020, our board of directors, upon recommendation of the compensation committee, approved the grant to Dr. Gendreau of 90,000 options to purchase ordinary shares pursuant to the 2015 Plan. The foregoing options have an exercise price of $0.4287 per share, a seven-year term and, subject to Mr. 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, June 2018 and April 2019. 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. Also, as required by the Companies Law, we intend to seek approval for a revised compensation policy at the annual general shareholders meeting which will take place in 2020.

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, 2019, 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	-	22,610	-	-	-	102,610
Gil Bianco (2)	48,067	-	4,014	-	-	-	52,082
Hila Karah	58,302	-	32,219	-	-	-	90,521
Issac Silberman (2)	43,122	-	4,014	-	-	-	47,136
Anthony J. Maddaluna	55,750	-	21,791	-	-	-	77,541
Roger J. Pomerantz	54,182	-	26,326	-	-	-	80,508
William B. Hayes	58,750	-	30,476	-	-	-	89,226

(1) Represents the share-based compensation expenses recorded in our consolidated financial statements for the year ended December 31, 2019, 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) Messrs. Bianco and Silberman departed from our board of directors effective December 2, 2019.

Our independent, non-employee directors' receive a yearly retainer of US$45,000 with an additional payment of up US$7,500 per each committee membership and up to $15,000 for chairing a committee in lieu of the committee membership payment membership. 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, 2019, the 2005 Plan has expired, however 82,675 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. All of these options were vested as of December 31, 2019, with a weighted average exercise price of NIS 40.6 per share and will expire in 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, another increase by 1,000,000 was approved by the general meeting of our shareholders on June 28, 2018, and another increase by 1,000,000 was approved by the general meeting of our shareholders on December 2, 2019. 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, 2019, outstanding awards under the 2015 Plan totaled 3,922,895 ordinary shares and an additional 1,459,238 awards were available for grant. Of the 3,922,895 outstanding options, options to purchase 1,767,416 ordinary shares were vested as of December 31, 2019, with a weighted average exercise price of $4.39 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, 2019.

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	3,922,895	$ 4.13	1,459,238
Equity compensation plans not approved by security holders-2005 Plan	82,675	NIS 40.6	-
Total	4,005,570		1,459,238

(1) The weighted average remaining term for the expiration of stock options under the 2005 Plan is 0.61 years. The weighted average remaining term for the expiration of stock options under the 2015 Plan is 6.05 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 29, 2020, unless indicated below, 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 52,973,580 ordinary shares outstanding as of February 29, 2020. 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 29, 2020 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.

	Shares Beneficially Owned	
Name of Beneficial Owner	**Ordinary Shares**	**Percentage**
Persons or entities holding 5% or more our outstanding ordinary shares		
Intracoastal Capital LLC (1)	5,287,761	9.9%
Sabby Volatility Warrant Master Fund, Ltd.(2)	4,030,000	7.6%
Armistice Capital LLC(3)	2,731,268	5.2%
Executive officers and directors		
Jeffrey A. Meckler	766,761(4)	1.4%
John W. Kozarich	376,239(5)	*
Nadav Navon	272,664(6)	*
Walt A. Linscott	192,500(7)	*
R. Michael Gendreau	212,500(8)	*
Nir Sassi	167,056(9)	*
Anthony J. Maddaluna	68,570(10)	*
Hila Karah	44,918(11)	*
Roger J. Pomerantz	13,333(12)	*
William B. Hayes	11,667(13)	-
All executive officers and directors as a group (10 persons)	2,126,208(14)	3.9%

* Less than 1%

(1) Based on information contained in a Schedule 13G filed with the SEC on February 10, 2020 jointly by Intracoastal Capital LLC, or Intracoastal, Mitchell P. Kopin and Daniel B. Asher. As of the close of business on February 10, 2020, each of Intracoastal, Mr. Kopin and Mr. Asher may have been deemed to have beneficial ownership of 5,287,761 ordinary shares, which consisted of (i) 4,360,800 ordinary shares held by Intracoastal and (ii) 926,961 ordinary shares issuable upon exercise of a warrant held by Intracoastal, or the Intracoastal Warrant. The foregoing excludes 4,073,039 ordinary shares issuable upon exercise of the Intracoastal Warrant because the Intracoastal Warrant contains a blocker provision under which the holder thereof does not have the right to exercise the Intracoastal Warrant to the extent (but only to the extent) that such exercise would result in beneficial ownership by the holder thereof, together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates, of more than 9.99% of the ordinary shares. Without such blocker provision, each of the Intracoastal, Mr. Kopin and Mr. Asher may have been deemed to have beneficial ownership of 9,360,800 ordinary shares. The address of Intracoastal and Mr. Kopin is 245 Palm Trail, Delray Beach, Florida 33483 and Mr. Asher is 111 W. Jackson Boulevard, Suite 2000, Chicago, Illinois 60604.

(2) Based on information contained in a Schedule 13G filed with the SEC on February 5, 2020 jointly by Sabby Volatility Warrant Master Fund, Ltd., or Sabby Warrant Master Fund, Sabby Management, LLC, or Sabby Management, and Hal Mintz. Sabby Management indirectly owns 4,030,000 shares of ordinary shares because it serves as the investment manager of Sabby Volatility Warrant Master Fund. The address of Sabby Volatility Warrant Master Fund is c/o Ogier Fiduciary Services (Cayman) Limited 89 Nexus Way, Camana Bay Grand Cayman KY1-9007 Cayman Islands and the address of Sabby Management is 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458.

(3) Based on information contained in a Schedule 13G filed with the SEC on February 7, 2020 jointly by Armistice Capital, LLC, Armistice Capital Master Fund and Steven Boyd.

(4) Consists of (i) 196,761 ordinary shares, and (ii) 570,000 ordinary shares issuable upon exercise of outstanding, of which 121,667 will vest within 60 days of February 29, 2020.

(5) Consists of (i) 151,761 ordinary shares, and (ii) 224,478 ordinary shares issuable upon exercise of outstanding options.

(6) Consists of (i) 19,456 ordinary shares, and (ii) 253,208 ordinary shares issuable upon exercise of outstanding options of which 25,969, will vest within 60 days of February 29, 2020.

(7) Consists of 192,500 ordinary shares issuable upon exercise of outstanding options of which 24,167 will vest within 60 days of February 29, 2020.

(8) Consists of 212,500 ordinary shares issuable upon exercise of outstanding options of which 9,167 will vest within 60 days of February 29, 2020.

(9) Consists of 167,056 ordinary shares issuable upon exercise of outstanding options of which 18,540 will vest within 60 days of February 29, 2020.

(10) Consists of (i) 53,570 ordinary shares, and (ii) 15,000 ordinary shares issuable upon exercise of outstanding options of which 1,667 will vest within 60 days of February 29, 2020.

(11) Consists of 44,918 ordinary shares issuable upon exercise of outstanding options of which 1,667 will vest within 60 days of February 29, 2020.

(12) Consists of 13,333 ordinary shares issuable upon exercise of outstanding options of which 1,667 will vest within 60 days of February 29, 2020.

(13) Consists of 11,667 ordinary shares issuable upon exercise of outstanding options of which 1,667 will vest within 60 days of February 29, 2020.

(14) Consists of (i) 421,548 ordinary shares, and (ii) 1,704,660 ordinary shares issuable upon exercise of outstanding options, of which 206,178 will vest within 60 days of days of February 29, 2020.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Certain Relationships and Related Transactions

During years ended December 31, 2019 and 2018, 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 served as a consultant (on a 50% basis) until June 11, 2019. 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.

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.

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, 2019 and 2018, 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 2019 and 2018.

	2019	2018
	(US$ in thousands)	(US$ in thousands)
Audit Fees[1]	212	186
Audit-Related fees [2]	-	23
Tax Fees [3]	-	20
All Other Fees	-	-
Total	212	229

(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 2018 and 2019.

(2) Audit-related fees would be 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 2019 and 2018 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 (incorporated herein by reference to Exhibit 3.4 to the Company's Annual Report on Form 10-K filed with the SEC on February 27, 2019)
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)
4.2	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Report on Form 8-K filed with the SEC on February 3, 2020)
4.3	Form of Pre-Funded Warrant (incorporated herein by reference to Exhibit 4.2 to the Company's Report on Form 8-K filed with the SEC on February 3, 2020)
4.4*	Description of Securities Registered under Section 12
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 Exhibit 10.1 to the Company's Report on Form 8-K filed with the SEC on April 5, 2019)
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	Form of Intec Pharma Ltd. Grant Letter – Section 102*
10.9	Form of Intec Pharma Ltd. 2015 Equity Incentive Plan Notice Of Non-Qualified Stock Option Award*
10.10	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)
10.11+	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	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)
10.15	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)
10.16†	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)
10.17+	Employment Agreement dated October 23, 2017 between Intec Pharma, Inc. and Walt Addison Linscott, Esq. (incorporated herein by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K filed with the SEC on February 27, 2019)
10.18+	Employment Agreement dated February 1, 2018 between Intec Pharma, Inc. and Michael Gendreau, MD (incorporated herein by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K filed with the SEC on February 27, 2019)
10.19†	Process Development Agreement dated as of December 17, 2018 by and between Intec Pharma Ltd. and LTS LOHMANN Therapie-Systeme AG (incorporated herein by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K filed with the SEC on February 27, 2019)
10.20	Sales Agreement between Intec Pharma Ltd. and Cowen and Company, LLC dated March 1, 2019 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 12, 2019)

10.21	Ordinary Shares Purchase Agreement, dated December 2, 2019 between Intec Pharma Ltd. and Aspire Capital Fund, LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed with the SEC on December 3, 2019)
10.22	Registration Rights Agreement, dated December 2, 2019, between Intec Pharma Ltd. and Aspire Capital Fund, LLC (incorporated herein by reference to Exhibit 10.2 to the Company's Report on Form 8-K filed with the SEC on December 3, 2019)
10.23	Underwriting Agreement, dated January 30, 2020, by and between the Company and H.C. Wainwright & Co., LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 3, 2020)
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.

Certain agreements filed as exhibits to this Annual Report contain representations and warranties that the parties thereto made to each other. These representations and warranties have been made solely for the benefit of the other parties to such agreements and may have been qualified by certain information that has been disclosed to the other parties to such agreements and that may not be reflected in such agreements. In addition, these representations and warranties may be intended as a way of allocating risks among parties if the statements contained therein prove to be incorrect, rather than as actual statements of fact. Accordingly, there can be no reliance on any such representations and warranties as characterizations of the actual state of facts. Moreover, information concerning the subject matter of any such representations and warranties may have changed since the date of such agreements.

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: March 13, 2020

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)	March 13, 2020
/s/ Nir Sassi Nir Sassi	Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2020
/s/ Dr. John Kozarich Dr. John Kozarich	Chairman of the Board of Directors	March 13, 2020
/s/ Hila Karah Hila Karah	Director	March 13, 2020
/s/ Anthony J. Maddaluna Anthony J. Maddaluna	Director	March 13, 2020
/s/ Dr. Roger J. Pomerantz Dr. Roger J. Pomerantz	Director	March 13, 2020
/s/ William B. Hayes William B. Hayes	Director	March 13, 2020

Exhibit 4.4

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES
EXCHANGE ACT OF 1934

The descriptions of the securities contained herein summarize the material terms and provisions of the ordinary shares of Intec Pharma Ltd., registered under Section 12 of the Securities Exchange Act of 1934.

General

The following are summaries of material provisions of our articles of association and the Israeli Companies Law 5759-1999, or the Companies Law, insofar as they relate to the material terms of our ordinary shares.

As of December 31, 2019, our authorized share capital consists of 100,000,000 ordinary shares, no par value, of which 35,892,209 ordinary shares were issued and outstanding. All of our outstanding ordinary shares are validly issued, fully paid and non-assessable. Our ordinary shares are not redeemable and do not have any preemptive rights.

Holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders at a shareholder meeting. 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, subject to the special approval requirements for external directors (if applicable). Shareholders may vote at shareholder meetings either in person, by proxy or by written ballot. The Companies Law does not allow public companies to adopt shareholder resolutions by means of written consent in lieu of a shareholder meeting. The board of directors shall determine and provide a record date for each shareholders meeting and all shareholders at such record date may vote. Unless stipulated differently in the Companies Law or in our articles of association, all shareholders' resolutions shall be approved by a simple majority vote. An amendment to our articles of association requires the prior approval of a simple majority of our shares represented and voting at a general meeting and of the holders of a class of shares whose rights are being affected. Our number with the Israeli Registrar of Companies is 513022780. Our purpose is set forth in Section 2 of our articles of association and as to engage in any legal business.

Transfer of Shares

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

Exercise of Power by the Board

Pursuant to the Companies Law and our articles of association, our board of directors may exercise all powers and take all actions that are not required under law or under our articles of association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

Changes in Share Capital

Our articles of association enable us to increase or reduce our share capital. Any such change is subject to the provisions of the Companies Law and must be approved by a resolution duly passed by our shareholders at a general or special meeting by voting on such change in the capital. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings and profits and an issuance of shares for less than their nominal value, require a resolution of our board of directors and court approval.

Dividends

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 financial statements, provided that the date of the 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.

Shareholder Meetings

Under the Companies Law, we are required to hold an annual general meeting of our shareholders once in every calendar year and no later than 15 months following the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to as special meetings. Our board of directors may call special meetings whenever it deems fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Companies Law and our articles of association provide that our board of directors is required to convene a special meeting upon the written request of (i) any two of our directors or one quarter of the directors then in office or (ii) one or more shareholders holding, in the aggregate, (a) 5% of our issued share capital and 1% of our outstanding voting power or (b) 5% of our outstanding voting power.

Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors. Furthermore, the Companies Law and our articles of association require that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- amendments to our articles of association;
- appointment or termination of our auditors;
- appointment and dismissal of external directors (if applicable);
- approval of acts and transactions requiring general meeting approval pursuant to the Companies Law;
- director compensation and compensation of the principal executive officer (subject to certain exceptions);
- increases or reductions of our authorized share capital;
- a merger;
- the exercise of our board of directors' powers by a general meeting, if our board of directors is unable to exercise its powers and the exercise of any of its powers is required for our proper management; and
- authorization of the chairman of the board of directors or his relative to act as the company's chief executive officer or act with such authority; or authorization of the company's chief executive officer or his relative to act as the chairman of the board of directors or act with such authority.

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

The Companies Law does not allow shareholders of publicly traded companies to approve corporate matters by written consent.

Pursuant to our articles of association, holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting.

Quorum

The quorum required for our general meetings of shareholders consists of at least two shareholders present in person, by proxy or written ballot who hold or represent between them at least thirty three and one third percent ($33^{1/3}$%) of the total outstanding voting rights, within half an hour from the appointed time.

A meeting adjourned for lack of a quorum is adjourned to the same day in the following week at the same time and place or on a later date if so specified in the summons or notice of the meeting. At the reconvened meeting, the quorum required consists of at least two shareholders present in person, by proxy or written ballot who hold or represent between them at least thirty three and one third percent ($33^{1/3}$%) of the total outstanding voting rights, within half an hour from the appointed time.

Resolutions

Our articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by applicable law.

Under the Companies Law, a shareholder of a public company may vote in a meeting and in a class meeting by means of a written ballot in which the shareholder indicates how he or she votes on resolutions relating to the following matters:

- an appointment or removal of directors;
- an approval of transactions with office holders or interested or related parties, that require shareholder approval;
- an approval of a merger;
- authorizing the chairman of the board of directors or his relative to act as the company's chief executive officer or act with such authority; or authorize the company's chief executive officer or his relative to act as the chairman of the board of directors or act with such authority;
- any other matter that is determined in the articles of association to be voted on by way of a written ballot. Our articles of association do not stipulate any additional matters; and
- other matters which may be prescribed by Israel's Minister of Justice.

The Companies Law provides that a shareholder, in exercising his or her rights and performing his or her obligations toward the company and its other shareholders, must act in good faith and in a customary manner, and avoid abusing his or her power. This is required when voting at general meetings on matters such as changes to the articles of association, increasing the company's authorized share capital, mergers and approval of certain interested or related party transactions. A shareholder also has a general duty to refrain from depriving any other shareholder of its rights as a shareholder. In addition, any controlling shareholder, any shareholder who knows that its vote can determine the outcome of a shareholder's vote and any shareholder who, under such company's articles of association, can appoint or prevent the appointment of an office holder or has other power towards the company, is required to act with fairness towards the company. The Companies Law does not describe the substance of this duty except that the remedies generally available upon a breach of contract will also apply to a breach of the duty to act with fairness, and, to the best of our knowledge, we believe there is no binding case law that addresses this subject directly.

Under the Companies Law, unless provided otherwise in a company's articles of association, a resolution at a shareholders meeting requires approval by a simple majority of the voting rights represented at the meeting, in person, by proxy or written ballot, and voting on the resolution. Generally, a resolution for the voluntary winding up of the company requires the approval of holders of 75% of the voting rights represented at the meeting, in person, by proxy or by written ballot and voting on the resolution.

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

Access to Corporate Records

Under the Companies Law, all shareholders of a company generally have the right to review minutes of the company's general meetings, its shareholders register and principal shareholders register, its articles of association, its financial statements and any document it is required by law to file publicly with the Israeli Companies Registrar and the Israeli Securities Authority, or ISA. Any of our shareholders may request access to review any document in our possession that relates to any action or transaction with a related party, interested party or office holder that requires shareholder approval under the Companies Law. We may deny a request to review a document if we determine that the request was not made in good faith, that the document contains a commercial secret or a patent or that the document's disclosure may otherwise prejudice our interests.

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares or a class of shares of an Israeli public company and who would, as a result, own more than 90% of the target company's issued and outstanding share capital or of a certain class of its shares, is required by the Companies Law to make a full tender offer (as defined in the Companies Law) to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company or class of shares. If either (i) the shareholders who do not accept the offer hold, in the aggregate, less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, or (ii) the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class, then all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a shareholder that had its shares so transferred, whether or not it accepted the tender offer (unless otherwise provided in the offering memorandum), may, within six months from the date of acceptance of the tender offer, petition the court to determine that the tender offer was for less than fair value and that the fair value should be paid as determined by the court. If either (i) the shareholders who did not accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class of shares or the shareholders who accept the offer constitute less than a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (ii) the shareholders who did not accept the tender offer hold 2% or more of the issued and outstanding share capital of the company (or of the applicable class), the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer. Shares purchased not in accordance with those provisions shall become "dormant shares" and shall not grant the purchaser any rights so long as they are held by the purchaser.

Special Tender Offer

According to the Companies Law, an acquisition pursuant to which a purchaser shall hold a "controlling stake", that is defined as 25% or more of the voting rights if no other shareholder holds a controlling stake, or an acquisition pursuant to which such purchaser shall hold more than 45% of the voting rights of the company if no other shareholder owns more than 45% of the voting rights, may not be performed by way of market accumulation, but only by way of a special tender offer (as defined in the Companies Law) made to all of the company's shareholders on a pro rata basis. A special tender offer may not be consummated unless a majority of the shareholders who announced their stand on such offer have accepted it (in counting the total votes of such shareholders, shares held by the controlling shareholders, shareholders who have a personal interest in the offer, shareholders who own 25% or more of the voting rights in the company, relatives or representatives of any of the above or the bidder and corporations under their control, shall not be taken into account). A shareholder may be free to object to such an offer without such objection being deemed as a waiver of his right to sell its respective shares if the transaction is approved by a majority of the company's shareholders despite his objection. Shares purchased not in accordance with those provisions shall become "dormant shares" and shall not grant the purchaser any rights so long as they are held by the purchaser. If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Under regulations enacted pursuant to the Companies Law, the above special tender offer requirements may not apply to companies whose shares are listed for trading on a foreign stock exchange if, among other things, the relevant foreign laws or the rules of the stock exchange include provisions limiting the percentage of control which may be acquired or that the purchaser is required to make a tender offer to the public. However, we believe the ISA's current opinion is that such leniency does not apply with respect to companies whose shares are listed for trading on stock exchanges in the United States, including the Nasdaq Capital Market.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, a majority of each party's shares voted on the proposed merger at a shareholders' meeting called with at least 35 days' prior notice.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person who holds 25% or more of the outstanding shares or the right to appoint 25% or more of the directors of the other party, vote against the merger. If the transaction would have been approved but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value of the parties to the merger and the consideration offered to the shareholders.

Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of any of the parties to the merger, and may further give instructions to secure the rights of creditors.

In addition, a merger may not be completed unless at least 50 days have passed from the date that a proposal for approval of the merger was filed by each party with the Israeli Registrar of Companies and 30 days have passed from the date the merger was approved by the shareholders of each party.

Antitakeover Measures

The Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights, distributions or other matters and shares having preemptive rights. As of the date of this prospectus, we do not have any authorized or issued shares other than our ordinary shares. In the future, if we do create and issue a class of shares other than ordinary shares, such class of shares, depending on the specific rights that may be attached to them, may delay or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization of a new class of shares will require an amendment to our articles of association which requires the prior approval of the holders of a majority of our shares at a general meeting.

The Nasdaq Capital Market

Our ordinary shares are listed on the Nasdaq Capital Market and trade under the symbol "NTEC."

Transfer agent

The transfer agent of our ordinary shares is VStock Transfer, LLC.

Exhibit 10.8

INTEC PHARMA LTD.

Date: [____]

Grant Letter No: [____]

GRANT LETTER – SECTION 102

To the Participant **[_____].**

1. You are hereby notified that the shareholders of **Intec Pharma Ltd.** (the "**Company**") have approved, at the annual general meeting of the shareholders which was held on [____], that you shall be granted annually (provided that you are still in office as a director) with an option to purchase [____] ordinary shares of the Company, having no par value per share. In accordance with the foregoing approval, the options shall have an exercise price per share of US $[__], reflecting the average price of the Company's ordinary shares on Nasdaq in the last 30 days prior to the anniversary date of your previous grant date (collectively, the "**Option**").

2. The Option, shares resulting from its exercise (the "**Shares**") and any additional rights including cash dividend that shall be distributed to you in connection with the Option (the "**Additional Rights**"), shall be granted on your behalf to the trustee, "Altshuler Shaham Trusts Ltd" (the "**Trustee**").

3. The Option, Shares and Additional Rights shall be granted on your behalf to the Trustee under the provisions of the Capital Gains Tax Track Through a Trustee, and will be held by the Trustee for the period stated in Section 102 of the Income Tax Ordinance, 1961 and the Income Tax Regulations (Tax Relieves for Issuance of Shares to Employees), 2003 promulgated thereunder ("**Section 102**").

4. The Option, Shares and Additional Rights are granted on your behalf to the Trustee according to the provisions of Section 102, the 2015 Equity Incentive Plan, adopted by the Company (the "**Plan**") and the Trust Agreement signed between the Company and the Trustee attached herewith, as **Exhibit A** and made a part of this Grant Letter. Defined terms not explicitly defined in this Grant Letter but defined in the Plan shall have the meaning ascribed to them in the Plan.

5. Unless otherwise determined by the Administrator, the Option granted to you on this date shall, subject to your continued engagement as a director of the Company or Affiliate, become vested and exercisable in accordance with the vesting schedule detailed below. The commencement date of your vesting schedule is [____] (the "**Vesting Commencement Date**"). The Option will become vested and exercisable following the Vesting Commencement Date as follows:

(i) 1/3 of the shares underlying the Option shall become vested and exercisable on the first anniversary of the Vesting Commencement Date;

(ii) 2/3 of the shares underlying the Option shall become vested and exercisable in eight (8) equal quarterly installments thereafter.

(iii) The options will accelerate upon the occurrence of a "Merger Transaction" (as such term is defined in the 2015 Equity Incentive Plan) or the entry into a "Material Agreement" (as shall be defined by the Compensation Committee and the Board of Directors of the Company).

6. Unless otherwise expired earlier or extended in accordance with the Plan, the right to exercise the Options shall expire on the seventh (7^{th}) anniversary of this date.

7. For the avoidance of doubt, all tax consequences (including any withholding tax) under any applicable law which may arise from the grant of the Option, from the exercise thereof or from the holding or sale of the Shares deliverable upon exercise (or other securities issued in connection of the Option) shall be borne solely by you.

8. The Option is granted to you on condition that you sign the Approval of the Participant as detailed below.

Sincerely,

Intec Pharma Ltd.

By: _____
Name: _____
Title: _____

Grant Letter No: 2019-[_]

APPROVAL OF THE PARTICIPANT (SECTION 102):

I hereby agree that the Option and Additional Rights granted to me, shall be granted to the Trustee under provisions of the Capital Gains Tax Track Through a Trustee and shall be held by the Trustee for the period stated in Section 102 and in accordance with the provisions of the Trust Agreement, or for a shorter period if an approval is received from the Israeli Tax Authorities.

I am aware of the fact that upon termination of my engagement as a director of the Company or its Affiliate(s), I shall not have a right to the Option, except as specified in the Plan.

I hereby confirm that:

1. I have read the Plan and I understand and accept its terms and conditions. I am aware of the fact that the Company agrees to grant me the Option based on my confirmation.

2. I understand the provisions of Section 102 and the applicable tax track of this grant of Option.

3. I agree to the terms and conditions of the Trust Agreement.

4. Subject to the provisions of Section 102, I confirm that I shall not sell nor transfer the Option, Shares or Additional Rights from the Trustee until the end of the Holding Period.

5. If I shall sell or withdraw the Shares from the Trust before the end of the Holding Period as defined in Section 102 (the "**Violation**"), either (A) I shall reimburse the Company within three (3) days of its demand for the "employer" portion of the payment by the Company or an Affiliate to the National Insurance Institute plus linkage and interest in accordance with the law, as well as any other expense that the Company shall bear as a result of the said Violation (all such amounts defined as the "**Payment**"); or (B) I agree that the Company may, in its sole discretion, deduct such amounts directly from any monies to be paid to me as a result of my disposition of the Shares.

6. I understand that this grant of Option is conditioned upon the receipt of all required approvals from the Israeli Tax Authorities.

7. I hereby confirm that I read this letter thoroughly, received all the clarifications and explanations I requested, I understand the contents of this letter and the obligations I undertake in signing it.

Name of Participant	**Signature**	**Date**

Exhibit A

מכתב נאמנות

שנחתם בתל אביב ביום 7 בחודש ינואר 2016

בין:

חברת מיטב דש נאמנויות בע"מ
רחוב ששת הימים 30, בני ברק
(להלן: "**הנאמן**")

מצד אחד

לבין:

חברת אינטק פארמה בע"מ
ח.פ. 513022780
(להלן: "**החברה המקצה**")

מצד שני

הואיל וביום 6 בינואר, 2016 אימצה החברה המקצה תוכנית הקצאת מניות לעובדים, כמשמעותה בסעיף 102 לפקודה (להלן: "**התוכנית**");

והואיל ועל פי התוכנית תקצה החברה המקצה מדי פעם בפעם מניות או זכויות למניות לעובדים בהקצאת מניות באמצעות נאמן;

והואיל ועל פי התוכנית יוקצו כל המניות בהקצאה לנאמן כדי שיחזיק אותן בנאמנות עד תום התקופה, כאמור בפקודה, בכללי מס הכנסה (הקלות מס בהקצאת מניות לעובדים), התשס"ג – 2003 (להלן: "**הכללים**"), בתכנית ובכתב נאמנות זה;

והואיל והחברה בחרה בחברת מיטב דש נאמנויות בע"מ, לשמש כנאמן לצורך תוכנית ההקצאה האמורה והיא הביעה את הסכמתה לשמש כנאמן בעבור כל החברות המעבידות ועובדיהן;

לפיכך הוסכם על הצדדים, כדלקמן:

1. המבוא לכתב נאמנות זה מהווה חלק בלתי נפרד ממנו.

2. על פי התוכנית לא יוקצו מניות החברה המקצה לעובדי החברה המעבידה אלא יוקצו על שם הנאמן ויוחזקו בידיו עד לתום התקופה, כהגדרתה בסעיף 102 לפקודה.

3. לפני ששולם המס החל כאמור בסעיף 7 לכללים, המניות לא יהיו ניתנות להעברה, המחאה, משכון, עיקול, או שיעבוד אחר מרצון ולא יינתן בשלהן ייפוי כוח או כתב העברה בין אם תוקפם מיידי ובין אם תוקפם בתאריך עתידי, למעט העברה מכוח צוואה או על פי דין;
הועברו המניות מכוח צוואה או על פי דין כאמור, יחולו הוראות סעיף 102 והוראות הכללים על יורשיו או נעברים של העובד.

4. לאחר תום התקופה יהיה כל עובד רשאי בכל עת לדרוש מהנאמן להעביר על שמו את המניות שהוא זכאי להן, ובלבד שהנאמן לא יעביר את המניות כאמור אלא לאחר ששולם המס החל לפי סעיף 102 לפקודה ולפי הכללים (להלן: "**המס החל**") ובידי הנאמן אישור לכך מפקיד השומה.

5. אם על פי תנאי התכנית יוענקו לעובד זכויות לרכישת מניות או שיוקצו לו בשל המניות מניות הטבה, יוקצו הזכויות או מניות ההטבה על שם הנאמן. העובד יהיה זכאי להורות לנאמן לממש את הזכויות או את מניות ההטבה לאחר תום התקופה כקבוע בתוכנית. המניות נשוא הזכויות יוקצו לנאמן בהתאם לאמור בסעיף 2 לכללים ויחולו עליהם הוראות התוכנית, לרבות בחירת מסלול המיסוי והוראות כתב התחייבות זה, ואולם פרק הזמן עד תום התקופה יימנה מיום הקצאת המניות שבשלן הוקצו הזכויות או מניות ההטבה.

6. החברה המקצה מתחייבת כלפי הנאמן כי לא תקצה מניות לעובדי החברה המעבידה במסגרת תוכנית הקצאה, אם לא הציהיר העובד כי ידועים לו הוראות סעיף 102 לפקודה ומסלול המס החל עליו, וכן על הסכמתו בכתב לאמור בכתב נאמנות זה ועל התחייבותו שלא לממש את המניות לפני תום התקופה, כהגדרתה בסעיף 102 לפקודה.

Exhibit 10.9

INTEC PHARMA LTD. 2015 EQUITY INCENTIVE PLAN

NOTICE OF NON-QUALIFIED STOCK OPTION AWARD

Participant's Name and Address: [____], of [_____], USA.

You (the "Participant") have been granted an option to purchase ordinary shares, no par value of Intec Pharma Ltd. (the "Company"), subject to the terms and conditions of this Notice of Non-Qualified Stock Option Award (the "Notice") and the Intec Pharma Ltd. 2015 Equity Incentive Plan, as amended from time to time (the "Plan"). Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Notice.

Date of Award	[_____]
Vesting Commencement Date	[_____]
Exercise Price per Share	$[____], the average price of the Company's ordinary shares on NASDAQ Capital Market in the last 30 days prior to the Date of the Award, which is equal to or greater than the fair market value of a Share (as determined in accordance with Section 409A of the U.S. Internal Revenue Code of 1986, as amended).
Total Number of Shares Subject to the Option (the "Shares")	[____]
Total Exercise Price	$[_____]
Type of Option:	Non-Qualified Stock Option
Expiration Date:	Seven Year Anniversary of Date of Award

Vesting Schedule:

Subject to the Participant's continued status as director of the Company, and other limitations set forth in this Notice and the Plan, the Option may be exercised, in whole or in part, in accordance with the following schedule:

1/3 of the Shares subject to the Option shall vest on the first anniversary date of the Vesting Commencement Date, and the additional 2/3 of the Shares subject to the Option shall vest in eight equal quarterly installments thereafter over a period of two years, provided that the Participant continues to serve as director of the Company.

The options will accelerate upon the occurrence of a "Merger Transaction" (as such term is defined in the 2015 Equity Incentive Plan) or the entry into a "Material Agreement" (as shall be defined by the Compensation Committee and the Board of Directors of the Company)

IN WITNESS WHEREOF, the Company and the Participant have executed this Notice and agree that the Option is to be governed by the terms and conditions of this Notice and the Plan.

Intec Pharma Ltd.

By: _____

Title: _____

THE PARTICIPANT ACKNOWLEDGES AND AGREES THAT THE OPTION SHALL VEST, IF AT ALL, ONLY DURING THE PERIOD OF THE PARTICIPANT'S CONTINUOUS STATUS AS A DIRECTOR OF THE COMPANY. THE PARTICIPANT FURTHER ACKNOWLEDGES AND AGREES THAT NOTHING IN THIS NOTICE OR THE PLAN SHALL CONFER UPON THE PARTICIPANT ANY RIGHT WITH RESPECT TO FUTURE AWARDS OR CONTINUATION OF THE PARTICIPANT'S STATUS AS A DIRECTOR OF THE COMPANY OR ANY OF ITS AFFILIATES, NOR SHALL IT INTERFERE IN ANY WAY WITH THE PARTICIPANT'S RIGHT OR THE RIGHT OF THE COMPANY OR ANY OF ITS AFFILIATES TO TERMINATE THE PARTICIPANT'S STATUS AS A DIRECTOR.

The Option shall be exercisable during its term in accordance with the Vesting Schedule set out in this Notice and with the applicable provisions of the Plan. The Participant shall be subject to reasonable limitations on the number of requested exercises during any monthly or weekly period as determined by the Administrator. In no event shall the Company issue fractional Shares.

The Participant may incur tax liability as a result of the Participant's purchase or disposition of the Shares. THE PARTICIPANT IS ADVISED TO CONSULT WITH A TAX ADVISOR WITH RESPECT TO THE TAX CONSEQUENCES OF RECEIVING OR EXERCISING THE OPTION IN LIGHT OF THE PARTICIPANT'S PARTICULAR CIRCUMSTANCES

The Participant acknowledges receipt of a copy of the Plan and this Notice, and represents that he or she is familiar with the terms and provisions thereof, and hereby accepts the Option subject to all of the terms and provisions hereof and thereof. The Participant has reviewed this Notice and the Plan in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Notice, and fully understands all provisions of this Notice and the Plan. The Participant hereby agrees that all questions of interpretation and administration relating to this Notice and the Plan shall be resolved by the Administrator in accordance with Section 5 of the Plan.

The Company and the Participant agree that any suit, action, or proceeding arising out of or relating to the Notice and/or the Plan shall be brought in the competent Court located in Tel-Aviv, Israel, and that the parties shall submit to the jurisdiction of such court. The parties irrevocably waive, to the fullest extent permitted by law, any objection the party may have to the laying of venue for any such suit, action or proceeding brought in such court. If any one or more provisions of this Notice and/or the Plan shall for any reason be held invalid or unenforceable, it is the specific intent of the parties that such provisions shall be modified to the minimum extent necessary to make it or its application valid and enforceable. The Participant further agrees to notify the Company upon any change in the residence address indicated in this Notice.

This Notice and the Plan, pertaining to this Option constitute the entire agreement of the parties with respect to the subject matter hereof and supersede in their entirety all prior undertakings and agreements of the Company and the Participant with respect to the subject matter hereof, and may not be modified adversely to the Participant's interest except by means of a writing signed by the Company and the Participant. Nothing in this Notice and/or the Plan (except as expressly provided therein) is intended to confer any rights or remedies on any persons other than the parties. This Notice and the Plan are to be construed in accordance with and governed by the internal laws of the State of Israel without giving effect to any choice of law rule that would cause the application of the laws of any jurisdiction other than the State of Israel to the rights and duties of the parties. Should any provision of this Notice and/or the Plan be determined to be illegal or unenforceable, such provision shall be enforced to the fullest extent allowed by law and the other provisions shall nevertheless remain effective and shall remain enforceable.

Dated: _____ Signed: _____

Participant

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-3 (No. 333-230016) and S-8 (No. 333-227027, No. 333-222217, No. 333-209700 and No. 333-212801) of Intec Pharma Ltd. of our report dated March 13, 2020 relating to the financial statements, which appears in this Form 10-K.

Tel-Aviv, Israel
March 13, 2020

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

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

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, 2019 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: March 13, 2020

/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, 2019 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: March 13, 2020

/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, 2019 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: March 13, 2020

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, 2019 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: March 13, 2020