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

FORM 20-F

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

Or

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2015

Or

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

Or

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

Commission File No. 001-37521

INTEC PHARMA LTD.

(Exact name of Registrant as specified in its charter)

N/A
(Translation of Registrant's name into English)

State of Israel
(Jurisdiction of incorporation or organization)

12 Hartom Street, Har Hotzvim, Jerusalem 9777512, Israel
(Address of principal executive offices)

Zeev Weiss
Chief Executive Officer
12 Hartom Street, Har Hotzvim
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Tel: (+972) (2) 586-4657
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class	*Name of each exchange on which registered*
Ordinary shares, no par value	**Nasdaq Capital Market**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report. 11,448,191

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such a shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§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, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one): Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

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

U.S. GAAP ☐	**International Financial Reporting Standards as issued by the International Accounting Standards Board ☒**	**Other ☐**

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the Registrant has elected to follow: Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☐ No ☐

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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 20-F, or our annual report, are to Intec Pharma Ltd., 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 financial statements are prepared and presented in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. 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.

Our functional and reporting currency for the years ended December 31, 2014 and 2015 was the New Israeli Shekel. Effective January 1, 2016, our reporting and functional currency is the U.S. dollar as a result of the significant increase in our expenses denominated in U.S. dollars, primarily due to expenses associated with our Phase III clinical trial. 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 on Form 20-F 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.
- Because of our limited operating history, we may not be able to successfully operate our business or execute our business plan.
- We face continuous technological change, and developments by competitors may render our products or technologies obsolete or non-competitive. If our new or existing product candidates are rendered obsolete or non-competitive, our marketing and sales will suffer and we may never be profitable.
- We license our core technology on an exclusive basis from Yissum (Hebrew University), and we could lose our rights to this license if a dispute with Yissum arises or if we fail to comply with the financial and other terms of the license.
- If we fail to adequately protect, enforce or secure rights to the patents which were licensed to us or any patents we may own in the future, the value of our intellectual property rights would diminish and our business and competitive position would suffer.

- Our product candidates are at various stages of preclinical and clinical development and may never be commercialized.
- We cannot be certain that the results of our potential Phase III clinical trials, even if all endpoints are met, will support regulatory approval of any of our product candidates for any indication.
- Our product candidates are subject to extensive regulation and are at various stages of regulatory development and may never obtain regulatory approval.
- We are subject to anti-kickback laws and regulations. Our failure to comply with these laws and regulations could have adverse consequences to us.
- Potential political, economic and military instability in the State of Israel, where our senior management, our head executive office, research and development, and manufacturing facilities are located, may adversely affect our results of operations.
- If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our shares, our share price and trading volume could be negatively impacted.

We believe these forward-looking statements are reasonable; however, these statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in this annual report in greater detail under the heading "Risk Factors" and elsewhere in this annual report. Given these uncertainties, you should not rely upon forward-looking statements as predictions of future events.

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

EXPLANATORY NOTE

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

PART I

ITEM 1. Identity of Directors, Senior Management and Advisers.

Not applicable.

ITEM 2. Offer Statistics and Expected Timetable.

Not applicable.

ITEM 3. Key Information.

A. Selected Financial Data.

The following tables summarize our financial data. We have derived the selected statements of comprehensive loss data for the years ended December 31, 2013, 2014 and 2015 and the statements of financial position as of December 31, 2013, 2014 and 2015 from our audited financial statements included elsewhere in this annual report. The following selected financial data for our company should be read in conjunction with the financial information, "Item 5. Operating and Financial Review and Prospects" and other information provided elsewhere in this Annual Report on Form 20-F and our financial statements and related notes. The selected financial data in this section is not intended to replace the financial statements and is qualified in its entirety thereby.

Our financial statements included in this annual report were prepared in accordance with IFRS, as issued by the IASB, and reported in NIS.

The following selected financial data for the periods and as of the dates indicated are qualified by reference to and should be read in conjunction with our financial statements and related notes and "Operating and Financial Review and Prospects," both of which are included elsewhere in this annual report.

	Year ended December 31,			
	2013	2014	2015	2015
	NIS in thousands			Convenience translation into USD in thousands
Statements of comprehensive loss data:[1]				
Research and development expenses	17,410	17,740	29,257	7,498
Less-participation in research and development expenses	(8,393)	(5,544)	(10,556)	(2,705)
Research and development expenses, net	9,017	12,196	18,701	4,793
General and administrative expenses	9,633	9,332	10,828	2,775
Other gains, net	(474)	(836)	(76)	(19)
Operating loss	18,176	20,692	29,453	7,549
Financial income	(434)	(1,136)	(2,458)	(630)
Financial expenses	648	812	889	228
Financial expenses (income), net	214	(324)	(1,569)	(402)
Loss and comprehensive loss	18,390	20,368	27,884	7,147

	NIS			USD
Basic and diluted loss per ordinary share	4.25	4.22	3.58	0.92
Number of ordinary shares used in computing loss per ordinary share (in thousands)	4,322	4,825	7,791	7,791

	December 31,			
	2013	2014	2015	2015
	NIS in thousands			Convenience translation into USD in thousands
Statement of financial position:				
Cash and cash equivalents	11,763	22,287	92,277	23,649
Short term bank deposits			19,510	5,000
Financial assets at fair value through profit or loss	17,887	7,820	7,897	2,024
Restricted bank deposits	260	292	240	62
Other receivables	2,583	1,120	9,211	2,361
Property and equipment	14,991	17,101	15,906	4,076
Total assets	47,484	48,620	145,041	37,172
Accounts payable and accruals	4,923	7,219	5,125	1,315
Derivative financial instruments	10,298	4,528	1,277	327
Total liabilities	15,221	11,747	6,402	1,642
Total equity	32,263	36,873	138,639	35,530

We prepare our financial statements in NIS. This annual report contains conversions of NIS amounts into U.S. dollars at specific rates solely for the convenience of the reader. Unless otherwise noted, for the purposes of annual financial data, all conversions from NIS to U.S. dollars and from U.S. dollars to NIS were made at a rate of 3.902 NIS to $1.00 U.S. dollar, the daily representative rate in effect as of December 31, 2015. No representation is made that the NIS amounts referred to in this annual report could have been or could be converted into U.S. dollars at any particular rate or at all.

As of December 31, 2015, the daily representative rate of NIS per U.S. dollars was 3.902. The following table sets forth information regarding the exchange rates of NIS per U.S. dollars for the periods indicated. Average rates are calculated by using the daily representative rates as reported by the Bank of Israel on the last day of each month during the periods presented.

	NIS per U.S. $			
Year Ended December 31,	**High**	**Low**	**Average**	**Period End**
2015	4.053	3.761	3.884	3.902
2014	3.994	3.402	3.577	3.889
2013	3.791	3.471	3.609	3.471

	NIS per U.S. $			
Month Ended	**High**	**Low**	**Average**	**Period End**
February 2016	3.964	3.871	3.908	3.910
January 2016	3.983	3.913	3.951	3.951
December 2015	3.905	3.855	3.881	3.902
November 2015	3.921	3.868	3.889	3.877
October 2015	3.923	3.816	3.863	3.867
September 2015	3.949	3.863	3.913	3.923

B. Capitalization and Indebtedness.

Not applicable.

C. Reasons for the Offer and Use of Proceeds.

Not applicable.

D. Risk Factors.

Risks Related to Our Company and Its Business

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 on Form 20-F, including the audited financial statements and the related 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.

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

We are a clinical stage biopharmaceutical company that was incorporated in 2000. Since our incorporation, we have primarily focused our efforts on research and development and clinical trials. Our two most advanced therapeutic candidates are in clinical 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 will increase substantially in the foreseeable future as we:

- initiate and manage preclinical development and clinical trials for our current and any new product candidates;
- prepare 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, 2013, 2014, and 2015, we had net losses of NIS 18.4 million, NIS 20.4 million and NIS 27.9 million, respectively, and we expect such losses to continue for the foreseeable future. As a result, we will ultimately need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. If our product candidates fail in clinical trials or do not gain regulatory clearance or approval, or if our product candidates do not achieve market acceptance, we may never become profitable. Our failure to achieve or maintain profitability, or substantial delays in achieving profitability, could negatively impact the value of our ordinary shares and our ability to raise additional financing. A substantial decline in the value of our ordinary shares would also affect the price at which we could sell shares to secure future funding, which could dilute the ownership interest of current shareholders.

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

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 U.S. Food and Drug Administration, or the 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;
- operating in multiple currencies;
- social and political unrest;
- our ability to anticipate and adapt to a developing market(s);
- acceptance of the 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 will be harmed.

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. We are currently seeking a potential strategic partner for further clinical development and commercialization of AP–ZP. If we are not able to enter into a relationship with a strategic partner for further clinical development and commercialization of AP–ZP, we may not be able to obtain sufficient capital to independently develop and commercialize AP–ZP. 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 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.

Our business is currently in the research and development stage, and we have not yet generated revenues from our operations.

Our business is currently in the research and development stage, and we have not yet generated revenues from our operations. Our financial statements include a note describing our current operations and the incurrence of future losses from our research and development activities. As of December 31, 2015, we had incurred cumulative losses of approximately NIS 193 million. 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 one of our product candidates and/or we successfully commercialize (including out-licensing) such product candidate. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations. If we are unsuccessful in raising capital, we may need to curtail or cease operations.

If we are unable to establish sales, marketing and distribution capabilities, 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 organization.

In the future, we may consider building a focused sales and marketing infrastructure to market AP-CDLD 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 is 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 and enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves.

In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates 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 that 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 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.

We will 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 currently include companies with marketed products and/or an advanced research and development pipeline. The competitive landscape of improving Levodopa for the treatment of Parkinson's disease symptoms includes Novartis AG, Orion Corporation, AbbVie, Impax Laboratories, Inc., XenoPort Inc., Depomed, Inc. and more. The competitive landscape in the insomnia field includes Sanofi S.A., Sepracor Inc. (now known as Sunovion Pharmaceuticals Inc.), King Pharmaceuticals, Merck, Somnus Therapeutics, Inc., Neurim Pharmaceuticals, Ltd., and more. The competitive landscape in the gastric retention system field includes Depomed, Inc., Merrion Pharmaceuticals, Flamel Technologies S.A., XenoPort Inc., Sun Pharma and more. Management is not aware of any companies that are developing or planning to develop a drug delivery system similar to our Accordion Pill platform technology.

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

In addition, potential adverse events caused by our product candidates could lead to product liability lawsuits. If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit the marketing and commercialization of our product candidates. Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We may not be able to avoid product liability claims. Product liability insurance for the pharmaceutical and biotechnology industries is generally expensive, if available at all. If, at any time, we are unable to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims, we may be unable to clinically test, market or commercialize our product candidates. A successful product liability claim brought against us in excess of our insurance coverage, if any, may cause us to incur substantial liabilities, and, as a result, our business, liquidity and results of operations would be materially adversely affected. 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 will be reduced or eliminated. The extent to which any of our product candidates achieve market acceptance will depend on competitive factors, many of which are beyond our control. Competition in the biotechnology and biopharmaceutical industry is intense and has been accentuated by the rapid pace of technology development. Our competitors include large integrated pharmaceutical companies, biotechnology companies that currently have drug and target discovery efforts, universities, and public and private research institutions. Almost all of these entities have substantially greater research and development capabilities and financial, scientific, manufacturing, marketing and sales resources than we do. These organizations also compete with us to:

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

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

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

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

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

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

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

We could incur substantial costs in connection with product liability claims relating to our current or potential product candidates.

The nature of our business exposes us to potential liability inherent in the testing and manufacturing of pharmaceutical and therapeutic products. Our product candidates and the clinical trials utilizing our product candidates may expose us to product liability claims and possible adverse publicity. For example, any of our product candidates could cause adverse events, including injury, disease or adverse side effects. These adverse events may not be observed in clinical trials, but may nonetheless occur in the future. If any of these adverse events occur, they may render our product candidates ineffective or harmful in some patients, and our sales would suffer, materially adversely affecting our business, financial condition and results of operations. Furthermore, changes in laws outside the U.S. are expanding our potential liability for injuries that occur during clinical trials.

Product liability insurance is expensive, subject to deductibles and coverage limitations, and may not be available in the amounts that we desire for a price we are willing to pay. We currently do not maintain product liability insurance coverage. In addition, we cannot be sure that we will be able to obtain or maintain insurance coverage at acceptable costs or in sufficient amounts, or that a product liability claim would not otherwise adversely affect our business, operating results or financial condition. The cost of defending any products liability litigation or other proceeding, even if resolved in our favor, could be substantial. Uncertainties resulting from the initiation and continuation of products liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Product liability litigation and other related proceedings may also absorb significant management time.

Recent disruptions in the financial markets and economic conditions could affect our ability to raise capital and could disrupt or delay the performance of our third-party contractors and suppliers.

In past years, the U.S. and global economies have taken a dramatic downturn as the result of the deterioration in the credit markets and related financial crisis as well as a variety of other factors including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. The U.S. and certain foreign governments have recently taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If the actions taken by these governments are not successful, the continued economic decline may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all. In addition, we rely and intend to rely on third parties, including our clinical research organizations, third-party manufacturers and second-source suppliers, and certain other important vendors and consultants. As a result of the current volatile and unpredictable global economic situation, there may be a disruption or delay in the performance of our third-party contractors and suppliers. If such third parties are unable to satisfy their contractual commitments to us, our business could be severely adversely affected.

Our current management team only has experience in managing and operating a publicly traded U.S. company since August 7, 2015. Any failure to comply or adequately comply with federal securities laws, rules or regulations could subject us to fines or regulatory actions, which may materially adversely affect our business, results of operations and financial condition.

Although our Ordinary Shares trade on the NASDAQ Capital Market and the TASE and we previously filed reports in Israel as an Israeli public company, our current management team only has experience managing and operating a publicly-traded U.S. company since August 7, 2015. Failure to comply or adequately comply with any laws, rules or regulations applicable to our business may result in fines or regulatory actions, which may materially adversely affect our business, results of operation or financial condition and could result in delays in achieving the development of an active and liquid trading market for our ordinary shares.

We will incur significant additional increased 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 as well as in Israel, and our management is required to devote substantial additional time to new compliance initiatives as well as to compliance with ongoing U.S. and Israeli reporting requirements.

As a public company in the U.S., we incur additional significant accounting, legal and other expenses that we did not incur before the offering. We also anticipate that we will incur costs associated with corporate governance requirements of the Securities and Exchange Commission, or the SEC, and the NASDAQ Capital Market, as well as requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. We expect these rules and regulations to increase our legal and financial compliance costs, introduce new costs such as investor relations, stock exchange listing fees and shareholder reporting, and to make some activities more time consuming and costly. The implementation and testing of such processes and systems may require us to hire outside consultants and incur other significant costs. Any future changes in the laws and regulations affecting public companies in the United States, 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. These laws, rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, if any, or as executive officers.

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

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

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

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

- have an auditor report on our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- comply with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis);
- submit certain executive compensation matters to shareholders advisory votes pursuant to the "say on frequency" and "say on pay" provisions (requiring a non-binding shareholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010; and
- include detailed compensation discussion and analysis in our filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and instead may provide a reduced level of disclosure concerning executive compensation.

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

In addition, as an "emerging growth company," we may elect under the JOBS Act to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. We are choosing to "opt out" of this provision and, as a result, we will comply with new or revised pronouncements applicable to public companies when they are required to be adopted by public companies. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

We are a "foreign private issuer" and have disclosure obligations that are different from those of U.S. domestic reporting companies.

We are a foreign private issuer and are not subject to the same requirements that are imposed upon U.S. domestic issuers by the SEC. Under the Exchange Act, we will be subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. For example, we will not be required to issue quarterly reports or proxy statements that comply with the requirements applicable to U.S. domestic reporting companies. Furthermore, although under a recent amendment to the regulations promulgated under the Israeli Companies Law, 5759-1999, or the Companies Law, as an Israeli public company listed overseas we will be required to disclose the compensation of our five most highly compensated officers on an individual basis (rather than on an aggregate basis, as was previously permitted for Israeli public companies listed overseas), this disclosure will not be as extensive as that required of U.S. domestic reporting companies. We will also have four months after the end of each fiscal year to file our annual reports with the SEC and will not be required to file current reports as frequently or promptly as U.S. domestic reporting companies. Furthermore, our officers, directors and principal shareholders will be exempt from the requirements to report short-swing profit recovery contained in Section 16 of the Exchange Act. Also, as a "foreign private issuer," we are not subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act. These exemptions and leniencies will reduce the frequency and scope of information and protections available to you in comparison to those applicable to a U.S. domestic reporting companies.

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

As a "foreign private issuer," we are permitted to follow certain home country corporate governance practices instead of those otherwise required under the Listing Rules of the NASDAQ Capital Market for domestic U.S. issuers. For instance, we currently follow home country practice in Israel with regard to, among other things, board independence requirements, director nomination procedures and quorum requirements. In addition, we may follow our home country law instead of the Listing Rules of the NASDAQ Capital Market that require that we obtain shareholder approval for certain dilutive events, such as the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of our company, certain transactions other than a public offering involving issuances of a 20% or greater interest in our company, and certain acquisitions of the stock or assets of another company. We also currently follow our home country practices with respect to our compensation committee, which conducts itself in accordance with the provisions governing its composition and responsibilities as set forth in the Companies Law, not the Listing Rules of the NASDAQ Capital Market. We may in the future elect to follow home country corporate governance practices in Israel with regard to other matters. Following our home country corporate governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on the NASDAQ Capital Market may provide less protection to you than what is accorded to investors under the Listing Rules of the NASDAQ Capital Market applicable to domestic U.S. issuers. See "Management — NASDAQ Capital Market Listing Rules and Home Country Practices."

Risks Related to Our Intellectual Property

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.

We license our core intellectual property from Yissum, an affiliate of Hebrew University. 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 IP 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 IP 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 the 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. If any dispute arises with respect to our arrangement with Yissum, such dispute may disrupt our operations and would likely have a material and adverse impact on us if resolved in a manner that is unfavorable to us. Most of our current product candidates are partly based on the intellectual property licensed under the License Agreement, and if the License Agreement was terminated, it would have a material adverse effect on our business, prospects and results of operations.

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 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 meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;

- other companies may challenge patents licensed or issued to us or our customers;
- other companies may independently develop similar or alternative technologies, or duplicate our technologies;
- other companies may design around technologies we have licensed or developed;
- 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 United States Patent and Trademark Office, or the USPTO, or foreign patent offices issue patents to us or our licensors, others may challenge the patents or design around the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against our competitors.

We cannot be certain that patents will be issued as a result of any pending applications, and we cannot be certain that any of our issued patents 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.

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. Recent decisions by the Committee (which have been upheld by the Israeli Supreme Court on appeal) have created uncertainty in this area, as it held that employees may be entitled to remuneration for their service inventions despite having specifically waived any such rights. However, a recent decision by the Committee held that such right can be waived by the employee. The Committee further held that an explicit reference to the waived right is not necessary in every circumstance in order for the employee's waiver of such right to be valid. Such waiver can be formalized in writing or orally or be implied by the actions of the parties in accordance with the rules of interpretation of Israeli contract law. 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. Although our employees have agreed to assign to us service invention rights, we may face claims demanding remuneration in consideration for assigned inventions.

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

The cost to us of any patent litigation or other proceeding relating to our licensed patents or patent applications, even if resolved in our favor, could be substantial and could divert management's resources and attention. Our ability to enforce our patent 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 patents and may go to court to stop us from engaging in our normal operations and activities, such as research, development and the sale of any future products. Such lawsuits are expensive and would consume time and other resources. There is a risk that the court will decide that we are infringing the third party's patents and will order us to stop the activities claimed by the patents, redesign our products or processes to avoid infringement or obtain licenses (which may not be available on commercially reasonable terms 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.

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

We entered into a feasibility and option agreement with a pharmaceutical company and engaged in a feasibility study over a period of several months during the early stage of formulation of the Accordion Pill for Carbidopa/Levodopa. The agreement included a right of first offer, under certain circumstances. In 2012, the pharmaceutical company asserted that it has a right of first refusal in the event that we seek to grant a license to certain intellectual property contained in AP-CDLD to any third party. We believe that the pharmaceutical company does not have such right and that the right of first offer included in the agreement terminated in 2008. In addition, we believe that such right of first offer only applied to licenses for use in the United States. If we seek to grant a license to certain intellectual property contained in AP-CDLD to any third party, we can, in our discretion, either first offer the main terms of such license to the other pharmaceutical company pursuant to the alleged right of first offer, which we believe terminated in 2008, or seek to grant such license to a third party without first offering the main terms of such license to the other pharmaceutical company, in which case the other pharmaceutical company may seek to challenge such third-party license or claim damages. Although we would intend to vigorously defend against any such challenge or claim, there can be no guarantee that we would be successful in such defense. Any such challenge or claim for damages made by the other pharmaceutical company, if we choose not to make a first offer, could adversely affect our ability to develop, or the timing of our development of, AP-CDLD. Further, the allegation that any such right exists, even though we believe that any such right has terminated, could discourage other potential licensees from working with us. Either of these events could have a material adverse effect on our business, prospects 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, disputes may arise as to the intellectual property rights associated with our products. If a dispute arises, a court may determine that the right belongs to a third party. In addition, enforcement of our rights can be costly and unpredictable. We also rely on trade secrets and proprietary know-how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

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

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

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

Risks Related to the Regulation of our Company and Its Business

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

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

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 rigorous 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 Federal Food, Drug, and Cosmetic Act, or 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 will severely undermine our business by delaying or halting commercialization of our products, imposing costly procedures, diminishing competitive advantages and reducing the number of salable products and, therefore, corresponding product revenues.

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

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

Given that these were open label studies, not conducted under an FDA issued IND, the FDA may decide not to consider the data that we collected from these open-label studies, even though we are obligated to submit these data to the FDA.

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

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

We intend to seek FDA approval for our product candidates implementing our Accordion Pill technology through the Section 505(b)(2) regulatory pathway. Pursuant to Section 505(b)(2) of the FDCA, a new drug application, or NDA, under Section 505(b)(2) is permitted to reference safety and effectiveness data submitted by the original manufacturer of the underlying 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 on 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, 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.

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 will seek approval in the European Union, or the EU, on a product-by-product basis, either by ourselves or with a third-party licensee.

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We may seek fast track designation for some of our product candidates and may seek such designation for future product candidates. The FDA has broad discretion whether to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we apply for and receive fast track designation for one or more of our product candidates or future product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

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

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

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

Endpoints for most Phase III clinical trials may vary from drug candidate to drug candidate and from indication to indication; therefore, there are no universally accepted endpoints for Phase III clinical trials. Accordingly, the development pathway for AP-CDLD, which is being developed for the indication of treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, and our other product candidates, is not completely clear yet.

It is possible that even if the results of a potential Phase III clinical trial meet the primary endpoints, the FDA will require other data of our product candidates prior to granting marketing approval.

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

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

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

- unforeseen safety issues;
- clinical holds or suspension of a clinical trial by the FDA, us, the institutional review board, or IRB, or the data safety monitoring board, or DSMB, determination of proper dosing;
- lack of effectiveness or efficacy during clinical trials;
- failure of our contract manufacturers to manufacture our product candidates in accordance with current Good Manufacturing Practices, or 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 the conduct of these trials. For example, a DSMB has been selected for the Phase III clinical trial of AP-CDLD and will periodically review the safety data of the trial, specifically focusing on the safety of AP-CDLD in the upper GI tract because the Accordion Pill is retained in the stomach for a prolonged period of time, to measure whether AP-CDLD causes damage such as erosions or ulcers. Any suspension of clinical trials will delay possible regulatory approval, if any, and adversely impact our ability to develop products and generate revenue.

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

Upon the completion of any clinical trial, if at all, the results of these trials might not support the claims sought by us. Further, success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for 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 abandon, which would significantly impair our ability to generate product revenues and would materially adversely affect our business, financial condition or results of operations.

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

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

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, 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. 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, 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. 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. While we cannot predict the full effect PPACA will have on federal reimbursement policies in general or on our business specifically, the PPACA may result in downward pressure on drug reimbursement, which could negatively affect market acceptance of our products. 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 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, other divisions of the U.S. Department of Health and Human Services, including its Office of Inspector General, the Office of Civil Rights, which administers the privacy provisions of the Health Insurance Portability and Accountability Act of 1996, or 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 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.

We are subject to additional federal and state 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 event that we were to market products in the United States, we would be subject to additional 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 or service for which payment may be made under government healthcare programs such as the Medicare and Medicaid programs;

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

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

- federal false claims laws 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; and

- state 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.

Further, the recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback 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 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 imposes new reporting requirements on device and pharmaceutical manufacturers to make annual public disclosures of payments to physicians and teaching hospitals and ownership of their stock by physicians. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not reported. Manufacturers were required to begin data collection on August 1, 2013 and report such data to CMS by March 31, 2014, but that has been delayed and final reconciliation of data was supposed to have occurred on October 31, 2014.

In addition, there has been a recent trend of increased federal and state 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 AdvaMed 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.

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.

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.

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 granting 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. We have not currently determined whether we will engage in the manufacture of our products for commercial purposes. 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 United States Drug Enforcement Agency, or 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 manufacture our own product candidates for Phase III clinical trials and may, to some extent, manufacture our product candidates for commercialization or rely on third parties to implement our manufacturing strategies. 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.

Completion of any potential future Phase III clinical trials and commercialization of our product candidates will require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. There can be no assurance that our product candidates, if approved, can be manufactured in sufficient commercial quantities, in compliance with regulatory requirements and at an acceptable cost. Although we believe our facilities are sufficient to manufacture our product candidate needs for Phase III clinical trials, we may be incorrect and we may not have the resources or facilities to manufacture our product candidates for Phase III clinical trials or commercial purposes on our own, and we may not develop or acquire facilities for the manufacture of product candidates for such purposes in the foreseeable future. We may rely on contract manufacturers to produce sufficient quantities of our product candidates necessary for any Phase III clinical testing we undertake in the future and for commercialization of our products. Such contract manufacturers may be the sole source of production, and they may have limited experience at manufacturing, formulating, analyzing, filling and finishing our types of product candidates. Establishing a manufacturing facility to produce commercial quantities of our products will require a substantial investment by any party intending to manufacture our products. 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.

Manufacturing our product candidates is subject to extensive governmental regulation. See "Business — Government Regulation." Future FDA, state and foreign inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers, if any, 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, FDA-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 policies may change, which could delay or prevent regulatory approval of our products under development. The FDA will likely condition granting any marketing approval on a satisfactory on-site inspection of our manufacturing facilities.

We have limited experience manufacturing our product candidates at a commercial scale. We may not be able to manufacture our product candidates in quantities sufficient for commercial launch of our product candidates, if our product candidates are approved, or for any future commercial demand for our product candidates.

Although we have manufactured clinical quantities of AP-CDLD and other products and product candidates in our manufacturing facility, we have only limited experience in manufacturing commercial quantities of our product candidates. If AP-CDLD or AP–ZP is approved for commercialization and marketing, we may be required to manufacture the product in large quantities to meet demand. 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 us to manufacture commercial-scale quantities of products at acceptable costs, we cannot provide assurance that such processes and protocols will enable us to manufacture AP-CDLD or AP–ZP in quantities that may be required for commercialization of the applicable product with yields and at costs that will be commercially attractive. If we are unable to establish or maintain commercial manufacture of the product or are unable to do so at costs that we currently anticipate, our business will be adversely affected.

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

We currently manufacture all clinical supply of AP-CDLD and AP–ZP 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 38.0 million, business interruption insurance coverage of up to NIS 17.0 million for damage to our property and the disruption of our business from fire and other casualties, and up to NIS 35.0 million for expenses related to our Phase III clinical trial for AP-CDLD, 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 may rely on third-party manufacturers to manufacture commercial quantities of our product candidates, if our products are approved, 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 and Phase II clinical trials of our product candidates in our own manufacturing facility and have started, and expect to continue, to do so for our pivotal Phase III clinical trial of AP-CDLD. We have relied, and we expect to continue to rely, on third-party manufacturers for certain raw materials (excipients, solvents and APIs). 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. We have recently ordered enough of these items to complete our pivotal Phase III clinical trial for AP-CDLD. 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-CDLD, 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-CDLD, 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.

Our third-party manufacturers and suppliers may be subject to FDA inspection from time to time. Failure by our third-party manufacturers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our product candidates may result in regulatory actions such as the issuance of Form FDA 483 notices of observations, 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.

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.

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. 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. 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.

We are subject to government regulations and we may experience delays or may be unsuccessful in obtaining required regulatory approvals within or outside of the United States to market our proposed product candidates, and even if we obtain approval, the approved indications may impair our ability to successfully market the product or make commercial distribution not feasible.

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

Delays in regulatory approval, limitations in regulatory approval and withdrawals of regulatory approval may have a material adverse effect on us. If we experience significant delays in testing or receiving approvals or sign-offs to conduct clinical trials, our product development costs, or our ability to license product candidates, will increase. If the FDA or other foreign regulatory entities grant regulatory approval to market a product, this approval will be limited to those diseases and conditions for which the product has demonstrated, through clinical trials, to be safe and effective. Any product approvals that we receive in the future could also include significant restrictions on the use or marketing of our products. Product approvals, if granted, can be withdrawn for failure to comply with regulatory requirements or upon the occurrence of adverse events following commercial introduction of the products. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other regulatory action against our product candidates or us. If approval is withdrawn for a product, or if a product were seized or recalled, we would be unable to sell or license that product and our revenues would suffer. In addition, outside the United States, our ability to market any of our potential products is contingent upon receiving market application authorizations from the appropriate regulatory authorities. These foreign regulatory approval processes may include all of the risks associated with the FDA approval process described above, if not more.

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 Medicare Modernization Act 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 Medicare Modernization Act 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 Affordable Care Act, 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. Although it is too early to determine the effect of the PPACA, it appears likely to continue to put pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. More recently, in August 2011, the 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 a inflation-based rebate formula to generic 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.

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.

Risks Related to Our Industry

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 harmed, possibly materially.

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 PPACA requires drug manufacturers to report to the government any payments to physicians for consulting services and the like.

Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, monetary penalties, imprisonment, denial of Medicare and Medicaid payments or exclusion from the Medicare and Medicaid programs, or both, and debarment. As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to 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 to sue on behalf of the government. The Fraud Enforcement and Recovery Act of 2009 may further encourage 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.

Risks Related to Our Operations in Israel

Potential political, economic and military instability in the State of Israel, where 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. Our officers and all of our 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 as recently as 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 instead. Such political turbulence and violence may damage peaceful and diplomatic relations between Israel and Egypt, and could affect the region as a whole. Similar civil unrest and political turbulence has occurred in other countries in the region, including Syria which shares a common border with Israel, and is affecting the political stability of those countries. Since April 2011, internal conflict in Syria has escalated, and evidence indicates that chemical weapons have been used in the region. Intervention may be contemplated by outside parties in order to prevent further chemical weapon use. This instability and any intervention may lead to deterioration of the political and economic relationships that exist between the State of Israel and some of these countries, and may have the potential for additional conflicts in the region. In addition, Iran has threatened to attack Israel and may be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, and various rebel militia groups in Syria. These situations may potentially escalate in the future to more violent events which may affect Israel and us. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained or that it will sufficiently cover our potential damages. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

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

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

Many Israeli citizens are obligated to perform several 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.

None of our directors or officers are residents of the United States and most of their and our assets 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. our 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 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 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 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. Because Israeli corporate law has undergone extensive revision in recent years, 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. See "Additional Information — Memorandum and Articles of Association — Acquisitions under Israeli Law."

Furthermore, under the Encouragement of Industrial, Research and Development Law, 5744-1984, or the Research Law, to which we are subject due to our receipt of grants from the Office of the Chief Scientist of the Israeli Ministry of Economy, or OCS, a recipient of OCS grants such as us must report to the applicable authority of the OCS regarding any change of control or any change in the holding of the means of control of our Company which transforms any non-Israeli citizen or resident into an "interested party", as defined in the Research Law, in our Company, and in the latter event, the non-Israeli citizen or resident shall execute an undertaking in favor of the OCS, in a form provided under the OCS guidelines.

Because a certain portion of our expenses is incurred in currencies other than the U.S. Dollar, our results of operations may be harmed by currency fluctuations and inflation.

Beginning in 2016, our reporting and functional currency is the U.S. dollar, but some portion of our expenses is in the NIS and Euro. As a result, we are exposed to some currency fluctuation risks. We may, in the future, decide to enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rate of the currencies mentioned above in relation to the U.S. dollar. These measures, however, may not adequately protect us from adverse effects.

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 Research Law, research and development programs which meet specified criteria and are approved by a committee of the OCS are eligible for grants. The grants awarded are typically up to 50% of the project's expenditures, as determined by the research committee. The grantee is required to pay royalties to the OCS on income generated from the sale of products (and related services associated with such products), whether received by the grantee or any affiliated entity, as defined in the Encouragement of Industrial Research and Development Regulations (Royalty Rates and Rules for Payment), 5756-1996, or the Royalty Regulations, developed, in whole or in part, within the framework of an OCS-funded project or deriving therefrom. In accordance with the provisions of the Royalty Regulations, royalties are paid beginning from the date of the sale of the first product developed according to an OCS-funded project at rates between 3% to 6% (though typically not greater than 4.5%) of sales of the product, depending on the situation and applicable criteria, and are payable until the repayment of the full amount of the total OCS funding linked to the U.S. Dollar and accrued interest (LIBOR), or in certain cases, payable up to the increased royalty cap. The terms of the OCS participation also require that products developed using government grants be manufactured in Israel and that the technology developed thereunder may not be transferred outside of Israel, unless approval is received from the OCS (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 abroad in the applications for funding, in which case only notification is required) and additional payments are made to the OCS. However, this does not restrict the export of products that incorporate the funded technology. Following the full payment of such royalties and interest, there is generally no further liability for payment. Nonetheless, the restrictions under the Research Law (as generally specified herein) will continue to apply even after we have repaid the full amount of royalty payable pursuant to the grants.

Ordinarily, as a condition to obtaining approval to manufacture outside Israel, we would be required to pay increased royalties, as set forth in the Research Law. The total amount to be repaid to the OCS would also be adjusted to between 120% and 300% of the grants, depending on the manufacturing volume that is performed outside Israel. A company also has the option of declaring in its OCS grant application its intention to exercise a portion of the manufacturing capacity abroad, thus avoiding the need to obtain additional approval after approval of such application by the OCS.

The Research Law restricts the ability to transfer know-how funded by the OCS outside of Israel. Transfer of OCS-funded know-how outside of Israel requires prior OCS approval and is subject to certain payments to the OCS calculated according to formulae provided under the Research Law. A transfer for the purpose of the Research Law means an actual sale of the OCS-funded know-how, any license to develop the OCS-funded know-how or the products resulting from the OCS-funded know-how or any other transaction, which, in essence, constitutes a transfer of the OCS-funded know-how. A mere license solely to market products resulting from the OCS-funded know-how would not be deemed a transfer for the purpose of the Research Law. It should be noted that the OCS is in the process of promulgating regulations that deal with granting of licenses to use know-how developed as a result of research financed by the OCS. Such regulations may have an effect on our company, in respect of the amount of payments to the OCS for the grant of sub-licenses to third parties. As of the date of this annual report, we are unable to assess the effect, if any, of the promulgation of such regulations on our company.

If we wish to transfer OCS-funded know-how, the terms for approval shall be determined according to the character of the transaction and the consideration paid to us for such transfer. The OCS approval to transfer know-how created, in whole or in part, in connection with an OCS-funded project to third party outside Israel where the transferring company remains an operating Israeli entity is subject to payment of a redemption fee to the OCS calculated according to a formula provided under the Research Law that is based, in general, on the ratio between the aggregate OCS grants received by the company and the company's aggregate investments in the project that was funded by these OCS grants, multiplied by the transaction consideration. The transfer of such know-how to a party outside Israel where the transferring company ceases to exist as an Israeli entity is subject to a redemption fee formula that is based, in general, on the ratio between aggregate OCS grants received by the company and the company's aggregate research expenses, multiplied by the transaction consideration. The Regulations for the Encouragement of Research and Development in the Industry (the Maximum Payment for the Transfer of Know-How in Accordance with Section 19B(b)(1) and (2), 5777-2012), or the Cap Regulations, establish a maximum payment of the redemption fee paid to the OCS under the above mentioned formulas and differentiates between two situations: (i) in the event that the company sells its OCS-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 annual interest) for the applicable know-how being transferred, or the entire amount received, as applicable; (ii) in the event that following the transactions described above (i.e., asset sale of OCS-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 and keeps on staff at least 75% of the number of research employees it had for the six months before the know-how was transferred), then the company is eligible for a reduced cap of the redemption fee of no more than three times the amounts received (plus annual interest) for the applicable know-how being transferred, or the entire amount received, as applicable.

On July 29, 2015, the Research Law was amended, or Amendment Number 7. Pursuant to Amendment Number 7, the National Authority for Technological Innovation, or NATI, a statutory corporation, will be established and will replace the OCS. Pursuant to Amendment Number 7, the current restrictions under the R&D Law will be replaced by a new set of arrangements in connection with ownership obligations of know-how (including with respect to restrictions on transfer of know-how and manufacturing activities outside of Israel), as well as royalties obligations associated with approved programs, which will be promulgated by NATI. The commencement date of Amendment Number 7 was January 1, 2016, however, until new arrangements are adopted by NATI, the R&D Law as it existed prior to Amendment Number 7 continues to be in force and effect. Pursuant to Amendment Number 7, NATI should be constituted no later than July 28, 2018, and the new arrangements should be adopted no later than one year thereafter. As of the date of this annual report, we are unable to assess the effect, if any, of the promulgation of such arrangements on our company.

Subject to prior consent of the OCS, the company may transfer the OCS-funded know-how to another Israeli company. If the OCS-funded know-how is transferred to another Israeli entity, the transfer would still require OCS approval but will not be subject to the payment of the redemption fee (although there will be an obligation to pay royalties to the OCS 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 responsibilities towards the OCS as a condition to OCS approval.

Our research and development efforts have been financed, partially, through grants that we have received from the OCS. We therefore must comply with the requirements of the Research Law and related regulations. As of December 31, 2015, we have received approximately NIS 32.6 million. Therefore, the discretionary approval of an OCS 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 OCS funding. The restrictions under the Research Law may impair our ability to enter into agreements for OCS funded products or technologies without the approval of the OCS. We cannot be certain that any approval of the OCS 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 this technology, 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 technology developed with OCS 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 the OCS. Any approval, if given, will generally be subject to additional financial obligations. Failure to comply with the requirements under the Research Law may subject us to mandatory repayment of grants received by us (together with interest and penalties), as well as may expose us to criminal proceedings. In addition, the Government of Israel may from time to time audit sales of products which it claims incorporate technology funded via OCS programs and this 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. OCS approval is not required for the export of any products resulting from the OCS-funded research or development in the ordinary course of business.

Risks Related to Ownership of Our Ordinary Shares

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

The trading market for our ordinary shares will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts, and we cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding our 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 our ordinary shares in the foreseeable future. Moreover, the Companies Law imposes certain restrictions on our ability to declare and pay dividends. See "Additional Information—Memorandum and Articles of Association—Dividends" for additional information. 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 and the TASE. 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.

Our ordinary shares are traded on more than one market and this may result in price variations.

Our ordinary shares have been traded on the NASDAQ Capital Market since August 2015 and the TASE since 2010. Trading in our ordinary shares on these markets will take place in different currencies (U.S. dollars on the NASDAQ Capital Market and NIS on the TASE), and at different times (resulting from different time zones, trading days and public holidays in the United States and Israel). The trading prices of our ordinary shares on these two markets may differ due to these and other factors. Any decrease in the price of our ordinary shares on the TASE could cause a decrease in the trading price of our ordinary shares in the United States.

We do not know whether a market in the United States for our ordinary shares will be sustained or what the market price of our ordinary shares will be and as a result it may be difficult for you to sell your ordinary shares at or above the purchase therefor or at all.

Although our ordinary shares now trade on the NASDAQ Capital Market and on the TASE, an active trading market for our 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 market price of our ordinary shares may fluctuate significantly, which could result in substantial losses by our investors.

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

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

- the other factors described in this "Risk Factors" section.

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

Further, the stock market in general, the NASDAQ Capital Market and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of small 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 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.

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.

We expect to be characterized as a passive foreign investment company for the taxable year ending December 31, 2016, 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. The characterization of our Company as a PFIC for 2016 has not yet been determined. Because PFIC status is determined annually and is based on our income, assets and activities for the entire taxable year, 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. Investor, as defined in "Taxation — U.S. Federal Income Tax Consequences", owns ordinary shares, such U.S. Investor 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. Investors, 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 mark-to-market treatment) of our ordinary shares; however, we do not intend to provide the information necessary for U.S. Investors to make "qualified electing fund elections" if we are classified as a PFIC. See "Taxation — U.S. Federal Income Tax Consequences."

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 11,448,191 ordinary shares outstanding as of December 31, 2015. Of those shares, 11,273,625 were freely tradable, without restriction, in the public markets in the United States and Israel. Such shares represented approximately 98.47% of our outstanding ordinary shares as of that date. Any sales of those shares or any perception in the market that such sales may occur could cause the trading price of our ordinary shares to decline. The remaining 174,566 shares are currently restricted as a result of securities laws, but will become eligible to be sold at various times after the date of this annual report. In addition, in connection with our August 2013 financing round, we agreed to file a registration statement in the U.S., registering for resale by the purchasers, subject to certain conditions, up to 976,225 ordinary shares, consisting of (a) 697,247 ordinary shares, including 376,584 ordinary shares issued as a result of Downside Protection events, (b) 198,812 ordinary shares underlying warrants issued as part of the August 2013 financial round and (c) an additional 80,166 ordinary shares underlying warrants that were issued as part of the August 2013 financing round because we did not complete certain obligations by September 30, 2014, as described below. On July 8, 2015, we entered into a registration rights agreement with respect to these shares to better define these registration rights. In addition, we issued to these investors an additional 80,166 warrants exercisable into ordinary shares because we did not complete (i) a public offering raising at least $12.0 million on the NASDAQ Stock Market or (ii) a merger with a company traded on the NASDAQ Stock Market which holds at least $12.0 million of unencumbered cash prior to September 30, 2014. We agreed to file a registration statement registering for resale the ordinary shares underlying these warrants as well.

In addition, up to 1,516,098 ordinary shares that are subject to outstanding options under the 2005 Share Option Plan, or the 2005 Plan, and reserved for future issuance under our 2015 Incentive Compensation Plan, or the 2015 Plan, will be eligible for sale in the public market. We filed a registration statement on Form S-8 under the Securities Act on February 25, 2016, to register such ordinary shares.

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

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

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

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

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

We are required to meet the continued listing requirements of the NASDAQ Capital Market and comply with the other NASDAQ rules, including those regarding director independence and independent committee requirements, minimum shareholders' equity, minimum share price and certain other corporate governance requirements. In particular, we are required to maintain a minimum bid price for our listed ordinary shares of $1.00 per share. If we do not meet these continued listing requirements, our ordinary shares could be delisted. Delisting of our ordinary shares from the NASDAQ Capital Market would cause us to pursue eligibility for trading on other markets or exchanges, or on the pink sheets. In such case, our shareholders' ability to trade, or obtain quotations of the market value of, our ordinary shares would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our securities. There can be no assurance that our ordinary shares, if delisted from the NASDAQ Capital Market in the future, would be listed on a national securities exchange or quoted on a national quotation service, the OTCBB or the pink sheets. 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.

ITEM 4. Information on the Company.

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. On February 14, 2010, we successfully completed an initial public offering in Israel on the TASE. We do not have any subsidiaries and do not hold any investments in other entities.

We completed our initial public offering of securities in Israel on February 10, 2010. In connection with the offering, 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.

We completed our initial public offering of securities in the United States on August 7, 2015. In connection with the offering, we raised gross proceeds of approximately $34.0 million before deducting underwriting discounts and commissions and other offering expenses.

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 three product candidates in clinical trial stages. Our leading product candidate, Accordion Pill Carbidopa/Levodopa, or AP-CDLD, is being developed for the indication of treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients. We have successfully completed a Phase II clinical trial for AP-CDLD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients and have agreed with the U.S. Food and Drug Administration, or the FDA, on the remaining clinical development program for AP-CDLD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, including the main principles of the single required pivotal Phase III clinical trial in advanced Parkinson's disease patients. See "— Current Regulatory Status of AP-CDLD." In December 2015, we received a United States centralized institutional review board, or IRB, approval to initiate a Phase III clinical trial for AP-CDLD. See "— Current Regulatory Status of AP-CDLD." Our second product candidate, Accordion Pill Zaleplon, or AP–ZP, is being developed for the indication of treatment of insomnia, including sleep induction and the improvement of sleep maintenance. We have successfully completed a Phase II clinical trial for AP–ZP for the treatment of insomnia under an Investigational New Drug, or IND, application that we submitted to the FDA on August 4, 2009 for AP–ZP as a treatment for the induction and maintenance of sleep in patients suffering from insomnia. In our correspondence with the FDA, the FDA previously agreed that an acceptable regulatory pathway for AP-CDLD and AP–ZP would be to file a new drug application, or NDA, pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, which is a streamlined approval pathway that may accelerate the time to commercialize and decrease the costs of AP–CDLD and AP–ZP, as compared to those typically associated with a NCE. See "— Government Regulation — 505(b)(2) Applications." The FDA has 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. However, at this point in the development process of AP-ZP, the details of such a trial have not been determined or confirmed with the FDA. In March 2016, we completed a Phase I clinical trial for our third pipeline product candidate which is being developed for the prevention and treatment of gastroduodenal and small bowel Nonsteroidal Anti-Inflammatory Drug, or NSAID, induced ulcers. The pharmacokinetics, or PK, results demonstrated in the Phase I trial were within the well-defined safety levels of the drug, which enable us to proceed with further development of the Accordion Pill with the existing drug.

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 property protection period of the drug incorporated into the Accordion Pill.

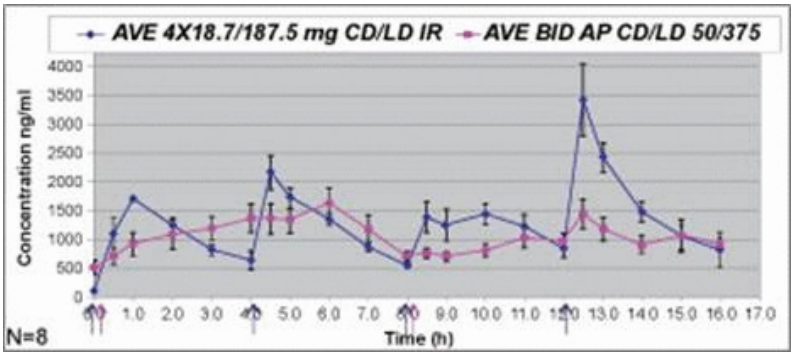
Our anticipated ability to file NDAs pursuant to Section 505(b)(2) for our existing pipeline and future products increases the likelihood of accelerating the time to commercialization of our products and decreasing costs when compared to those typically associated with NCEs.

Our Accordion Pill platform technology is designed to increase the time that drugs are retained in the stomach as compared to other oral dosage forms, such as tablets and capsules. This capability is particularly important to drugs with a 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 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 Drug Development & Delivery, in 2006 approximately 90% of NCEs in development were either BCS 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 an NAW:

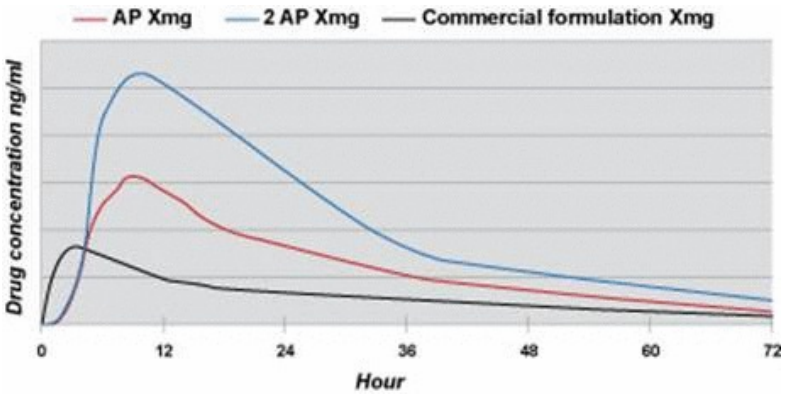
AP-CDLD Phase II clinical trial — more stable Levodopa levels with statistically significant reduced peak-to-trough fluctuations



Levodopa plasma levels in n=8 advanced Parkinson's disease patients following twice daily, or b.i.d, administration (eight hours apart) of AP-CDLD 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-CDLD. Demonstration of the clinical benefits of these peak to trough ratios will be further studied and confirmed in the Phase III clinical trial.

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

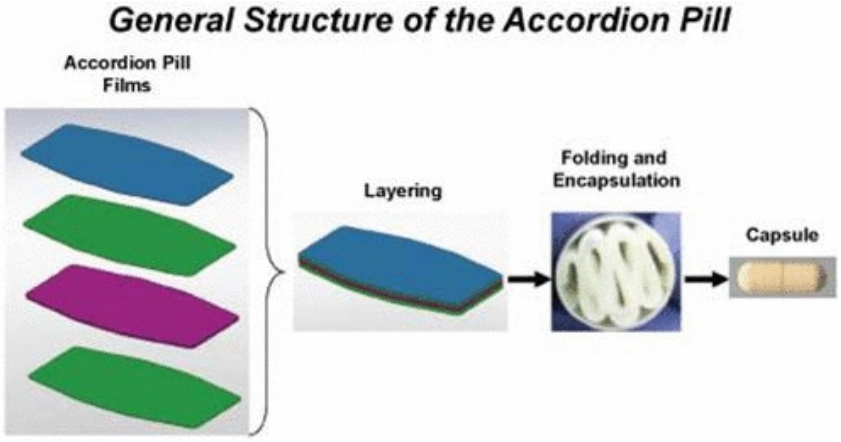


The results of our clinical trial have demonstrated approximately a 100% increase in bioavailability in 12 healthy volunteers with our Accordion Pill technology, as compared to the commercial formulation of the drug. Furthermore, the results demonstrated that the increase in bioavailability obtained 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. 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 Drug Development & Delivery, in 2006 approximately 90% of NCEs in development were either BCS Class II or Class IV drugs.

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:



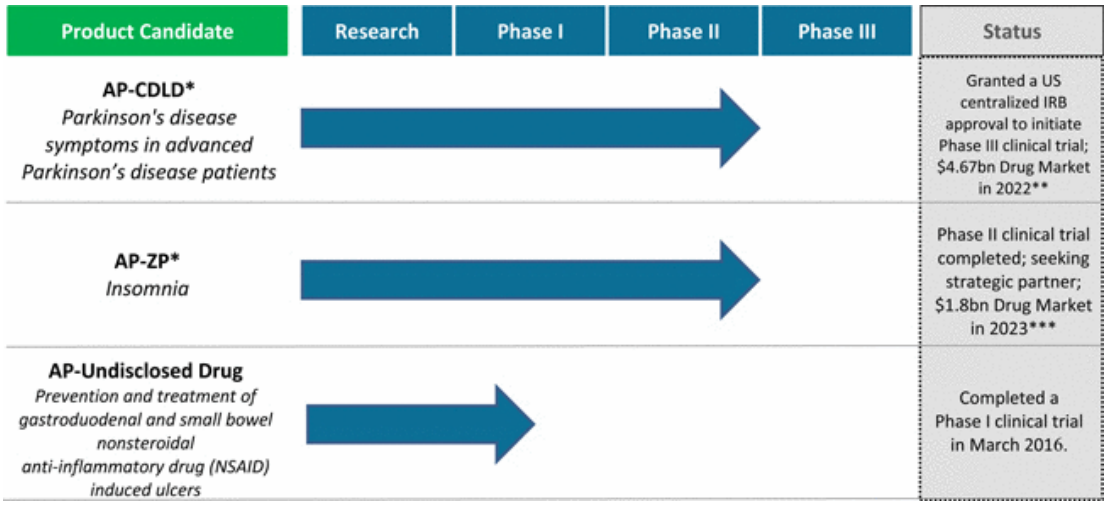
All of the ingredients in the Accordion Pill (active and inactive) are combined physically, not chemically, thus maintaining the chemical composition of the active ingredients.

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.

We have conducted more than 30 clinical trials with more than 3,000 administrations to study the safety and efficacy of the Accordion Pill, including the Accordion Pill platform alone and the Accordion Pill platform with various APIs. No significant adverse events related to the Accordion Pill were reported in these clinical studies. These studies demonstrated that increasing gastro-retention time improves the performance of certain NAW and BCS Class II/IV drugs.

Our Product Pipeline

Our current product development pipeline includes three products in clinical trial stages. Our leading pipeline product, AP-CDLD, is focused on leveraging our Accordion Pill technology to improve the efficacy and safety of an approved drug for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients. We have agreed with the FDA on the remaining clinical development program for AP-CDLD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, including the main principles of the single required pivotal Phase III clinical trial in advanced Parkinson's disease patients. In December 2015, we received a United States centralized institutional review board, or IRB, approval to initiate a Phase III clinical trial for AP-CDLD. Our second product, AP–ZP, is for the treatment of insomnia. We are currently seeking a potential strategic partner for further clinical development and commercialization of AP–ZP and our future development plans for AP–ZP will depend on the results of this process. We have an exclusive license from Yissum, an affiliate of The Hebrew University of Jerusalem, for developing, manufacturing and global marketing of products based on the core technology used in the Accordion Pill. In March 2016, we completed a Phase I clinical trial for our third pipeline product candidate which 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, which enable us to proceed with further development of the Accordion Pill with the existing drug.



* Under 505(b)(2)

** Forecasted Parkinson's Disease drug market in the seven major markets plus Brazil according to Global Data

*** Forecasted insomnia drug market according to Global Data

New Product Development for Biogen MA Inc.

On April 15, 2015, we entered into an agreement with Biogen MA Inc., which we refer to as Biogen, for the development of a designated Accordion Pill with one marketed, proprietary drug of Biogen. Pursuant to the agreement, we will conduct activities for the development of the designated Accordion Pill pursuant to an agreed upon research plan, which will be funded by Biogen, subject to the achievement of certain research plan milestones. We granted Biogen an option to obtain an exclusive, worldwide, royalty bearing license to our technology, as implemented in the product being developed, for the current approved indication of its proprietary drug. Pursuant to the agreement and to the extent we are not contractually precluded from doing so, at the request of Biogen, we will negotiate in good faith the expansion of the license field for additional indications, and the terms and conditions thereof. Upon exercise of the option, Biogen will be responsible for, and bear all costs associated with, pre-clinical and clinical activities required for the purpose of obtaining regulatory approval for the product being developed, as well as for the manufacturing and commercialization thereof. Biogen has also agreed to consider in good faith engaging us as a manufacturer of commercial supply of the product being developed.

Pursuant to the agreement, we either received or will be entitled to the following payments:

- $250,000, which we received within 15 days from the execution of the agreement, for funding the research plan, and an additional aggregate amount of up to $670,000 for the achievement of research plan milestones;
- $8,000,000 in consideration for the exercise of the option;
- Several payments in an aggregate amount of $39 million upon the achievement of milestones related to the development of the product, regulatory filings for the purpose of obtaining regulatory approvals and reaching first commercial sales in the United States and Europe; and

- Royalties in a low single-digit rate on net sales, provided that the aggregate annual royalties will not exceed $25 million and the aggregate amount of royalties payable under the agreement will not exceed $100 million.

We are entitled to the aforementioned royalty payments for the duration of the royalty term. The royalty term is defined with respect to the product being developed in each country as the period beginning on the date of the first commercial sale of the product being developed in such country and ending on the later of (a) the expiration of the last to expire valid patent right claim that covers such product in such country and (b) the expiration of a regulatory exclusivity period granted or afforded by applicable laws or by a regulatory authority with respect to such product in such country. We currently estimate that the royalty term will last until at least 2028 in the United States based on the expiration of our IN-3 family patents.

The agreement includes separate research, option exercise and commercialization periods. The research period includes certain research performance milestones and begins on the date of the agreement and ends on the earlier of (a) Biogen's termination of the agreement upon failure to meet such milestones or in accordance with the agreement's general termination provisions or (b) the acceptance date of such research materials. The option exercise period begins on the date of the agreement and ends on the earliest of (i) termination of the agreement upon failure to meet the research milestones, (ii) termination of the agreement in accordance with the agreement's general termination provisions, which include the ability of Biogen to terminate the agreement without cause on at least 60 days prior written notice beginning on the earlier to occur of (x) receipt of specified research deliverables and (y) the six month anniversary of the agreement, (iii) the date that is 24 months after the acceptance date of the research materials (subject to extension due to clinical hold), or (iv) the exercise of the option by Biogen. The commercial period begins on the option exercise date and ends with the expiration of the royalty term in all countries of the territory, subject to the agreement's general termination provisions.

The agreement further includes provisions with respect to regulatory collaboration, confidentiality, title and maintenance of intellectual property owned by the parties and developed under the agreement, liability, indemnification and insurance. Pursuant to the agreement, our know-how and intellectual property existing as of the date of the agreement and new know-how and intellectual property developed by the parties under the agreement in connection with the Accordion Pill, which is not specifically related to the collaboration product referred to in the agreement as "General Accordion Pill Technology", will be owned by us and may be used by us for products and for purposes of additional collaborations, subject to the limits of the license.

Our Competitive Strengths

We believe our principal competitive strengths include the following:

- ***A leading product candidate, AP-CDLD, being developed for the indication of treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, received a U.S. centralized IRB approval in December 2015 to initiate a Phase III clinical trial***. AP-CDLD, our leading product candidate, being developed for the indication of treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, received a U.S. centralized IRB approval in December 2015 to initiate a Phase III clinical trial. We intend to begin recruiting patients for the trial in the first half of 2016. The European Parkinson's Disease Association, or EPDA, estimated in 2007 that 6.3 million people worldwide suffer from Parkinson's disease, and a 2015 report by Global Data estimated that the pharmaceutical market for Parkinson's disease will reach $4.67 billion in the United States, Japan, France, Germany, Italy, Spain and the United Kingdom, or the Seven Major Markets, plus Brazil by 2022.

- ***Innovative and leverageable platform technology that enables us to develop multiple products and to provide substantial benefits for various classes of drugs with large potential markets***. Our platform enables us to develop and produce multiple products for diverse markets, including our leading product – AP-CDLD. Our platform includes our proprietary technology and know-how, with which we have developed the Accordion Pill, including its independent drug release and GR mechanisms, and have combined various drugs with the Accordion Pill. Our platform technology can combine immediate and controlled release drug profiles and more than one drug and can incorporate drugs of various chemical and physical characteristics. Our Accordion Pill has improved PK and efficacy in clinical studies via its combination with various drugs belonging to different drug classes such as NAW and poorly soluble drugs (BCS Class II/IV).

- ***Lower development risks and costs for our pipeline products***. We believe that developing Accordion Pills for additional drug candidates will be associated with reduced costs and regulatory risks compared to the development of NCEs and will allow us to develop our products in a cost-effective manner. The FDA has previously agreed that our two pipeline products in clinical trial stages would likely be eligible to file under Section 505(b)(2), assuming the successful completion of their respective Phase III clinical trials.

- ***No high fat or high calorie diet requirements when using our Accordion Pill products***. In our clinical trials, our Accordion Pill products provided modified PK to achieve desired clinical efficacy and safety of the drugs with which it was combined through prolonged GR under a regular calorie diet and did not require administration with a high calorie and high fat meal, which is a prerequisite for the administration of approved GR products currently on the market. This is highly important in the treatment of various diseases. In a food effect study that we conducted of our Phase III formulation of AP-CDLD, our results demonstrated that plasma concentrations of Carbidopa and Levodopa were similar, with no statistically significant differences in all PK parameters measured, when AP-CDLD was taken with various food compositions. This suggests that the treatment with AP-CDLD, intended to be taken b.i.d (two times a day) or t.i.d (three times a day) with food, is independent of food content.

- ***Strong intellectual property protection***. We believe that we have a strong intellectual property portfolio protecting our platform, combination of specific drugs with our platform and manufacturing and production processes. See "— Intellectual Property."

- ***Proven manufacturing capabilities for clinical batches of our Accordion Pill platform technology***. We have proven manufacturing capacity of clinical batches of our platform technology in a compliant GMP facility. See "— Manufacturing."

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

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

- ***Continue to advance our current pipeline by developing improved versions of drugs with reduced side effects and that enhance the efficacy of existing drugs***. We expect that our products will potentially offer significant advantages over the original versions of the drugs. Results from our completed Phase II clinical trial demonstrate that AP-CDLD can improve motor function in patients suffering "off time" episodes. "Off time" refers to debilitating periods of decreased motor and non-motor functions. We are pursuing the development and approval of AP-CDLD under the Section 505(b)(2) pathway, which allows an abbreviated path to approval relying on a single pivotal Phase III clinical trial. In December 2015 we received a U.S. centralized IRB approval to initiate a Phase III clinical trial of AP-CDLD. We intend to begin recruiting patients for the trial in the first half of 2016. If our pivotal Phase III clinical trial is successful, we intend to file for regulatory approval in the United States.

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

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

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

- ***Develop products that target significant commercial opportunities***. Our existing product candidates are directed at diseases that have major global markets. Our intent is to continue to develop products that present significant market opportunities by leveraging our According 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 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-CDLD 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.

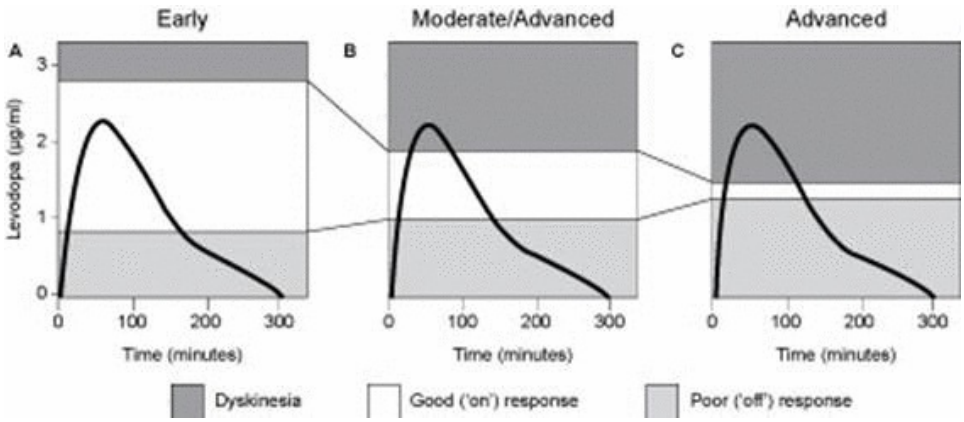
Although there is presently no cure for Parkinson's disease, there are a number of medications that provide relief from the symptoms. Dopamine replacement therapy with Levodopa is generally considered to be the most effective treatment for Parkinson's disease. After 50 years of clinical use, Levodopa 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.

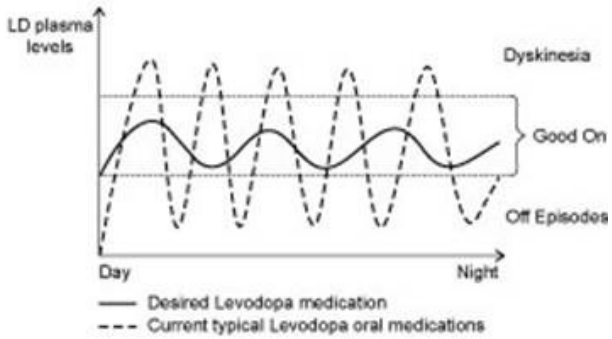
Parkinson's disease patients typically experience a satisfactory response to initial treatment with Levodopa. However, at later stages of Parkinson's disease, there is a decline in the capacity of the nigrostriatal dopaminergic system, or the brain pathways that moderate control of voluntary movement, 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 Datamonitor, 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 2015 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. The EPDA estimated in 2007 that 6.3 million people worldwide suffer from Parkinson's disease. According to a 2015 report by Global Data, the annual growth of Parkinson's disease cases in individuals over the age of 65 from 2012 to 2022, in the Seven Major Markets plus Brazil, is estimated to be 3.28%. According to Global Data, in 2012 the market for pharmaceutical treatments for Parkinson's disease was approximately $3.6 billion a year in the Seven Major Markets plus Brazil. Global Data estimates that the pharmaceutical market for Parkinson's disease will reach $4.67 billion in the Seven Major Markets plus Brazil by 2022.

Our Solution — AP-CDLD

AP-CDLD, our lead product candidate, is in development for the treatment of Parkinson's disease symptoms. AP-CDLD 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-CDLD. On May 5, 2015, we held an end of Phase II meeting with the FDA, for which we have received the FDA's memorandum of minutes, to discuss the clinical development program for AP-CDLD. We agreed with the FDA on the remaining clinical development program for AP-CDLD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, including the main principles of the single required pivotal Phase III clinical trial in advanced Parkinson's disease patients, and we amended our clinical trial protocol to submit to the FDA for review. The protocol we submitted is as follows:

- A multicenter, randomized, double-blind, double-dummy, parallel, active-controlled trial, comparing the efficacy and safety of AP-CDLD to Sinemet IR, an immediate release CDLD, which is a conventional Levodopa medication for the treatment of Parkinson's disease symptoms that is currently on the market.

- Approximately 460 advanced Parkinson's disease patients will be enrolled into the trial.

- The total treatment period for each patient will be 25 weeks, composed of:

  ™ Six weeks open-label titration on Sinemet IR (all patients);

  ™ Six weeks open-label titration on two AP-CDLD strengths, given b.i.d. or t.i.d. (all patients); and

  ™ 13 weeks double-blind, double-dummy active comparator period, in which half of the patients will be randomized to AP-CDLD and half of the patients will be randomized to Sinemet IR.

- The primary efficacy endpoint will be a change from baseline to termination of treatment in the percent of daily off time during waking hours based on Hauser home diaries.

In addition, we will be required to submit evidence of the adequate safety experience of 100 patients receiving AP-CDLD for one year, with at least 50% receiving the highest proposed dose of AP-CDLD, as is required for drugs intended for long-term treatment of non-life-threatening conditions. We intend to collect this safety data, fully or partially, from an open label extension of the Phase III study of AP-CDLD.

We also agreed, at the FDA's request, to conduct an additional bioavailability study to compare the PK between Sinemet IR and the to-be-marketed formulation of AP-CDLD because the formulation of AP-CDLD has changed from our previously completed comparative bioavailability study. We currently intend to conduct this study during 2016. The FDA also strongly suggested that we conduct additional dissolution testing and we anticipate doing so. See "— Current Regulatory Status of AP-CDLD."

In December 2015, we received a U.S. centralized IRB approval to initiate a Phase III clinical trial of AP-CDLD. We intend to begin recruiting patients for the trial in the first half of 2016.

AP-CDLD is designed to provide a combination of immediate release and a continuous release of Levodopa, in the stomach, in proximity to its absorption site through our Accordion Pill. AP-CDLD is designed to provide stable Levodopa plasma therapeutic levels, resulting in reduced total off time while reducing or avoiding inducement of troublesome dyskinesia, or involuntary movements. The stable therapeutic levels of Levodopa in a patient's plasma provided by AP-CDLD are intended to significantly reduce the motor complications because the motor complications which are associated with Levodopa treatment are strongly correlated with the drug's peripheral PK profile. More specifically, AP-CDLD is intended to reduce total off time while not increasing, or even reducing, troublesome dyskinesia.

We anticipate that AP-CDLD will be available in three dosages of Levodopa (250 mg, 400 mg and 500 mg), each provided in two release profiles (immediate release and controlled release), along with 50 mg of Carbidopa that is included in AP-CDLD. This array of dosages is designed to cover Parkinson's disease patients in various stages of the disease. AP-CDLD is designed to be taken b.i.d. and t.i.d.

AP-CDLD – Clinical Trials

Phase II Clinical Trial

Our Phase II clinical trial with AP-CDLD 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-CDLD 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-CDLD 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-CDLD 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-CDLD 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-CDLD 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

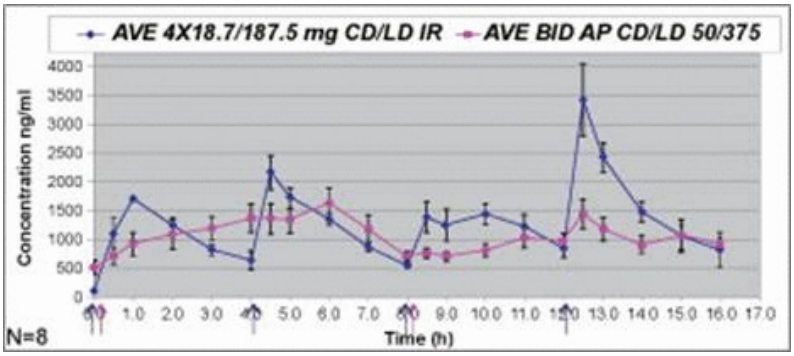
Group 1 of our Phase II clinical trial with AP-CDLD was conducted with 12 male and female patients with non-fluctuating Parkinson's disease. The crossover design included the following treatment arms: (i) AP-CDLD 50/250 mg administered b.i.d and (ii) immediate release CDLD 25/250 mg administered by half 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-CDLD was similar to the immediate release reference; (ii) AP-CDLD provided more stable plasma levels of Levodopa, with reduced peak-to-trough ratio, when compared to the immediate release reference; and (iii) AP-CDLD provided higher morning Levodopa plasma levels than the immediate release reference.

Group 3 of our Phase II clinical trial with AP-CDLD 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-CDLD treatment arm, the AP-CDLD 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-CDLD 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-CDLD 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-CDLD 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-CDLD, were significantly higher than the control; and (vi) Levodopa's high bioavailability was preserved when using AP-CDLD.

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

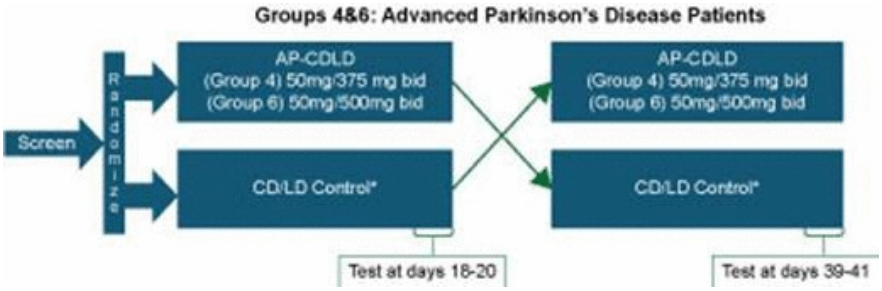
AP-CDLD Phase II clinical trial — more stable Levodopa levels with statistically significant reduced peak-to-trough fluctuations



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-CDLD. Cmax/Cmin with the AP-CDLD 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.

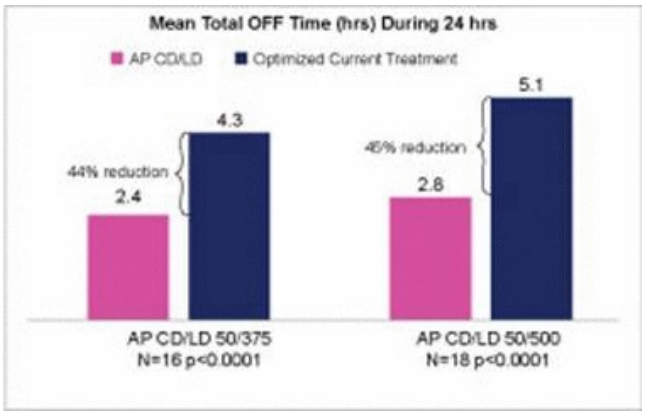
CD/LD = Carbidopa/Levodopa

Groups 3, 4 and 6 of our Phase II clinical trial examined the pharmacodynamic effects of AP-CDLD. 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-CDLD in the 50/375 mg strength, administered b.i.d. with additional CDLD immediate release tablets if needed; Group 6 tested the 50/500 mg strength administered b.i.d. with additional CDLD immediate release tablets if needed. In these three trials, AP-CDLD 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-CDLD 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-CDLD 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-CDLD 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-CDLD 50/500 mg troublesome dyskinesia was decreased by 0.5 hours (statistically significant $p = 0.002$); (iii) the effect of AP-CDLD 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-CDLD were achieved with fewer daily doses; and (v) the improvements in treating symptoms with AP-CDLD correlate with stable Levodopa plasma levels throughout the day with appropriate therapeutic levels of the drug.

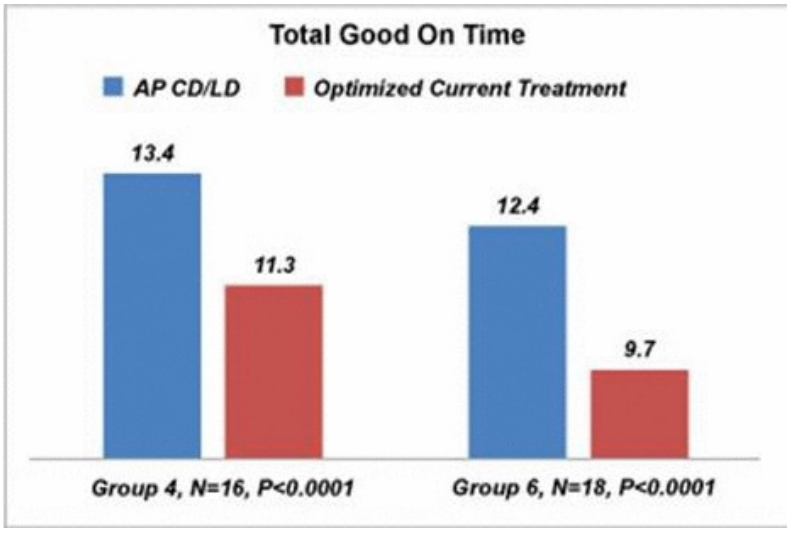
The figure below reflects the mean total off time in hours over a 24 hour period during days 18 through 20 of Groups 4 and 6. The average total off time was reduced by 1.9 hours and 2.3 hours with AP-CDLD 50/375 mg (Group 4) and 50/500 mg (Group 6), respectively. This reduction is statistically significant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

AP-CDLD – Significant reduction of total off time compared to current Levodopa treatment



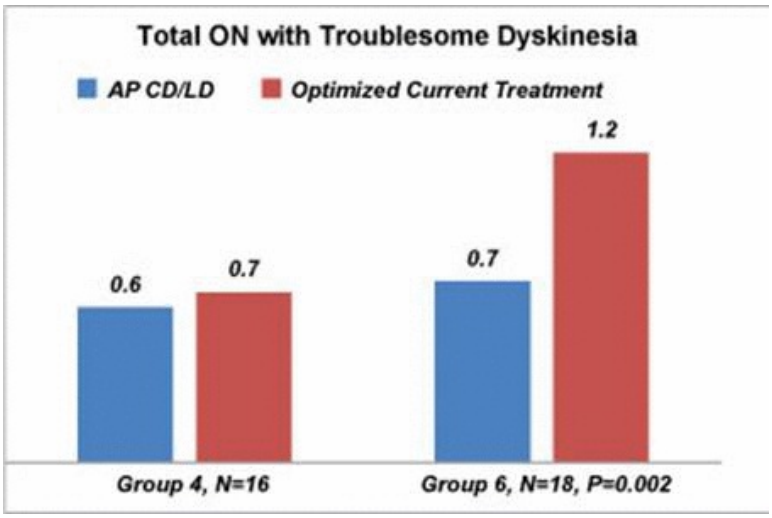
The figure below reflects the mean total "good" on time (on time without troublesome dyskinesia) in hours over a 24 hour period during days 18 through 20 of Groups 4 and 6. The average total "good" on time was increased by 2.1 hours and 2.7 hours with AP-CDLD 50/375 mg (Group 4) and 50/500 mg (Group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

AP-CDLD – Increase of total "good" on time compared to current Levodopa treatment



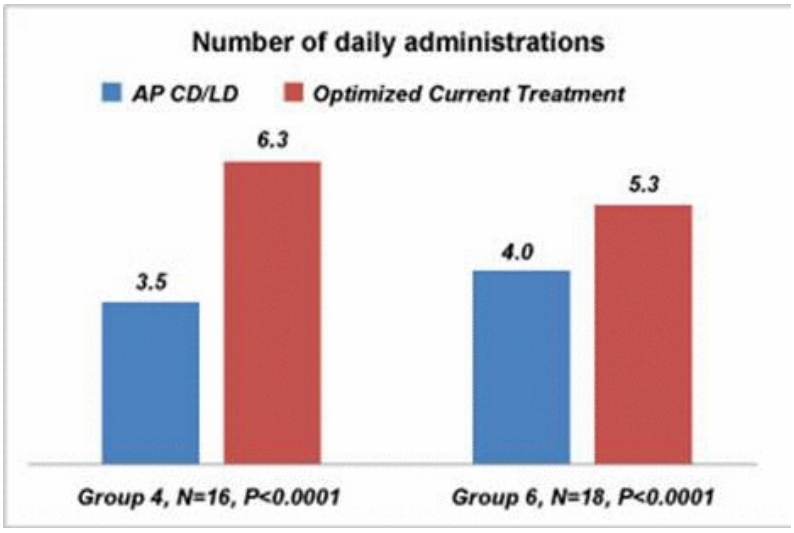
The figure below reflects the mean total on time with troublesome dyskinesia in hours over a 24 hour period during days 18 through 20 of Groups 4 and 6. On time with troublesome dyskinesia was not changed and decreased by 0.5 hours (p = 0.002) with AP-CDLD 50/375 mg (Group 4) and 50/500 mg (Group 6),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

AP-CDLD – 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-CDLD –Number of daily Levodopa administrations compared to current Levodopa treatment



* In the administration of the AP-CDLD arm, patients received b.i.d AP-CDLD 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-CDLD 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 Phase III clinical trial.

Phase I Clinical Trials

We conducted four Phase I clinical trials - three to assess the PK profile of Levodopa when administered in several formulations and one to measure the gastric retention, or 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-CDLD 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-CDLD 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 10 hours when administered with the Accordion Pill compared to approximately two hours with Sinemet.

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

Safety

AP-CDLD 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-CDLD 50/400 mg three times daily, AP-CDLD 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-CDLD.

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

Current Regulatory Status of AP-CDLD

On May 5, 2015, we held an end of Phase II meeting with the FDA, for which we have received the FDA's memorandum of minutes, to discuss the clinical development program for AP-CDLD. We agreed with the FDA on the remaining clinical development program for AP-CDLD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, including the main principles of the single required pivotal Phase III clinical trial in advanced Parkinson's disease patients, which is as follows:

- A multicenter, randomized, double-blind, double-dummy, parallel, active-controlled trial, comparing the efficacy and safety of AP-CDLD to Sinemet IR, an immediate release CDLD, which is a conventional Levodopa medication for the treatment of Parkinson's disease symptoms that is currently on the market.

- Approximately 460 advanced Parkinson's disease patients will be enrolled into the trial.

- The total treatment period for each patient will be 25 weeks, composed of:

  ™ Six weeks open-label titration on Sinemet IR (all patients);

  ™ Six weeks open-label titration on two AP-CDLD strengths, given b.i.d. or t.i.d. (all patients); and

  ™ 13 weeks double-blind, double-dummy active comparator period, in which half of the patients will be randomized to AP-CDLD and half of the patients will be randomized to Sinemet IR.

- The primary efficacy endpoint will be a change from baseline to termination of treatment in the percent of daily off time during waking hours based on Hauser home diaries.

In addition, we will be required to submit evidence of the adequate safety experience of 100 patients receiving AP-CDLD for one year, with at least 50% receiving the highest proposed dose of AP-CDLD, as is required for drugs intended for long-term treatment of non-life-threatening conditions. We intend to collect this safety data, fully or partially, from an open label extension of the Phase III study of AP-CDLD.

A Data Safety Monitoring Board, or DSMB, has been selected for the Phase III clinical trial of AP-CDLD, as is commonly done in double blind multicenter studies. The DSMB will periodically review the safety data of the trial and will specifically focus on the safety of AP-CDLD in the upper GI tract, including through gastric evaluations to be performed before and after the treatment period in the first 100 patients enrolled in the study.

We also agreed, at the FDA's request, to conduct an additional bioavailability study to compare the PK between Sinemet IR and the to-be-marketed formulation of AP-CDLD because the formulation of AP-CDLD has changed from our previously completed comparative bioavailability study. We currently intend to conduct this study during 2016. The FDA also strongly suggested that we conduct additional dissolution testing and we anticipate doing so.

In December 2015, we received a U.S. centralized IRB approval to initiate a Phase III clinical trial for AP-CDLD. We intend to begin recruiting patients for the trial in the first half of 2016. According to our current plans, the Phase III clinical trial for AP-CDLD will be conducted in 130 sites in the U.S., Europe and Israel.

AP–ZP for the Treatment of Insomnia

Insomnia

Insomnia is a condition characterized by difficulty falling asleep or maintaining sleep during the night. Chronic insomnia, or insomnia lasting more than four weeks, is often associated with a wide range of adverse conditions, including mood disturbances, difficulties with concentration and memory, and certain cardiovascular, pulmonary and GI disorders. Chronic sleep deprivation has also been associated with an increased risk of depression, diabetes and obesity, among other disorders. Historically, insomnia therapies have addressed sleep onset rather than sleep maintenance. Newer therapies have been approved with indications for sleep maintenance, although the ability of currently-available drugs to maintain sleep throughout the night without unwanted next-day residual effects remains limited.

Zaleplon, branded as Sonata, is a sedative (also called a hypnotic) approved for the treatment of insomnia. Zaleplon belongs to the nonbenzodiazepines hypnotic drug family, which is the most common type of class of drug used to treat insomnia. Zaleplon is known to induce the rapid and effective onset of sleep and generally does not have the next-day residual effects, that are characteristic of many other drugs that are currently being marketed to treat insomnia. The lack of next-day effects is largely due to Zaleplon's short half-life (approximately one hour), but, because of this short half-life, Zaleplon is cleared from the blood relatively rapidly and is generally not effective for maintaining sleep throughout the night. Thus, Zaleplon is currently not approved for a sleep maintenance indication and Zaleplon is not recommended for chronic use in the elderly. Sonata has been off patent since June 2008.

Market. Global Data estimates that, in 2013, there were approximately 140 million prevalent cases of chronic insomnia (including cases both fulfilling the definition of chronic insomnia in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV), and not fulfilling the DSM-IV criteria) in the Seven Major Markets. In 2015, Global Data estimated that the sleep disorder drug market in the Seven Major Markets will reach approximately $1.8 billion in 2023.

Although there are currently numerous drugs available for the treatment of insomnia, according to members of our Scientific Advisory Team, such as Dr. Thomas Roth, none of the currently available drugs provides a comprehensive solution that (i) rapidly induces the onset of sleep within a short time after administration, (ii) maintains continuous sleep throughout the night and (iii) has no or minimal "next-day" residual side effects, such as drowsiness or "hangover." According to Medscape from WebMD, in 2011 the Centers for Disease Control and Prevention estimated that drowsy driving contributes to an estimated 100,000 car accidents and approximately 1,500 deaths each year in the United States.

The FDA's policy with regard to insomnia drugs has been changed due to concerns regarding next day alertness and functionality. To date, the two leading insomnia drugs that are indicated for both sleep induction and sleep maintenance are Zolpidem CR and Lunesta. In May 2013, the FDA announced that patients who take modified-release formulations of Zolpidem should refrain, for the day after using the drug, from driving or engaging in any activity that requires full alertness, even if the patient has slept for the required eight-hour period after taking the drug. Further, in January 2014, the FDA ordered a reduction of the recommended dosages of certain sleep drugs that contained Zolpidem by one half due to the decline in next day functionality and alertness of people using such drugs. According to the FDA, Zolpidem was the most widely used drug in prescription sleep medications in 2011. In May 2014, the FDA ordered a reduction of the recommended starting dose of Lunesta (eszopiclone) to the minimum approved dose because eszopiclone levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving, even if the patients feel fully awake. Accordingly, we believe that, notwithstanding the expected minimal hangover effects of AP–ZP, the FDA will require the labeling for AP–ZP to carry a "next day" warning.

Our Solution – AP–ZP

AP–ZP, our second product candidate, is intended to provide a comprehensive solution for the treatment of insomnia. AP–ZP is designed, using our patented Accordion Pill technology, to induce and maintain sleep and minimize "next-day" residual side effects. Due to the short half-life of Zaleplon, minimal hangover effects are expected, improving on certain leading currently marketed treatments. However, as noted below, the FDA will require the labeling for AP–ZP to carry the required "next-day" warning relating to potential residual side effects, such as impairment of activities that require alertness. AP–ZP is an Accordion Pill that contains 25 mg to 35 mg of the generic drug Zaleplon, with combined immediate and controlled release profiles. We achieved our primary endpoints in our Phase II clinical trial of AP–ZP, and in the third quarter of 2014 we had a Type C meeting with the FDA to discuss the clinical development pathway of AP–ZP. See "— Current Regulatory Status of AP–ZP."

AP–ZP – Clinical Trials

Proof of Concept and Phase II Clinical Trial

A double-blind, three-way crossover, randomized, placebo-controlled proof of concept, or POC, study of AP–ZP was performed in two medical centers in Israel, following which a separate double-blind, two-way crossover, randomized, placebo-controlled Phase II clinical trial of AP–ZP was conducted under an IND in five medical centers in the United States and in one medical center in Israel. The POC study was initiated in October 2010 and was completed in February 2011. The Phase II clinical trial of AP–ZP was initiated in April 2011 and was completed in November 2011. Both studies assessed the efficacy, next day residual effects and safety in patients with primary insomnia, who experience difficulty both falling and staying asleep, comparing AP–ZP versus a placebo. Both studies assessed efficacy by using polysomnography, or PSG, a multi-parametric objective test for studying sleep conducted at night. The next day residual effect was assessed in both studies within one hour of waking using: Digital Symbol Substitution Test, or DSST, a neuropsychological test used to evaluate cognitive condition by having the patient match provided symbols to digits as quickly as possible, Visual Analog Scale, or VAS, a questionnaire aimed at measuring the patient's subjective impressions as to his or her cognitive condition, and memory testing.

The POC study included ten patients with primary insomnia and tested two AP–ZP strengths. This study demonstrated a trend toward improved efficacy in reducing wake time after sleep onset, or WASO, with the high dose tested. Similar trends of improved efficacy were demonstrated in the latency to persistent sleep, or LPS, and total sleep time, or TST, with the same dose. No residual sedition was found by both DSST and VAS tests in both tested strengths.

The Phase II clinical trial with AP–ZP assessed the efficacy and safety in 83 patients with primary insomnia, who experienced difficulty both falling and staying asleep, comparing AP–ZP versus a placebo. This trial used PSG. The patients each participated in six nights of PSG (two nights for each of screening, test formulation and placebo) with four to seven days between each treatment. The primary endpoint was TST, measured by both PSG and patient reports, with secondary endpoints of (i) effectiveness of sleep induction, measured as LPS and (ii) sleep maintenance, measured as WASO and number of awakenings. Residual effects were evaluated within one hour of waking using the DSST, VAS and memory testing. Safety was also evaluated.

The primary endpoint of increased TST was achieved in the Phase II clinical trial. TST measured by PSG for patients after receiving the test article was 381 minutes, in comparison to 363.9 minutes for those same patients after receiving the placebo (statistically significant p =0.002). In addition, statistically significant improvement of LPS was achieved in the Phase II clinical trial as the mean LPS for patients after receiving the test article was 31 minutes, in comparison to 45 minutes for those same patients after receiving the placebo (statistically significant ($p<0.001$). Thus, this trial revealed that when patients received AP–ZP they tended to fall asleep faster and sleep longer when compared to the placebo. This trial, through both DSST and VAS, demonstrated an important attribute of AP–ZP. AP–ZP did not show residual sedative effect when compared to a placebo. There were no clinically significant adverse events reported, and the drug was well-tolerated. The WASO for the entire night was similar between AP–ZP and the placebo; however, in a post hoc analysis, a statistically significant improvement of WASO in the first four hours of the night was demonstrated as WASO in the first four hours was 16.1 minutes for patients after receiving the test article, in comparison to 26.3 minutes for those same patients after receiving the placebo (statistically significant ($p<0.0001$). In the post hoc analysis, gender differences were found in all efficacy tested parameters.

The following table demonstrates that no residual sedition was found by both DSST and VAS with the AP–ZP as compared to the placebo:

	Least Square Means and Standard Errors			
	AP–ZP		Placebo	
Outcome Measure	Mean	Standard Error	Mean	Standard Error
DSST	41.48	0.69	41.42	0.63
VAS	57.92	1.80	54.65	1.66

We believe that these results are important in light of the FDA's growing concern related to next day effects of hypnotic drugs.

Phase I Clinical Trials

We conducted four Phase I clinical trials of which three groups assessed the PK profile of Zaleplon when administered in several formulations, and one assessed the effect of food on the overnight GR of the Accordion Pill when administered immediately, one-and-a-half, or three hours after dinner.

The first trial was an open-label trial conducted with early formulations of AP–ZP in 16 healthy volunteers to compare the PK profile of Zaleplon in two AP–ZP strengths to the currently marketed drug. The trial results indicated a significant increase in the mean MRT of Zaleplon in the plasma when administered with AP–ZP compared with the drug currently on the market.

The second PK trial was an open-label trial conducted with AP–ZP Phase II formulations in 12 healthy volunteers to compare the PK profile of Zaleplon in two AP–ZP strengths to the currently marketed drug. The trial results showed that the PK profile was significantly better when the drug was administered with the Accordion Pill. The Accordion Pill maintained the rapid appearance of the drug in the blood and the drug blood concentration level was maintained for a significantly longer period compared with the preparation currently on the market.

The third PK trial was a Phase I double-blind, crossover, randomized, four-armed trial with 32 healthy volunteers to assess the "next day effect" of two additional AP–ZP formulations. The four arms included: (i) Zopiclone, a nonbenzodiazepine hypnotic agent that is used in the treatment of insomnia and is not commercially available in the United States, as a positive control, (ii) a placebo and (iii) two doses of AP–ZP. The trial revealed no difference in next-day cognitive side-effects between the AP–ZP groups and the placebo group; cognitive side effects were observed with the usage of the commercially available Zopiclone (the positive control).

The GR trial was a MRI open-label trial conducted in 14 healthy volunteers to assess the effect of food on the overnight GR of the Accordion Pill when administered immediately, one-and-a-half, or three hours after dinner. The results showed that very good GR can also be achieved if Accordion Pill is taken one-and-a-half or three hours following dinner.

Current Regulatory Status of AP–ZP

Based on various communications with the FDA regarding the clinical development pathway of AP–ZP, including a recent Type C meeting, the FDA has indicated that:

- the duration of treatment for each patient in any Phase III clinical trial must be three months;
- the Section 505(b)(2) pathway will be appropriate for the submission of the AP–ZP NDA;
- we may be able to design the development plan of AP–ZP in a manner that would allow one single Phase III clinical trial in separate groups of females (adults and elderly) and males (adults and elderly) may suffice for an NDA submission;
- a driving safety study prior to the approval of AP–ZP will be required;
- a three month safety non-clinical study will be required prior to the initiation of the Phase III clinical trial; and
- a detailed Phase III protocol should be submitted to and approved by the FDA.

We are currently seeking a potential strategic partner for further clinical development and commercialization of AP–ZP and our future development plans for AP–ZP will depend on the results of this process.

Accordion Pill Baclofen

We previously completed a Phase I clinical trial for an Accordion Pill using the drug Baclofen, which is indicated for the treatment of spasticity. Due to changes in the projected market for Baclofen, we have no current plans to further develop or commercialize our Accordion Pill Baclofen.

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 March 2016, we completed a Phase I clinical trial for our third pipeline product candidate which is being developed for the prevention and treatment of gastroduodenal and small bowel NSAID induced ulcers. Our Phase I clinical trial was a three arm, cross-over, single dose PK study, in 18 healthy volunteers. The trial compared the plasma levels of the drug when given with two different doses of the Accordion Pill with those of the current formulation of the existing drug. The PK results demonstrated in the Phase I trial were within the well-defined safety levels of the drug, which enable us to proceed with further development of the Accordion Pill with the existing drug.

Many drugs, such as proton pump inhibitors, are currently used to protect the stomach and duodenum from NSAID induced injuries, such as ulcers. Technological improvements in the detection of the small intestine have shown that injuries associated with NSAID usage also occur frequently in the small intestine. Currently, there are no proven-effective therapies for these NSAID induced injuries in the small intestine.

NSAIDs are widely used to manage the pain of osteoarthritis, rheumatoid arthritis and other painful conditions. The most common type of arthritis is called osteoarthritis, which is one of the most frequent causes of physical disability among adults. According to a 2010 report by the National Institutes of Health, it is estimated that by 2030, 20% of Americans, or approximately 70 million people, will be over 65 years old and at increased risk for osteoarthritis. The second most common form of arthritis is rheumatoid arthritis. According to a 2013 report by Global Data, it is estimated that by 2023, approximately 2 million Americans over 18 years old will be diagnosed with rheumatoid arthritis.

Manufacturing

We are currently manufacturing the Accordion Pill in our production and packaging facility located in Har Hotzvim, in Jerusalem, Israel, in the same building as our offices. This production and packaging facility granted the Certificate of GMP Compliance of Manufacturer from the Israeli Ministry of Health in April 2014. 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 for two years as of the day it was issued.

We have the capacity to manufacture the required quantities for our Phase III study of AP-CDLD. We completed installation a fully automated assembly line in September 2015 that enables us to manufacture approximately two to three million capsules annually. We have not yet determined if we or one or more of our future commercial partners will manufacture commercial quantities of our products. See “Risk Factors — Risks Related to Our Operations in Israel.” 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.”

The FDA will likely condition granting any marketing approval, if any, on a satisfactory on-site inspection of our manufacturing facilities. See “Risk Factors — Risks Related to the Regulation of Our Company and its Business — 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 anticipate that we will continue to produce our drug products for clinical trials and, we are evaluating several alternatives for the production of our drug products for commercialization. We are considering various possibilities for manufacturing, including, among others, outsourcing or licensing the manufacturing rights to third party manufacturers or business partners, or establishing a specially designed production plant in Israel to produce our drug products for commercialization. We may also pursue a combination of producing our own drug products, outsourcing and licensing. Establishing a manufacturing facility to produce commercial quantities of our products will require a substantial investment by any party intending to manufacture our products.

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-CDLD and AP–ZP, 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 our pipeline 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.

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

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

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

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

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

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. The combined sales of this product by Novartis and Orion in 2014 were approximately $457 million.

Solvay Pharmaceuticals, which has been acquired by Abbott Laboratories, and assigned to 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 has developed a product, RytaryTM, or IPX066, a continuous release Levodopa capsule formulation. The product was approved in January 2015.

XenoPort is developing a product, XP21279, based on the chemical modification of Levodopa to enable absorption along the entire GI tract. According to its 2015 annual report, XenoPort plans to seek partners for the further development and potential commercialization of XP21279.

Depomed, Inc. has a Phase II product candidate, DM-1992, for the treatment of motor symptoms associated with Parkinson's disease. Depomed completed a Phase II study for DM-1992 and it announced a summary of the results of the Phase II study in November 2012. According to its 2014 annual report, Depomed is continuing to evaluate partnering opportunities for DM-1992 and monitoring competitive developments.

Civitas Therapeutics, Inc., which was acquired by Acorda Therapeutics, Inc. in September 2014, had a Phase IIb product candidate, 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 2014, Acorda announced the initiation of a Phase III clinical trial of CVT-301 in Parkinson's disease.

NeuroDerm Ltd. has multiple product candidates, including subcutaneous (ND0612H and ND0612L) and intra-duodenal (ND0680) administration forms, for the treatment of patients suffering from severities of Parkinson's disease. These product candidates are currently in development, ranging from planned bioequivalence trials (ND0680) to an ongoing Phase IIa trial (ND0612H and ND0612L) to completed Phase II clinical trials (ND0612L). In December 2015, NeuroDerm announced the start of patient enrollment in its Phase II Trial of ND0612H for Advanced Parkinson's disease. In addition, NeuroDerm announced that it is planning to initiate a Phase III pivotal efficacy trial for its ND0612L treatment for patients with moderate to severe Parkinson's disease as well as a long-term safety follow-up study in the first half of 2016.

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-CDLD as well, but, to our knowledge, these technologies, formulations and modifications have not yet been submitted for approval.

Current Treatments for Insomnia

There are numerous drugs in use for sleep disorders and the global market is currently controlled by drugs belonging to a group of substances that activate GABA receptors in the brain, a neurotransmitter found in the brain that is involved in sleep. These drugs include Ambien and Ambien CR from Sanofi, Zolpidem, the generic form of Ambien, zolpidem ER, the generic form of Ambien CR, Lunesta from Sepracor and Sonata from King Pharmaceuticals, which became the generic drug Zaleplon during 2008. We will also compete against other drugs commonly used for sleep disorders, including melatonin agonists such as Rozerem, several hypnotic benzodiazepines such as temazapam (Restoril) and flurazepam (Dalmane), sedating antidepressants such as trazodone (Desyrel), and orexin receptor antagonists such as suvorexant (Belsomra), a recently approved insomnia drug from Merck. Furthermore, several new drugs are currently under development for treating insomnia. Based on a survey by Global Data, the following products are in Phase II and higher developmental stages: SKP1041 (controlled-release Zaleplon) from Somnus, Piromelatine from Neurim and EVT-201 from Evotec. We are not aware of any marketed product that does not contain the "next day" warning on its label.

Government Regulation

In the United States, the FDA regulates pharmaceuticals and biologics under the FDCA and the Public Health Service Act, or PHS Act, and their 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, all 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 may begin and must be updated annually; 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 a drug, and BLA for biological product, 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. We currently have effective INDs for two of our potential products: AP-CDLD for the treatment of Parkinson's disease symptoms and AP–ZP for the treatment of insomnia.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with Current Good Clinical Practices, or cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. A protocol for each clinical trial 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 find the potential dosing range. After a safe dose has been established, the drug is administered to small populations of sick 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 research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group 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 the dangers posed by the trial are unacceptable or the product is so effective as to make it unethical to administer placebos or alternate treatments to the non-treatment arms. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

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 for one or more indications. 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.

Once the NDA submission has been accepted for filing, the FDA's goal is to review 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 where the drug product will be formulated and its drug will be produced, 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 review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data or an additional pivotal Phase III clinical trial(s), 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, a risk evaluation and strategy to mitigate risks, 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 are 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 cGMP after approval to ensure and preserve the long term stability of the drug product. 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 any deviations from cGMP 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 are 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, and 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 change 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 Orange Book, which is an FDA resource listing approved drug products with therapeutic equivalence evaluations. 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 particular condition of approval, 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.

Other U.S. Healthcare Laws and Compliance Requirements

For products distributed in the United States, we will also be subject to additional 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 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 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.

- 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 Payment Sunshine Act or Open Payments Program, imposes reporting and disclosure requirements for applicable drug and device manufacturers of covered products with regard to payments or other transfers of value made to physicians, dentists and teaching hospitals, and certain investment/ownership interests held by physicians in the reporting entity. These disclosures are publicly available.

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, exclusion from third party payor programs, such as Medicare and Medicaid, 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 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 eCommerce could result in more stringent consumer protection laws that impose additional compliance burdens on online retailers. These consumer protection laws could result in substantial compliance costs and could interfere with the conduct of our business.

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

Intellectual Property

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

Patents

As of December 31, 2015, we own or exclusively license three families of patents to use within our field of business that are registered in various countries, including in the United States, Israel, Australia, Canada, South Africa, France, Germany, Spain, Switzerland, Ireland, the United Kingdom and other countries. We have also filed patent applications with respect to eight additional patent families in various countries, four of which have active pending applications that have yet to be approved. Our patents and patent applications generally relate to gastroretentive delivery devices for oral intake of agents and the integration of drugs into our delivery systems and their production, and are expected to expire at various dates between 2020 and 2029. We also rely on trade secrets to protect certain aspects of our technology. The following discussion describes certain of what we consider to be our material patents and patent applications.

IN-1 and Yissum License Agreement

At present, among other patents, we consider our patent family 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, and which we refer to as IN-1, to be material to the operation of our business. This patent covers the gastroretentive 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 forms, and forms the foundation for the accordion technology in its most basic form. The system is intended mainly for drugs with an NAW, drugs that act locally in the digestive system and drugs whose active receptors are in the upper part of the GI tract. The system is intended for clinical use in humans and in animals. The patent is issued in the United States, Israel, Japan Australia, Canada, South Africa, the United Kingdom and six other European countries, and expires in 2020.

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

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 the 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.

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. The IN-3 family patents, which expire in 2027, except for the first United States patent of this family, which expires in 2028, allow the Accordion Pill to be manufactured in mass quantities and therefore to be more readily commercialized. We consider our licensed 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 three granted patents in the U.S. and an additional pending patent application in connection with IN-3, as well as granted patents in Israel, Europe and Japan. Importantly, the second IN-3 patent granted in the U.S. covers 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 this have already been granted in Israel and Japan.

IN-7 and IN-8

Two additional patents families (i.e., Accordion Pill with Levodopa and Zaleplon as the active ingredient, respectively) that we consider material to our business, which we refer to as IN-7 and IN-8, respectively, relate to the integration of specific drugs into Accordion Pill products. The accordion technology covered by our other patents cannot be applied in an obvious manner to any given drug that might benefit from prolonged gastroretentive release. This is because the layer structure of an Accordion Pill must 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 for which the release is indicated, the relative solubility of the particular drug molecule, and other factors. IN-7 and IN-8 relate to applications to protect the specific integration of Levodopa and Zaleplon, respectively, into an Accordion Pill. 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. These two patent applications were each filed in the United States, the European Patent Office, Japan and several other countries in April 2009. We have three granted U.S. patents for an Accordion Pill with Carbidopa/Levodopa as the active ingredient(s) (IN-7), which are in force until April 17, 2029, and applications for this patent in Israel and in South Korea have been allowed.

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

Patent applications with respect to IN-8 are still pending in some countries. European, Israeli and Chinese patents for IN-8 were granted.

General

We intend to submit patent applications for each Accordion Pill and 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 registered trademarks are registered in Israel and include RETACCORD and ACCORDION PILL. We are in the process of registering the ACCORDION PILL trademark in the United States and Europe.

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 "Risk Factors — Risks Related to Our Intellectual Property."

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 670 square meters, which includes production, packaging, warehousing and logistics areas, and our laboratory facilities of approximately 200 square meters.

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

We lease this space, which presently consists of a total area of approximately 1,770 square meters, from an unaffiliated third party, pursuant to a lease agreement which, as amended, expires June 30, 2018. Pursuant to the lease, as amended, our annual rental costs for 2015 were NIS 1.7 million (excluding VAT) and our expected rental costs for 2016 are approximately NIS 1.75 million (excluding VAT).

Although we will continue to produce product candidates ourselves for use in clinical trials, we are currently evaluating several alternatives for the production of our drug products for commercialization, including the possibility of establishing our own production plant, outsourcing or licensing the manufacturing rights to third-party manufacturers. However, at this time, no decision has been made regarding the location or method of production of our drug products for commercialization. We believe this existing property is sufficient for our needs in the foreseeable future and that we have the ability to renew our lease at market terms and expand if required.

Insurance

We have obtained directors' and officers' liability insurance with maximum coverage of $40 million in the aggregate for the benefit of our office holders and directors, effective upon the closing of our initial public offering in the United States. Such directors' and officers' liability insurance contains certain standard exclusions.

We also maintain insurance for our premises for a maximum of NIS 38.0 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 17.0 million for fixed cost and up to NIS 35.0 million for expenses related to our Phase III clinical trial for AP-CDLD. In addition, we maintain the following insurance: employer liability with coverage of NIS 20.0 million; third-party liability with coverage of NIS 20.0 million; and all risk coverage for machinery breakdown of our casting machine of approximately NIS 5.0 million.

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

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

Research Grants

Grants under the Israeli Encouragement of Industrial and Development Law

Under the Encouragement of Industrial and Development Law, 5744-1984, or the Research Law, research and development programs which meet specified criteria and are approved by a committee of the OCS are eligible for grants. The grants awarded are typically for up to 50% of the project's expenditures, as determined by the research committee. The grantee is required to pay royalties to the State of Israel on income generated from the sale of products (and related services associated with such products), whether received by the grantee or any affiliated entity (as defined in the Royalty Regulations), developed, in whole or in part, within the framework of an OCS-funded project or deriving therefrom. In accordance with the provisions of the Encouragement of Industrial Research and Development Regulations (Royalty Rates and Rules for Payment), 5756-1996, or the Royalty Regulations, royalties are paid beginning from the date of the sale of the first product developed according to an OCS-funded project at rates between 3% to 6% (though typically not greater than 4.5%) of sales of the product, depending on the situation and applicable criteria, and are payable until the repayment of the full amount of the total OCS funding, linked to the U.S. Dollar, and accrued interest (LIBOR), or in certain cases, payable up to the increased royalty cap. The terms of the Israeli government participation also require that products developed using government grants be manufactured in Israel and that the technology developed thereunder may not be transferred outside of Israel, unless approval is received from the OCS (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 abroad in the applications for funding, in which case only notification is required) and additional payments are made to the State of Israel. However, this does not restrict the export of products that incorporate the funded technology. See "Risk Factors — Risks Related to Our Operations in Israel" for additional information.

From January 1, 2009 through December 31, 2015, we received approximately NIS 32.6 million in grants from the OCS to support our research and development programs. In May and June 2015, the OCS approved a grant of up to NIS 9.1 million with respect to a follow-up program for the clinical development of the Accordion Pill for the period from January 1, 2015 through December 31, 2015. In October 2015, we submitted to the OCS a change request for the 2015 program and, consequently, the support grant was reduced to NIS 8 million. As of the date of this annual report, we have received approximately NIS 5.2 million of the 2015 grant. In December 2015, we submitted to the OCS a follow-up program for the clinical development of the Accordion Pill for the period from January 1, 2016 through December 31, 2016.

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 valid until December 31, 2017. 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 14, 2015, which is valid until July 29, 2018.

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

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

Legal Proceedings

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

ITEM 4A. Unresolved Staff Comments.

Not applicable.

ITEM 5. Operating and Financial Review and Prospects.

You should read the following discussion along with our 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." U.S. dollar amounts herein have been translated for the convenience of the reader from the original NIS amounts at the representative rate of exchange as of December 31, 2015 (NIS 3.902 = $1.00). Our actual results, performance and achievements may differ materially from those expressed in, or implied by, these forward-looking statements. See "Special Note About Forward-Looking Statements." We have prepared our financial statements in accordance with IFRS, as issued by the IASB.

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 three product candidates in clinical trial stages. Our leading product candidate, Accordion Pill Carbidopa/Levodopa, or AP-CDLD, is being developed for the indication of treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients. We have successfully completed a Phase II clinical trial for AP-CDLD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients and have agreed with the U.S. Food and Drug Administration, or the FDA, on the remaining clinical development program for AP-CDLD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, including the main principles of the single required pivotal Phase III clinical trial in advanced Parkinson's disease patients. See "Business — Current Regulatory Status of AP-CDLD." In December 2015, we received a centralized U.S. IRB approval to initiate a Phase III clinical trial for AP-CDLD. See "Business — Current Regulatory Status of AP-CDLD." Our second product candidate, Accordion Pill Zaleplon, or AP–ZP, is being developed for the indication of treatment of insomnia, including sleep induction and the improvement of sleep maintenance. We have successfully completed a Phase II clinical trial for AP–ZP for the treatment of insomnia under an Investigational New Drug, or IND, application that we submitted to the FDA on August 4, 2009 for AP–ZP as a treatment for the induction and maintenance of sleep in patients suffering from insomnia. In our correspondence with the FDA, the FDA previously agreed that an acceptable regulatory pathway for each of AP-CDLD and AP–ZP would be to file a new drug application, or NDA, pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA. See "Business — Government Regulation — 505(b)(2) Applications." The FDA has 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. However, at this point in the development process of AP-ZP, the details of such a trial have not been determined or confirmed with the FDA. In March 2016, we completed a Phase I clinical trial for our third pipeline product candidate which 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, which enable us to proceed with further development of the Accordion Pill with the existing drug.

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 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 Drug Development & Delivery, in 2006 approximately 90% of new chemical entities, or NCEs, in development were either BCS Class II or Class IV drugs. 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.

History of Losses

Since our inception, we have generated significant losses in connection with our research and development, including the clinical development of AP-CDLD and AP–ZP. As of December 31, 2015, we had an accumulated deficit of NIS 193 million (approximately $49.5 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 may continue to incur operating losses, and we may need to obtain additional funds to further develop our research and development programs and our product candidates.

As a result 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, 2015, our net loss was approximately NIS 27.9 million (approximately $7.1 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 TASE as described above), funding received from the OCS and other funds, and reimbursements received pursuant to collaborations with multinational pharmaceutical companies in connection with certain research and development activities. From our inception until our initial public offering in the United States in August 2015, we raised approximately NIS 208.7 million in various private placements, our initial public offering in Israel in February 2010 and in various rights issuances. We received approximately NIS 129.7 million (approximately $34 million) from our initial public offering in the United States in August 2015. As of December 31, 2015, we had approximately NIS 119.7 million (approximately $30.7 million) of cash, cash equivalents, short-term bank deposits and financial assets at fair value.

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 12 months ended 2013, 2014 and 2015 relate primarily to the development of AP–CDLD. 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, 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 and 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–CDLD for 2013, 2014 and 2015 were insignificant. We expect our research and development expense to remain our primary expense in the near future as we continue to develop our products. Increases or decreases in research and development expenditures are primarily attributable to the number and/or duration of the clinical studies that we conduct.

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

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

We expect our research and development expenses to increase in the future from current levels as we continue the advancement of our clinical product 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.

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.

Our general and administrative expenses, such as accounting and legal fees, have increased since we have become a public company in the United States.

Other Gains, Net

Other gains, net, consist of change in the fair value of the financial assets at fair value through profit or loss and in 2014 other gains, net, also consisted of indemnification from an insurance company.

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; change in fair value of derivative financial instruments and expenses or income resulting from fluctuations of the dollar and other currencies, in which a portion of our assets and liabilities are denominated, against the NIS (our functional currency).

Results of Operations

The table below provides our results of operations for the year ended December 31, 2015 as compared to the year ended December 31, 2014 and for the year ended December 31, 2014 compared to the year ended December 31, 2013.

	Year ended December 31,			
	2013	2014	2015	2015
	NIS in thousands			Convenience translation into USD in thousands
Statements of comprehensive loss data:				
Research and development expenses	17,410	17,740	29,257	7,498
Less-participation in research and development expenses	(8,393)	(5,544)	(10,556)	(2,705)
Research and development expenses, net	9,017	12,196	18,701	4,793
General and administrative expenses	9,633	9,332	10,828	2,775
Other gains, net	(474)	(836)	(76)	(19)
Operating loss	18,176	20,692	29,453	7,549
Financial income	(434)	(1,136)	(2,458)	(630)
Financial expenses	648	812	889	228
Financial expenses (income), net	214	(324)	(1,569)	(402)
Loss and comprehensive loss	18,390	20,368	27,884	7,147
		NIS		USD
Basic and diluted loss per ordinary share	4.25	4.22	3.58	0.92
Number of ordinary shares used in computing loss per ordinary share (in thousands)	4,322	4,825	7,791	7,791

Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

Research and Development Expenses, Net

Our research and development expenses, net, for the year ended December 31, 2015 amounted to approximately NIS 18.7 million (approximately $4.8 million), an increase of NIS 6.5 million compared to approximately NIS 12.2 million for the year ended December 31, 2014. The increase was primarily due to an increase in expenses related to preparation towards our Phase III clinical trial for AP-CDLD, payroll and related expenses and other expenses associated with our Phase III clinical trial for AP-CDLD, which were partially offset by increases in research and development-related grants and participation in research and development expenses from the OCS received in 2015 compared to 2014.

General and Administrative Expenses

Our general and administrative expenses for the year ended December 31, 2015 amounted to approximately NIS 10.8 million (approximately $2.8 million), an increase of NIS 1.5 million compared to approximately NIS 9.3 million for the year ended December 31, 2014. The increase was primarily due to an increase in professional services, payroll and related expenses and other expenses associated with being a public company in the United States.

Other Gains, Net

Our other gains, net, for the year ended December 31, 2015 amounted to approximately NIS 76,000 (approximately $19,000), compared to approximately NIS 836,000 for the year ended December 31, 2014. The other gains for the year ended December 31, 2014 consist primarily of indemnification from an insurance company in the amount of approximately NIS 887,000. Other gains, net for the year ended December 31, 2015 consists of change in the fair value of financial assets.

Operating Loss

As a result of the foregoing research and development, net, general and administrative expenses, and other gains, net, as well as our failure to generate revenues since our inception, for the year ended December 31, 2015 our operating loss was approximately NIS 29.4 million (approximately $7.6 million), an increase of NIS 8.7 million compared to our operating loss for the year ended December 31, 2014 of approximately NIS 20.7 million. This increase primarily resulted from an increase in expenses related to preparation towards our Phase III clinical trial for AP-CDLD, payroll and related expenses and other expenses associated with our Phase III clinical trial for AP-CDLD, which were partially offset by increases in research and development-related grants and participation in research and development expenses from the OCS increases in professional services, payroll and related expenses and other expenses associated with being a public company in the United States and a decrease in our other gains, net.

Financial Income (Expense), Net

For the year ended December 31, 2015, we had financial income from interest on cash equivalents and bank deposits in the amount of approximately NIS 174,000 and foreign currency exchange income in the amount of approximately NIS 2.3 million. In addition to bank fees, we also had financial expenses from change in fair value of derivative financial instruments in the amount of approximately NIS 829,000.

Loss and Comprehensive Loss

As a result of the foregoing research and development, net, general and administrative expenses, and other gains, net and financial expense/income, net, as well as our failure to generate revenues since our inception, for the year ended December 31, 2015 our loss and comprehensive loss was approximately NIS 27.9 million (approximately $7.1 million) an increase of NIS 7.5 million compared to our net loss for the year ended December 31, 2014 of approximately NIS 20.4 million. This increase primarily resulted from an increase in expenses related to preparation towards our Phase III clinical trial for AP-CDLD, payroll and related expenses and other expenses associated with our Phase III clinical trial for AP-CDLD, which were partially offset by increases in research and development-related grants and participation in research and development expenses from the OCS, increases in professional services, payroll and related expenses and other expenses associated with being a public company in the United States, an increase in our financial income, net and a decrease in our other gains, net.

Year Ended December 31, 2014 Compared to Year Ended December 31, 2013

Research and Development Expenses, Net

Our research and development expenses, net, for the year ended December 31, 2014 amounted to approximately NIS 12.2 million compared to approximately NIS 9.0 million for the year ended December 31, 2013. The increase was primarily due to the decrease in research and development-related grants received in 2014 compared to 2013 in the amount of approximately NIS 2.8 million.

General and Administrative Expenses

Our general and administrative expenses for the year ended December 31, 2014 amounted to approximately NIS 9.3 million compared to approximately NIS 9.6 million for the year ended December 31, 2013. The decrease was primarily due to a decrease in share-based compensation in the amount of approximately NIS 647,000 and an increase in professional services in the amount of approximately NIS 175,000.

Other Gains, Net

Our other gains, net, for the year ended December 31, 2014 amounted to approximately NIS 836,000, compared to approximately NIS 474,000 for the year ended December 31, 2013. The other gains for the year ended December 31, 2014 consist primarily of indemnification from an insurance company in the amount of approximately NIS 887,000. The other gains for the year ended December 31, 2013 consist of change in the fair value of the financial assets at fair value through profit or loss in the amount of approximately NIS 474,000.

Operating Loss

As a result of the foregoing research and development, net, general and administrative expenses, and other gains, net, as well as our failure to generate revenues since our inception, for the year ended December 31, 2014 our operating loss was approximately NIS 20.7 compared to our operating loss for the year ended December 31, 2013 of approximately NIS 18.2 million. This increase primarily resulted from a decrease in research and development-related grants received in 2014 compared to 2013 in the amount of approximately NIS 2.8 million.

Financial Income (Expense), Net

For the year ended December 31, 2014, we had financial income from interest on cash equivalents in the amount of approximately NIS 617,000 and foreign currency exchange income in the amount of approximately NIS 519,000. In addition to bank fees, we also had financial expenses from change in fair value of derivative financial instruments in the amount of approximately NIS 729,000.

Loss and Comprehensive Loss

As a result of the foregoing research and development, net, general and administrative expenses, and other gains, net and financial expense/income, net, as well as our failure to generate revenues since our inception, for the year ended December 31, 2014 our loss and comprehensive loss was approximately NIS 20.4 million compared to our net loss for the year ended December 31, 2013 of approximately NIS 18.4 million. This increase primarily resulted from a decrease in research and development-related grants received in 2014 compared to 2013 in the amount of approximately NIS 2.8 million, net of an increase in financial income in 2014 compared to 2013 in the amount of approximately NIS 702,000.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through public (in Israel and in the U.S.) and private offerings of our equity securities, grants from the OCS 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, 2015, we had cash and cash equivalents, short-term bank deposits and financial assets at fair value through profit or loss of approximately NIS 119.7 million (approximately $30.7 million) as compared to approximately NIS 30.1 million as of December 31, 2014.

Net cash used in operating activities was approximately NIS 30.8 million (approximately $7.9 million) for the year ended December 31, 2015 compared with net cash used in operating activities of approximately NIS 17 million for the year ended December 31, 2014. This increase primarily resulted from an increase in our loss and comprehensive loss of approximately NIS 7.5 million and an increase in changes in operating asset and liability items of approximately NIS 6.3 million.

We had negative cash flow from investing activities of approximately NIS 24.8 million (approximately $6.4 million) for the year ended December 31, 2015 compared to positive cash flow from investing activities of approximately NIS 9.7 million for the year ended December 31, 2014. The change primarily resulted from an increase in purchase of property and equipment in the amount of approximately NIS 5.4 million and from investing in a short-term bank deposit in the amount of approximately NIS 19.4 million.

We had positive cash flow from financing activities of approximately NIS 124.1 million (approximately $31.8 million) for year ended December 31, 2015 as compared to a positive cash flow from financing activities of approximately NIS 17.2 million for the year ended December 31, 2014. The positive cash flow from financing activities for the year ended December 31, 2015 was primarily due to proceeds from our initial public offering in the United States in the amount of approximately NIS 116.8 million.

As of December 31, 2015, we believe our existing cash resources will be sufficient to fund our projected cash requirements approximately through at least the next 12 months. Nevertheless, our current cash resources are not sufficient to complete the research and development of all of our product candidates and we will require significant additional financing in the future to fund our operations if and when we progress into additional clinical trials of our product candidates for their respective indications and clinical trials for other indications, obtain regulatory approval for one or more of our product candidates obtain commercial manufacturing capabilities and commercialize one or more of our product candidates.

Current Outlook

According to our estimates and based on our budget, we believe our existing cash resources will be sufficient to fund out projected cash requirements through at least the next 12 months. We believe we will need to raise significant additional funds before we have any cash flow from operations, if at all.

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. We currently anticipate that we will utilize approximately $18 million for clinical trial activities over the course of the next 12 months. 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 debt or equity financings 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, 2015 included the following (in thousands):

	Total	Less than 1 Year	1 – 3 Years	3 – 5 Years	More than 5 Years
Operating Lease Obligations in NIS	4.35 million	1.75 million	2.6 million	—	—
Operating Lease Obligations in $	1.1 million	450,000	665,000	—	—

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 "Operating and Financial Review and Prospects."

Critical Accounting Policies

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with IFRS as issued by the IASB. The preparation of these financial statements requires management 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 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 management believes 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 management's subjective or complex judgments, resulting in the need for management 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

For the purpose of the evaluation of the fair value and the manner of the recognition of share-based compensation, our management is required to estimate, among others, various parameters that are included in the calculation of the fair value of the option as well as our results and the number of options that will vest. Prior to our initial public offering in the United States, the fair value of our ordinary shares used in the calculation of the fair value of the option was the market price of our ordinary shares on the TASE. Since the completion of our initial public offering in the United States, the fair value of our ordinary shares used in the calculation of the fair value of the option is the market price of our ordinary shares on the NASDAQ Capital Market. The actual results and the estimates that are made in the future may be significantly different from the current estimates.

Financial derivatives instrument

The investors in our August 2013 financing round had the benefit of anti-dilution protection until the occurrence of the earliest of one of the following events: (1) the consummation of an initial public offering of our ordinary shares on the NASDAQ Stock Market in which we raise at least $12.0 million or a merger with a company traded on the NASDAQ Stock Market which immediately following the closure of such merger holds free and unencumbered cash and/or publically raised, prior to September 30, 2014, a cumulative amount of at least $12.0 million, (2) the consummation of a merger or acquisition event, or an M&A Event, or (3) four years from the execution of the investment agreement. During this period, in the event of the occurrence of an M&A Event or new investment in our company at a price per share that is lower than NIS 66.93, or the Protection Threshold Price, an investor who still held ordinary shares purchased in the August 2013 financing round was entitled to Downside Protection. As a result of anti-dilution shares issued to investors in our August 2013 financing round following our October 2014 rights offering, the Protection Threshold Price was effectively reduced to NIS 32.65. The sale of ordinary shares in our initial public offering in the United States at the initial public offering price of $6.00 per share required us to issue 174,566 ordinary shares to investors in our August 2013 financing round as a result of the Downside Protection based on 192,398 ordinary shares held by investors in our August 2013 financing round as of August 3, 2015 and the exercise price of the related warrants still held by investors in our August 2013 financing round was reduced from NIS 35 to NIS 21.7. The Downside Protection mechanism that was terminated following the initial public offering in the U.S. was accounted for as financial liability that was a financial derivative instrument. Under the terms of the investment agreement, the investors have the right to exercise the warrants into shares through a net-settlement mechanism. This net-settlement mechanism is accounted for as financial liability that is a financial derivative instrument.

Prior to the consummation of our initial public offering in the United States, these liabilities were measured at fair value using the Monte Carlo model, a standard valuation technique for this type of instrument, on the basis of observable inputs (such as the price of our shares, the risk-free interest and the exercise price) and unobservable inputs (such as expected volatility, expected life and the probability of potential scenarios as described in the investment agreement). Following the consummation of our initial public offering in the United States, the financial liability of the net-settlement mechanism is measured at fair value using a standard valuation technique for this type of instrument (Black-Scholes model) on the basis of various parameters (such as the price of the Company's shares, expected life, expected volatility, risk-free interest and exercise price).

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 financial statements and (iv) reduced disclosure obligations regarding executive compensation. We could remain an "emerging growth company" for up to five years from the date of our first sale of common equity securities pursuant to an effective registration statement under the Securities Act, or until the earliest of (a) the last day of the first fiscal year in which our annual gross revenue exceeds $1.0 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, setting the threshold to the nearest $1.0 million) 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 are choosing to "opt out" of this provision and, as a result, we will 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 is 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 "Risk Factors — Risks Related to Our Company and Its Business" and "Risk Factors — Risks Related to the Regulation of Our Company and Its Business."

ITEM 6. Directors, Senior Management and Employees.

A. Directors and Senior Management.

We are managed by a board of directors, which is currently comprised of six members, and our executive officers. Each of our executive officers is appointed by our board of directors. The table below sets forth our directors and executive officers as of December 31, 2015. The business address for each of our executive officers and directors is c/o Intec Pharma Ltd., 12 Hartom Street, Har Hotzvim, Jerusalem 9777512, Israel.

Name	Age	Position
Zvika Joseph	50	Chairman of the Board of Directors
Zeev Weiss	54	Chief Executive Officer and Director
Liat Flaishon	50	Vice President of Business Development and Clinical Affairs
Nadav Navon	47	Executive Vice President of Research & Development and Operations
Oren Mohar	45	Chief Financial Officer
Gil Bianco	64	External Director and Chairperson of the Audit Committee
Amir Hayek	52	Director
Hila Karah	47	Director
Issac Silberman	64	External Director and Chairperson of the Compensation Committee

Our Executive Officers and Directors

Mr. Zvika Joseph has been our chairman of the board of directors since March 2002. Mr. Joseph is the co-founder of Intec. Prior to co-founding Intec, Mr. Joseph served as head of marketing of Adgar Ltd., a public real estate investment and development company whose shares are traded on the TASE. Mr. Joseph is an experienced investment professional with diverse contacts within Israeli and European financial circles. He studied at Regent's College at the European Business School in London and holds a BSc in business administration from Mercy College in New York.

Mr. Zeev Weiss has been our Chief Executive Officer since October 2014 and has served on our board of directors since October 2014. Prior to that, he served as our Co-Chief Executive Officer from November 2013 until October 2014. Prior to serving as our Co-Chief Executive Officer, he served as our Executive Vice President of Commercial Operations commencing in September 2006. Mr. Weiss has approximately 15 years of experience in healthcare corporate development, strategic planning and corporate finance. Prior to his service with us, Mr. Weiss served as the Head of Life Sciences Strategic consulting with PricewaterhouseCoopers Israel, an accounting firm, from 2002 until 2006. He is a certified public accountant in Israel, and has a BSc in Biology, a B.A. in accounting and has completed MSc studies in neuro-biochemistry, each from Tel Aviv University in Tel Aviv, Israel.

Dr. Liat Flaishon joined us in December 2013 and was appointed as our Vice President Business Development and Clinical Affairs in March 2014. Prior to her service with us, Dr. Flaishon served as the business development director at Pluristem Therapeutics, a call-therapy biotechnology company, where she was responsible for the development of the clinical pipeline. Prior to that, from 2007 to 2011, Dr. Flaishon worked for over five years at Teva Pharmaceuticals, a pharmaceutical company, holding numerous positions, the most recent of which was the director of Drug Safety Risk Management Plans in the global pharmacovigilance department. Dr. Flaishon received her medical degree from the Sackler School of Medicine at Tel-Aviv University, and her Ph.D. in immunology from The Weizmann Institute of Science in Rehovot, Israel. Dr. Flaishon is also a board-certified internal medicine physician who worked for 10 years at the Tel-Aviv Sourasky Medical Center in Tel-Aviv, Israel.

Dr. Nadav Navon has been with us since March 2006 and has served as our Executive Vice President of Research & Development and Operations since March 2015. Before that he served as our Vice President of Research & Development and Operations since May 2013. 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 Beer-Sheva, Israel.

Oren Mohar has served as our Chief Financial Officer since January 2015. From January 2010 to December 2014, he was an Audit and Corporate Finance senior partner at PricewaterhouseCoopers in Tel Aviv, Israel. From July 2005 to December 2009, he was an Audit partner at PricewaterhouseCoopers in Tel Aviv, Israel. Prior to joining PricewaterhouseCoopers in 2002, he was a certified public accountant at Andersen in Tel Aviv, Israel. Mr. Mohar is a certified public accountant in Israel and holds a B. A. in Accounting and Business awarded by the Israeli College of Management in Rishon LeZion, Israel.

Mr. Gil Bianco has served as one of our external directors since April 2010. From November 2009 to November 2012, Mr. Bianco served as a director of D-Pharm Ltd., an Israeli public biopharmaceutical company, and from May 2007 to May 2010, Mr. Bianco served as a director of BioLineRx Ltd. (NASDAQ: BLRX), a clinical-stage biopharmaceutical development company. From December 2003 to December 2009, Mr. Bianco served as an external director of the Tel Aviv Stock Exchange Ltd. Prior to that, from 2001 to 2003, Mr. Bianco served as chief executive officer of Agis Industries Ltd., a pharmaceutical manufacturer. Mr. Bianco currently serves as an external director at Mazor Robotics Ltd. (NASDAQ: MZOR and TASE: MZOR.TA), a medical device company. Mr. Bianco is also a director of several private companies in the fields of biotech and medical devices. Mr. Bianco holds a B.A. in economics and accounting from Tel-Aviv University in Tel-Aviv, Israel and is a certified public accountant in Israel.

Mr. Amir Hayek has served as one of our directors since December 2009. Mr. Hayek was the chief executive officer of The Manufacturers Association of Israel until September 2015. Prior to joining The Manufacturers Association of Israel, Mr. Hayek was the president and chief executive officer of Electronics Line 3000, a developer, manufacturer and provider of advanced security, safety, connectivity and control solutions, and held many high-level business-related leadership roles with the Israeli government, including the chief executive officer of the Ministry of Industry and Trade, the chief executive officer of the Israeli Export Institute and economic advisor to the Minister of Industry and Trade. Mr. Hayek has also served as a director for many public and private companies, including Castro Ltd., a publicly-traded Israeli clothing company (TASE: CAST). Mr. Hayek has B.A. degrees in both economics and accounting from Tel-Aviv University in Tel-Aviv, Israel and is a certified public accountant in Israel.

Ms. Hila Karah has served as one of Intec Pharma's directors since December 2009. Ms. Karah was the chief investment officer of Eurotrust Ltd., an investment company, from 2006 until 2013, where she focused primarily on making early-stage investments in life science companies. Ms. Karah has been a private and public equity investor in several high-tech, bio-tech and internet companies since 1999. Prior to joining Eurotrust, she served as a partner and financial analyst at Perceptive Life Sciences Ltd., a New York-based hedge fund. Prior to her position at Perceptive Life Sciences, Ms. Karah was a research analyst at Oracle Partners Ltd., a healthcare-focused hedge fund based in Connecticut. Ms. Karah currently serves as a director at Cyren Ltd., a publicly-traded technology and security company (NASDAQ CYRN), a director of Labstyle Innovations Ltd., a publicly-traded biodiagnostics company headquartered in Israel (OTCMKTS: DRIO) and from May 2011 until May 2013, Mrs. Karah served as a director of Glycominds Ltd., a publicly-traded Israeli biodiagnostics company (TASE: GLCM). She has a B.A. in molecular and cell biology from the University of California, Berkeley, in Berkeley, California and has studied at the University of California, Berkeley – University of California, San Francisco School of Medicine Joint Medical Program.

Mr. Issac Silberman has served as one of our external directors since April 2010. Since 2007, Mr. Silberman has also served as a special investment advisor at Sullam Holdings L.R. Ltd., a financial services corporation in the Lenny Recanati Group, focusing primarily on investments in high-tech, biotechnology and real estate companies. Mr. Silberman also serves as a director in other private Israeli companies, and has over 20 years of prior experience as an executive officer of various public and private companies. Mr. Silberman holds a B.A. in economics and accounting from Tel Aviv University in Tel Aviv, Israel, and he is a certified public accountant in Israel.

Our Scientific Advisory Team

Our Scientific Advisory Team including specialists and experts from the United States, Europe and Israel, with experience in the fields of gastroenterology, the central nervous system, neurological diseases, and safety and regulation. Our Scientific Advisory Team plays an active role in advising us with respect to our products, technology development, clinical trials and safety. The following sets forth certain information with respect to our Scientific Advisory Team members.

Prof. Nir Giladi, a leader in the field of movement disorders, is an associate professor at the Sackler Faculty of Medicine at Tel Aviv University and chairman of the Department of Neurology at the Tel Aviv Sourasky Medical Center. Prof. Giladi has been a member of the International Movement Disorders Society (MDS) since 2010. Prof. Giladi is also a member of the International Board of the Research Group of the World Health Organization on Parkinson's Disease and other Movement Disorders. Prof. Giladi has published extensively in peer-reviewed journals and has served on the editorial boards of the *Movement Disorders Journal, Parkinsonism & Related Disorders* and the *Journal of Neural Transmission* (associate editor).

Dr. Peter LeWitt, a neurologist, is a professor of neurology at Wayne State University School of Medicine in Detroit and directs the Parkinson's Disease and Movement Disorders Program at Henry Ford Hospital in Detroit, Michigan, where he also maintains a movement disorders subspecialty practice. His clinical and basic neuroscience research has targeted neurodegenerative and symptomatic therapies for Parkinson's disease and other neurological disorders, and his range of research interests has included animal models of neurological disease, biomarkers, gene therapy and pharmacokinetic analysis. Dr. LeWitt is affiliated with the Parkinson Study Group and other clinical research consortia, and has extensive experience in clinical trials and regulatory aspects of drug development.

Dr. Werner Poewe, a neurologist, is a professor of neurology and director of the Department of Neurology at Innsbruck Medical University in Innsbruck, Austria. Dr. Poewe's main research interests are in the field of movement disorders with particular emphasis on the clinical pharmacology of Parkinson's disease and dystonia. He has authored and co-authored more than 550 original articles and reviews in the field of movement disorders. He served as President of the International Movement Disorder Society from 2000 through 2002, as President of the Austrian Society of Neurology from 2002 to 2004 and is the past President of the Austrian Parkinson's Disease Society.

Prof. Thomas Roth is the director of the Sleep Disorders and Research Center at Henry Ford Health System in Detroit, Michigan. Dr. Roth's research primarily focuses on sleep processes. His work includes research on sleep loss, sleep fragmentation and deviation from sleep processes, including pharmacological effects and sleep pathologies. Dr. Roth has held numerous leadership positions within his field. He is a former chairman of the National Center on Sleep Disorders Research Advisory Board at the National Institutes of Health and a former president of the United States Sleep Research Society, the American Sleep Disorders Association and the National Sleep Foundation. He also served as past editor-in-chief of the journal *Sleep*. In addition to his position at Henry Ford, he is a clinical professor of psychiatry at the University of Michigan School of Medicine in Ann Arbor, Michigan. He has published extensively in these areas.

Dr. James Walsh is the executive director and senior scientist of the Sleep Medicine and Research Center at St. Luke's Hospital in St. Louis, a visiting professor in the Department of Psychiatry at Stanford University and an adjunct professor of psychology at Saint Louis University. He also serves as executive director of the Academic Alliance for Sleep Research. His primary research interests include insomnia, clinical pharmacology, shiftwork and the relationship of sleep and behavior. Dr. Walsh has published extensively in these areas.

Most of the members of our Scientific Advisory team are paid for their services to us at their hourly consulting fees. We paid members of our Scientific Advisory Team an aggregate of approximately NIS 153,000 for services rendered during 2015.

B. Compensation.

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, 2015. We refer to the five individuals for whom disclosure is provided herein as our "Covered Executives." For purposes of the table below, "compensation" includes amounts accrued or paid in connection with salary cost, consultancy fees, bonuses, equity-based compensation, retirement or termination payments, benefits and perquisites such as car, phone and social benefits and any undertaking to provide such compensation. All amounts reported in the table are in terms of cost to the Company, as recognized in our financial statements for the year ended December 31, 2015, plus compensation paid to such Covered Executives following the end of the year in respect of services provided during the year. Each of the Covered Executives was covered by our D&O liability insurance policy and was entitled to indemnification and exculpation in accordance with applicable law and our articles of association.

Annual Compensation of our Senior Management

Name and Principal Position (1)	Salary (2)	Equity-Based Compensation (3)	All other compensation(4) NIS	Total	Total Convenience translation into USD
Zvika Joseph – Chairman of the Board of Directors	693,181	255,398	69,515	1,018,094	260,916
Zeev Weiss – Chief Executive Officer	691,819	71,099	60,745	823,663	211,087
Oren Mohar – Chief Financial Officer	724,779	365,370	62,437	1,152,586	295,383
Dr. Nadav Navon – Executive Vice President of Research & Development and Operations	680,067	116,511	55,489	852,067	218,367
Dr. Liat Flaishon – Vice President of Business Development and Clinical Affairs	597,532	173,051	52,378	822,961	210,970

(1) All Covered Executives, except our Chairman, are employed on a full time (100%) basis. Our Chairman is employed on a 75% basis.

(2) Salary includes the Covered Executive's gross salary plus payment of social benefits made by us on behalf of such Covered Executive. Such benefits may include, to the extent applicable to the Covered Executive, payments, contributions and/or allocations for savings funds (e.g., managers' life insurance policy), education funds (referred to in Hebrew as "keren hishtalmut"), pension, severance, risk insurances (e.g., life, or work disability insurance), payments for social security and tax gross-up payments, vacation, medical insurance and benefits, convalescence or recreation pay and other benefits and perquisites consistent with our policies.

(3) Represents the equity-based and phantom share based compensation expenses recorded in the Company's financial statements for the year ended December 31, 2015, 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 13 to our financial statements.

(4) Includes mainly leased car and mobile phone expenses.

Employment and Consulting Agreements

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. See "Risk Factors — Risks Related to Our Company and Its Business" for a further description of the enforceability of non-competition clauses. We also provide certain of our employees with a company car, which is leased from a leasing company.

Our office holders are also employed under the terms and conditions prescribed in personal contracts, with Zeev Weiss, our Chief Executive Officer, and Zvika Joseph, our chairman of the Board, being employed by us on an hourly basis and part-time, respectively. These personal contracts provide for notice periods of varying duration for termination of the agreement by us or by the relevant executive officer, during which time the executive officer will continue to receive base salary and benefits. These agreements also contain customary provisions regarding non-competition, confidentiality of information and assignment of inventions. However, the enforceability of the non-competition and assignment of inventions provisions may be limited under applicable law. See "Risk Factors — Risks Related to Our Company and Its Business."

Services and Employment Agreements with Our Chairman of the Board of Directors

Zvika Joseph

Mr. Joseph has been the chairman of our board of directors since 2002. Under Mr. Joseph's employment agreement, he is entitled to a gross monthly salary of NIS 45,000 linked to the Israeli consumer price index, and to social benefits, such as annual paid vacation days, convalescent payment, manager's insurance, sick leave vocational studies fund and disability insurance. In addition, we provide Mr. Joseph with a leased company car and a mobile phone. Mr. Joseph's employment agreement is terminable by either us or Mr. Joseph upon six months prior written notice.

As of December 31, 2015, Mr. Joseph held options to purchase 137,944 ordinary shares with a weighted exercise price of NIS 53.21, of which 40,160 were vested, 6,667 will vest over time and 91,117 will vest in the event that a material agreement, as defined in our compensation policy, is signed between us and a third party.

Services and Employment Agreements with Our Chief Executive Officer

Zeev Weiss

Mr. Weiss has served as our Chief Executive Officer since October 2014. Prior to that, he served as our Co-Chief Executive Officer alongside Mr. Giora Carni, from November 2013 until October 2014. Prior to serving as our Co-Chief Executive Officer, he served as our Executive Vice President of Commercial Operations commencing in September 2006. Mr. Weiss is an independent contractor, and pursuant to his consulting agreement with us, he is entitled to payment on an hourly basis, at the rate of NIS 315 per working hour, subject to a monthly aggregate cap of no more than 200 monthly billable working hours. The monthly consideration is linked to the Israeli consumer price index for April 2012 and is updated on a quarterly basis. In addition, we provide Mr. Weiss with a leased company car, for which we bear any expenses related thereto, and with a mobile phone. Furthermore, we will bear any travel expenses in connection with any of Mr. Weiss' travels on our behalf. Mr. Weiss's consulting agreement is terminable by either us or Mr. Weiss upon 180 days' prior written notice, or immediately by us upon certain "for cause" events. Mr. Weiss' employment agreement contains customary provisions regarding noncompetition, confidentiality of information and assignment of inventions.

As of December 31, 2015, Mr. Weiss held options to purchase 97,023 ordinary shares with a weighted exercise price of NIS 28.55, of which 37,500 were vested, 2,500 will vest over time and 57,023 will vest in the event that a material agreement, as defined in our compensation policy, is signed between us and a third party.

Services and Employment Agreement with Our Chief Financial Officer

Oren Mohar

Mr. Mohar has served as our Chief Financial Officer since January 2015. Under Mr. Mohar's employment agreement, he is entitled to a monthly gross salary of NIS 45,000, which is linked to the Israeli consumer price index for December 2014 and is updated on a quarterly basis, 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 provide Mr. Mohar with a leased company car and a mobile phone. Mr. Mohar's employment agreement is terminable by either us or Mr. Mohar upon 90 days' prior written notice. Mr. Mohar's employment agreement contains customary provisions regarding noncompetition, confidentiality of information and assignment of inventions.

As of December 31, 2015, Mr. Mohar held options to purchase 60,000 ordinary shares with an exercise price of NIS 27.93, of which 28,000 were vested, 20,000 will vest over time and 12,000 will vest in the event that a material agreement, as defined in our compensation policy, is signed between us and a third party.

Services and Employment Agreement with Our Vice President of Research & Development and Operations

Dr. Nadav Navon

Dr. Navon has served as our Executive Vice President of Research & Development and Operations since March 2015. Under Dr. Navon's employment agreement, he is entitled to a monthly gross salary of NIS 44,000, and to social benefits, such as annual paid vacation days, convalescent payment, manager's insurance, sick leave vocational studies fund and disability insurance. In addition, we provide Dr. Navon with a leased company car and a mobile phone. Dr. Navon's employment agreement is terminable by either us or Dr. Navon upon 3 months' prior written notice. Dr. Navon's employment agreement contains customary provisions regarding noncompetition, confidentiality of information and assignment of inventions.

As of December 31, 2015, Dr. Navon held options to purchase 88,200 ordinary shares with a weighted exercise price of NIS 53.10, of which 26,625 were vested, 4,375 will vest over time and 57,200 will vest in the event that a material agreement, as defined in our compensation policy, is signed between us and a third party.

Services and Employment Agreement with Our Vice President of Business Development and Clinical Affairs

Dr. Liat Flaishon

Dr. Flaishon has served as our Vice President of Business Development and Clinical Affairs since March 2014, after the completion of a successful trial period. Under Dr. Flaishon's employment agreement, she is entitled to a gross monthly salary of 38,000 NIS, and to social benefits, such as annual paid vacation days, convalescent payment, manager's insurance, sick leave, vocational studies fund and disability insurance. In addition, we provide Dr. Flaishon with a leased company car and a mobile phone. Dr. Flaishon's employment agreement is terminable by either us or Dr. Flaishon by prior written notice in accordance with the provisions of the Prior Notice Upon Termination Law (2001), or immediately by us upon certain "for cause" events. Dr. Flaishon's employment agreement contains customary provisions regarding noncompetition, confidentiality of information and assignment of inventions.

As of December 31, 2015, Dr. Flaishon held options to purchase 60,000 ordinary shares with an exercise price of NIS 39.55, of which 24,00 will vest over time and 36,000 will vest in the event that a material agreement, as defined in our compensation policy, is signed between us and a third party.

In January 2016, Dr. Flaishon submitted a resignation letter informing us of her decision to terminate her employment with the Company at the end of March 2016. We are currently in advanced stages of recruiting a substitute to Dr. Flaishon and expect to fill her position shortly after the date of this annual report on Form 20-F.

Equity Compensation Plan

We maintain 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, 2015, a total of 1,400,000 options were reserved for issuance under the 2005 Plan, of which options to purchase 816,098 ordinary shares were issued and outstanding thereunder. In addition, as of December 31, 2015, we had outstanding options to purchase 8,035 ordinary shares that were issued to consultants outside of the 2005 Plan; all of these options are vested and outstanding. Of such outstanding options, options to purchase 332,629 ordinary shares were vested as of December 31, 2015, with a weighted average exercise price of NIS 46.98 per share, and will expire between 2016 and 2020.

The 2005 Plan permits options to be awarded to Participants (as such term is defined in the 2005 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. 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 will be managed by the board of directors of the company or any other committee or person that our board of directors of authorizes for this purpose. According to our board of directors' resolution of September 19, 2005, the options granted under Section 102 of the Ordinance will be granted under the capital gains track. The 2005 Plan also permit us to grant options to U.S. residents, which may qualify as "incentive stock options" within the meaning of Section 422 of the U.S. Internal Revenue Code of 1986, as amended, or 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 shall 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, shall immediately cease and expire as of the date of such termination. If the Participant dies, retires or is disabled, any vested but unexercised options shall automatically expire 12 months from the termination of the engagement, unless expired earlier due to their term.

In the event that options allocated under the 2005 Plan expire or otherwise terminate in accordance with the provisions of the 2005 Plan, such expired or terminated options shall become available for future grant awards and allocations under the 2005 Plan.

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 Equity Incentive Plan, or the 2015 Plan. As of the date of this annual report on Form 20-F, the maximum number of ordinary shares reserved for issuance under the 2015 Plan is 700,00, subject to future adjustments. 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 permit 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 will be 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 shall automatically expire 12 months from the termination of the engagement, unless expired earlier due to their term and all unvested options shall expire upon the date of termination.

C. Board Practices.

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).

Prior to the consummation of our initial public offering in the United States, our board of directors affirmatively determined that a majority of our directors are independent in accordance with the NASDAQ Capital Market rules. Our board of directors determined that all of our directors other than Zeev Weiss and Zvika Joseph are independent under such rules. The definition of independent director under the NASDAQ Capital Market rules and external director under the Companies Law overlap to a significant degree such that we would generally expect the two directors serving as external directors to satisfy the requirements to be independent under the NASDAQ Capital Market rules. The definition of external director includes a set of statutory criteria that must be satisfied, including criteria whose aim is to ensure that there is no factor which would impair the ability of the external director to exercise independent judgment. The definition of independent director specifies similar, if slightly less stringent, requirements in addition to the requirement that the board consider any factor which would impair the ability of the independent director to exercise independent judgment. In addition, our external directors each serve for a period of three years. However, external directors must be elected by a special majority of shareholders while independent directors may be elected by a simple majority. See "— External Directors" below for a description of the requirements under the Companies Law for a director to serve as an external director.

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 required to be appointed under the Companies Law. Our board of directors currently consists of six members, including our non-executive Chairman of the board of directors. Other than our two external directors, 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, subject to the special approval requirements for external directors (See "— External 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. External directors are elected for an initial term of three years and may be elected for up to two additional three-year terms, provided that, for Israeli companies traded on NASDAQ Capital Market and certain other international exchanges, such term may be extended indefinitely in increments of additional three-year terms. External directors may be removed from office only under the limited circumstances set forth in the Companies Law. See "— External Directors."

Under the Companies Law, our board of directors must determine the minimum number of directors who are required to have accounting and financial expertise. See "— External Directors." In determining the number of directors required to have such expertise, our board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our board of directors has determined that the minimum number of directors of our Company who are required to have accounting and financial expertise is one. Our board of directors has determined that Mr. Amir Hayek, Mr. Bianco and Mr. Silberman have accounting and financial expertise and possess professional qualifications as required under the Companies Law.

Chairman of the Board

Our articles of association provide that the chairman of the board is appointed by the members of the board of directors and serves as chairman of the board throughout his term as a director, unless resolved otherwise by the board of directors. The Companies Law provides that a person, who is, directly or indirectly, subordinated to the chief executive officer of a public company, may not serve as the chairman of its board of directors. In addition, neither the chief executive officer nor his relative is eligible to serve as chairman of the board of directors (and vice versa), unless such nomination was approved by a majority of the company's shareholders for a term not exceeding three years, and either: (i) such majority included the majority of the voting shareholders (shares held by abstaining shareholders are not considered) which are not controlling shareholders and have no personal interest regarding the decision; or (ii) the aggregate number of shares voting against the proposal did not exceed 2% of company voting shareholders. The term can be extended for additional three year terms, in the same manner.

External Directors

Under the Companies Law, we are required to include at least two members who qualify as external directors, and following a recent amendment to the Companies Law, any and all such external directors are no longer required to be Israeli residents in the case of a company listed on a foreign stock exchange (such as our Company). One of the external directors must have accounting and financial expertise. Gil Bianco and Issac Silberman have served as our external directors since 2010. Mr. Bianco and Mr. Silberman were reelected to serve a second term from April 2013 and until April 2016. Our board of directors has determined that both Mr. Bianco and Mr. Silberman have accounting and financial expertise.

The provisions of the Companies Law set forth special approval requirements for the election of external directors. External directors must be elected by a majority vote of the shares present and voting at a shareholders meeting, provided that either:

- such majority includes at least a majority of the shares held by all shareholders who are non-controlling shareholders and do not have a personal interest in the election of the external director (other than a personal interest not deriving from a relationship with a controlling shareholder) that are voted at the meeting, excluding abstentions, to which we refer as a disinterested majority; or

- the total number of shares voted by non-controlling shareholders and by shareholders who do not have a personal interest in the election of the external director, against the election of the external director, does not exceed 2% of the aggregate voting rights in the company.

The term controlling shareholder is defined in the Companies Law as a shareholder with the ability to direct the activities of the company, excluding such ability deriving solely from his or her position as a director of the company or from any other position with the company. A shareholder is presumed to be a controlling shareholder if the shareholder holds 50% or more of the voting rights in a company or has the right to appoint the majority of the directors of the company or its general manager. With respect to certain matters, a controlling shareholder is deemed to include a shareholder that holds 25% or more of the voting rights in a public company if no other shareholder holds more than 50% of the voting rights in the company.

The initial term of an external director is three years. Thereafter, an external director may be reelected by shareholders to serve in that capacity for up to two additional three-year terms, except as provided below, provided that either:

(i) his or her service for each such additional term is recommended by one or more shareholders holding at least 1% of the company's voting rights and is approved at a shareholders' meeting by a disinterested majority, where the total number of shares held by non-controlling, disinterested shareholders voting for such reelection exceeds 2% of the aggregate voting rights in the company. In such event, the external director so reappointed may not be a Related or Competing Shareholder, or a relative of such shareholder, at the time of the appointment, and is not and has not had any affiliation with a Related or Competing Shareholder, at such time or during the two years preceding such person's reappointment to serve an additional term as external director. The term "Related or Competing Shareholder" means a shareholder proposing the reappointment or a shareholder holding 5% or more of the outstanding shares or voting rights of the company, provided, that at the time of the reappointment, such shareholder, the controlling shareholder of such shareholder, or a company controlled by such shareholder, have a business relationship with the company or are competitors of the company. Additionally, the Israeli Minister of Justice, in consultation with the Israeli Securities Authority, may determine matters that under certain conditions will not constitute a business relationship or competition with the company;

(ii) the external director proposed his or her own nomination, and such nomination was approved in accordance to the requirements described in the paragraph above; or

(iii) his or her service for each such additional term is recommended by the board of directors and is approved at a shareholders meeting by the same majority required for the initial election of an external director (as described above).

The term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including the NASDAQ Capital Market, may be extended indefinitely in increments of additional three-year terms, in each case provided that the audit committee and the board of directors of the company determined that in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the reelection for such additional period(s) is in the best interest of the company, and provided that the external director is reelected subject to the same shareholder vote requirements as if elected for the first time (as described above). Prior to the approval of the reelection of the external director at a general shareholders meeting, the company's shareholders must be informed of the term previously served by him or her and of the reasons, which led the board of directors and audit committee to recommend the extension of his or her tenure.

External directors may be removed from office by a special general meeting of shareholders called by the board of directors, which approves such dismissal by the same majority vote required for their election or by a court, in each case, only under limited circumstances, including ceasing to meet the statutory qualifications for appointment, or violating their duty of loyalty towards the company. If an external directorship becomes vacant and there are fewer than two external directors on the board of directors at the time, then the board of directors is required under the Companies Law to call a special shareholders' meeting as soon as practicable to appoint a replacement external director.

Each committee of the board of directors that is authorized to exercise the powers of the board of directors must include at least one external director, except that the audit committee and the compensation committee must include all external directors then serving on the board of directors. Under the Companies Law, external directors of a company are prohibited from receiving, directly or indirectly, any compensation from the company other than compensation and reimbursement of expenses amounts for their services as external directors prescribed under the Companies Law and the regulations promulgated thereunder. Compensation of an external director is determined prior to his or her appointment and may not be changed during his or her term subject to certain exceptions.

The Companies Law provides that a person is not qualified to serve as an external director if (i) the person is a relative of a controlling shareholder of the company, or (ii) if that person or his or her relative, partner, employer, another person to whom he or she was directly or indirectly subordinate, or any entity under the person's control, has or had, during the two years preceding the date of appointment as an external director: (a) any affiliation with the company, with any person or entity controlling the company or a relative of such person on the date of appointment, or with any entity controlled by or under common control with the company; or (b) in the case of a company with no shareholder holding 25% or more of its voting rights, had at the date of appointment as an external director, any affiliation with a person then serving as chairman of the board or chief executive officer, a holder of 5% or more of the issued share capital or voting power in the company or the most senior financial officer.

The term relative is defined as a spouse, sibling, parent, grandparent or descendant; spouse's sibling, parent or descendant; and the spouse of each of the foregoing persons.

The term affiliation includes (subject to certain exceptions):

- an employment relationship;
- a business or professional relationship even if not maintained on a regular basis (excluding insignificant relationships);
- control; and

- service as an office holder, excluding service as a director in a private company prior to the initial public offering of its shares if such director was appointed as a director of the private company in order to serve as an external director following the initial public offering.

Additionally, the Israeli Minister of Justice, in consultation with the ISA, is authorized to determine that certain matters will not constitute an affiliation.

The term "office holder" is defined under the Companies Law as a general manager, chief business manager, deputy general manager, vice general manager, any other person assuming the responsibilities of any of these positions regardless of that person's title, a director and any other manager directly subordinate to the general manager.

In addition, no person may serve as an external director of a company if: (i) that person's position or professional or other activities create, or may create, a conflict of interest with that person's responsibilities as a director or otherwise interfere with that person's ability to serve as an external director; (ii) at the time of appointment, such person serves as a director of another company and an external director of the other company is also a director of the company; (iii) the person is an employee of the ISA or of an Israeli stock exchange; or (iv) such person received direct or indirect compensation from the company in connection with such person's services as an external director, other than as permitted by the Companies Law and the regulations promulgated thereunder.

Following the termination of an external director's service on a board of directors, such former external director and his or her spouse and children may not receive a direct or indirect benefit by the company, its controlling shareholder or any entity under the control of its controlling shareholder. The foregoing includes engagement as an office holder or director of the company or a company controlled by its controlling shareholder or employment by, or provision of services to, any such company for consideration, either directly or indirectly, including through a corporation controlled by such former external director. This restriction extends for a period of two years with regard to the former external director and his or her spouse or child and for one year with respect to other relatives of the former external director.

If at the time at which an external director is appointed all members of the board of directors who are not controlling shareholders or relatives of controlling shareholders of the company are of the same gender, the external director to be appointed must be of the other gender.

According to regulations promulgated under the Companies Law, a person may be appointed as an external director only if he or she has professional qualifications. In addition, at least one of the external directors must be determined by our board of directors to have accounting and financial expertise. However, if at least one of our other directors (i) meets the independence requirements under the Exchange Act, (ii) meets the standards of the NASDAQ Capital Market Listing Rules for membership on the audit committee and (iii) has accounting and financial expertise as defined under Companies Law, then neither of our external directors is required to possess accounting and financial expertise as long as each possesses the requisite professional qualifications.

A director with accounting and financial expertise is a director who, due to his or her education, experience and skills, possesses an expertise in, and an understanding of, financial and accounting matters and financial statements, such that he or she is able to understand the financial statements of the company and initiate a discussion about the presentation of financial data. In determining whether the director has financial and accounting expertise the board of directors shall consider education, experience and the knowledge in the following subjects: (i) accounting issues and internal auditing issues typical to the company's industry and to companies of the same size and complexity as the company; (ii) the nature of the Internal Auditor's position in the company and his or her duties; and (iii) the preparation of financial statements and their approval subject to the Companies Law and the Israeli Securities Law.

A director is deemed to have professional qualifications if he or she has any of (i) an academic degree in economics, business management, accounting, law or public administration, (ii) an academic degree or has completed another form of higher education in the primary field of business of the company or in a field which is relevant to his/her position in the company, or (iii) at least five years of experience serving in one of the following capacities, or at least five years of cumulative experience serving in two or more of the following capacities: (a) a senior business management position in a company with a significant volume of business; (b) a senior position in the company's primary field of business; or (c) a senior position in public administration or service. The board of directors is charged with determining whether a director possesses financial and accounting expertise or professional qualifications.

Audit Committee

Our audit committee consists of Mr. Amir Hayek, along with our two external directors, Gil Bianco and Issac Silberman. Mr. Bianco serves as the Chairman of the audit committee.

Companies Law Requirements

Under the Companies Law, we are required to appoint an audit committee. The audit committee must be comprised of at least three directors, including all of the external directors, one of whom must serve as chairman of the committee. The audit committee may not include the chairman of the board of directors, a controlling shareholder of the company or a relative of a controlling shareholder, a director employed by or providing services on a regular basis to the company, to a controlling shareholder or to an entity controlled by a controlling shareholder or a director most of whose livelihood depends on a controlling shareholder.

In addition, under the Companies Law, the audit committee of a publicly traded company must consist of a majority of unaffiliated directors. An "unaffiliated director" under the Companies Law is generally defined as either an external director or as a director who meets the following criteria:

- he or she meets the qualifications for being appointed as an external director, except for the requirement that the director be an Israeli resident (which does not apply to companies such as ours whose securities have been offered outside of Israel or are listed outside of Israel); and

- he or she has not served as a director of the company for a period exceeding nine consecutive years, provided that, for this purpose, a break of less than two years in service shall not be deemed to interrupt the continuation of the service.

The Companies Law further requires that generally, any person who does not qualify to be a member of the audit committee may not attend the audit committee's meetings and voting sessions, unless such person was invited by the chairperson of the committee for the purpose of presenting on a specific subject, provided, however, that an employee of the company who is not the controlling shareholder or a relative thereof, may attend the discussions of the committee provided that the resolutions are resolved without his or her presence. A company's legal advisor and company secretary whom are not the controlling shareholder or a relative thereof may attend the meeting and voting sessions, if required by the committee.

The quorum required for the convening of meetings of the audit committee and for adopting resolutions by the audit committee is a majority of the members of the audit committee, provided such majority is comprised of a majority of independent directors, and at least one of those present is an external director.

Listing Requirements

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. Prior to the consummation of our initial public offering in the United States, our board of directors affirmatively determined that Gil Bianco is an audit committee financial expert as defined by the SEC rules and has the requisite financial experience as defined by the NASDAQ Capital Market corporate governance rules.

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

Audit Committee Role

Prior to the consummation of our initial public offering in the United States, our board of directors adopted an audit committee charter to be 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 the 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.

Our audit committee may not approve any actions requiring its approval (see "— Approval of Related Party Transactions under Israeli Law"), unless at the time of the approval a majority of the committee's members are present, which majority consists of unaffiliated directors including at least one external director.

Pursuant to a recent amendment to the Companies Law enacted on February 17, 2016, a company whose audit committee's composition meets the requirements set forth for the composition of a compensation committee (as further detailed below) is permitted to have one committee acting as both an audit and compensation committee.

Compensation Committee and Compensation Policy

Our compensation committee currently consists of Mr. Amir Hayek, Mr. Issac Silberman and Mr. Gil Bianco. Mr. Silberman serves as the Chairman of the compensation committee.

Under the Companies Law, the board of directors of a public company must appoint a compensation committee and adopt a compensation policy. The compensation committee must be comprised of at least three directors, including all of the external directors, who must constitute a majority of the members of the compensation committee, and one of the external directors must serve as chairman of the committee. However, subject to certain exceptions, Israeli companies whose securities are traded on stock exchanges such as the NASDAQ Capital Market, and who do not have a controlling shareholder, do not have to meet this majority requirement; provided, however, that the compensation committee meets other Companies Law composition requirements, as well as the requirements of the jurisdiction where the company's securities are listed. Each compensation committee member that is not an external director must be a director whose compensation does not exceed an amount that may be paid to an external director (under the Companies Law and applicable regulations). The compensation committee is subject to the same Companies Law restrictions as the audit committee as to who may not be a member of the committee.

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 company's board of directors after considering the recommendations of the compensation committee. In addition, the compensation policy needs to be approved by the company's 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 two percent 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, 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.

In accordance with the Companies Law, and following the recommendation of our compensation committee, our board of directors approved our compensation policy, and our shareholders, in turn, approved the compensation policy at our annual general meeting of shareholders that was held in January 2014. The duties of the compensation committee include the recommendation to the company's board of directors of a policy regarding the terms of engagement of office holders, to which we refer as a compensation policy. That policy must be adopted by the company's board of directors, after considering the recommendations of the compensation committee, and will need to be brought for approval by the company's shareholders, which approval requires a Special Approval for Compensation as defined below under "— Approval of related party transactions under Israeli law — Fiduciary duties of directors and executive officers."

The compensation policy must serve as the basis for decisions concerning the 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 financial statements;
- the minimum holding or vesting period for variable, equity-based compensation; and
- maximum limits for severance compensation.

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

- recommending whether a compensation policy should continue in effect, if the then-current policy has a term of greater than three years (approval of either a new compensation policy or the continuation of an existing compensation policy must in any case occur every three years);

- recommending to the board of directors periodic updates to the compensation policy;
- assessing implementation of the compensation policy; and
- determining whether the compensation terms of the chief executive officer of the company need not be brought to approval of the shareholders.

Compensation Committee Role

Under the Companies Law the compensation committee is responsible, among others, 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; and (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.

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. An internal auditor may not be:

- 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. Mr. Haim Halfon has been appointed as our internal auditor. Mr. Haim Halfon is a certified internal auditor and a partner of Amit, Halfon CPA.

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.

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 "Management — Executive Officers and Directors" 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 (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 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 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. In the context of a transaction involving a shareholder of the company, a controlling shareholder also includes a shareholder who holds 25% or more of the voting rights in the company if no other shareholder holds more than 50% of the voting rights in the company. For this purpose, the holdings of all shareholders who have a personal interest in the same transaction will be aggregated. 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. Under these regulations, a shareholder holding at least 1% of the issued share capital of the company or the voting rights may require, within 14 days of the publication of such determinations, that despite such determinations by the audit committee and the board of directors, such transaction will require shareholder approval under the same majority requirements that would otherwise apply to such transactions.

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.

Exculpation, Insurance and Indemnification of Directors and Officers

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our articles of association include such a provision. The company may not exculpate in advance a director from liability arising out of a prohibited dividend or distribution to shareholders.

Under the Companies Law, a company may indemnify an office holder in respect of the following liabilities and expenses incurred for acts performed by him or her as an office holder, either pursuant to an undertaking made in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification:

- monetary liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder (i) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (A) no indictment was filed against such office holder as a result of such investigation or proceeding; and (B) no financial liability, such as a criminal penalty, was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (ii) in connection with a monetary sanction; and

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf, or by a third party, or in connection with criminal proceedings in which the office holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent.

Under the Companies Law and the Israeli Securities Law 5728-1968, or the Israeli Securities Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder if and to the extent provided in the company's articles of association:

- a breach of the duty of loyalty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder; and
- a monetary liability imposed on the office holder in favor of a third party.

Under our articles of association, we may insure and indemnify an office holder against the aforementioned liabilities as well as the following liabilities:

- a breach of duty of care to the Company or to a third party;
- any other action which is permitted by law to insure an office holder against;
- expenses incurred and/or paid by the office holder in connection with an administrative enforcement procedure under any applicable law including the Efficiency of Enforcement Procedures in the Securities Authority Law (legislation amendments), 5771-2011 and the Israeli Securities Law, which we refer to as an Administrative Enforcement Procedure, and including reasonable litigation expenses and attorney fees; and
- a monetary liability in favor or a victim of a felony pursuant to Section 52ND of the Israeli Securities Law.

Under the Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of the duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of duty of care committed intentionally or recklessly, excluding a breach arising solely out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a civil or administrative fine or forfeit levied against the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders in a public company must be approved by the compensation committee and the board of directors and, with respect to certain office holders or under certain circumstances, also by the shareholders. See "— Approval of Related Party Transactions under Israeli Law."

Our articles of association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by the Companies Law and the Israeli Securities Law.

We have entered into agreements with each of our directors and executive officers exculpating them, to the fullest extent permitted by law and our articles of association, and undertaking to indemnify them to the fullest extent permitted by law and our articles of association. This indemnification is limited to events determined as foreseeable by the board of directors based on our activities, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances.

The maximum indemnification amount set forth in such agreements is limited to an amount which shall not exceed 25% of our shareholders equity based on our most recently audited or reviewed financial statements prior to actual payment of the indemnification amount. Such maximum amount is in addition to any amount paid (if paid) under insurance and/or by a third-party pursuant to an indemnification arrangement.

In the opinion of the SEC, indemnification of directors and office holders for liabilities arising under the Securities Act, however, is against public policy and therefore unenforceable.

We have obtained directors' and officers' liability insurance for the benefit of our office holders and intend to continue to maintain such coverage and pay all premiums thereunder to the fullest extent permitted by the Companies Law. In addition, prior to the closing of our initial public offering in the United States, we entered into agreements with each of our office holders undertaking to indemnify them to the fullest extent permitted by the Companies Law, including with respect to liabilities resulting from the offering to the extent that these liabilities are not covered by insurance.

Code of Ethics

In November 2011, our board of directors adopted a Code of Ethics that was amended in April 2014, applicable to all of our directors, officers, managers and employees, including our Chief Executive Officer, Chief Financial Officer, controller or principal accounting officer, or other persons performing similar functions. Our board of directors further amended the Code of Ethics prior to the effectiveness of the registration statement of our initial public offering in the United States so that the Code of Ethics qualifies as a "code of ethics" as defined in Item 16B of Form 20-F promulgated by the SEC. Upon the effectiveness of the registration statement of our initial public offering in the United States, the full text of the Code of Ethics was 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. If we make any amendment to the Code of Ethics or grant any waivers, including any implicit waiver, from a provision of the Code of 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. Under Item 16B of the SEC's Form 20-F, if a waiver or amendment of the Code of Ethics applies to our principal executive officer, principal financial officer, principal accounting officer or controller and relates to standards promoting any of the values described in Item 16B(b) of Form 20-F, we are required to disclose such waiver or amendment on our website in accordance with the requirements of Instruction 4 to such Item 16B.

D. Employees.

As of December 31, 2015, we had 52 employees, five of whom were employed in management, six of whom were employed in finance and administration, 34 of whom were employed in research and development and operations and seven of whom were employed in clinical trials and quality assurance. All of these employees are located in Israel.

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 (previously the Israeli Ministry of Trade, Industry and Labor). 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.

E. Share Ownership.

The following table sets forth certain information regarding the beneficial ownership of our ordinary shares as of December 31, 2015 by:

- each of our directors and executive officers;
- all of our executive officers and directors as a group; and
- each person (or group of affiliated persons) known by us to be the beneficial owner of more than 5% of the outstanding ordinary shares.

Except as otherwise indicated in the footnotes to this table, we believe the persons named in this table have sole voting and investment power with respect to all the ordinary shares indicated. The following table sets forth information relating to the beneficial ownership of our ordinary shares as of December 31, 2015.

	As of December 31, 2015	
	Ordinary Shares	%
Zvika Joseph	201,371(1)	1.76%
Zeev Weiss	97,163(2)	+
Oren Mohar	28,000(3)	+
Liat Flaishon	—	—
Nadav Navon	35,835(4)	+
Gil Bianco	10,751(5)	+
Amir Hayek	10,751(5)	+
Hila Karah	10,751(5)	+
Issac Silberman	10,751(5)	+
All executive officers and directors as a group (9 people)	405,373(6)	3.55%
Phoenix Holdings Ltd.	576,933(7)	5.04%
Cormorant Global Healthcare Master Fund, LP	800,000	6.99%
Sabby Healthcare Master Fund	670,449	5.86%
Opaleye Management Inc.	630,000	5.50%

\+ Less than 1%.

* Percentages and number of ordinary shares calculated in accordance with SEC rules and based upon 11,448,191 ordinary shares issued and outstanding as of December 31, 2015.

(1) Consists of 161,211 ordinary shares, options to purchase 20,827 ordinary shares with an exercise price of NIS 81.1 per share and with an expiration date of May 1, 2017 and options to purchase 19,333 ordinary shares with an exercise price of NIS 56.35 per share and with an expiration date of August 26, 2019. All such options have vested or will vest within 60 days of December 31, 2015.
(2) Consists of 59,663 ordinary shares, and options to purchase 37,500 ordinary shares with an exercise price of NIS 47.60 per share and with an expiration date of May 30, 2018. All such options have vested or will vest within 60 days of December 31, 2015.
(3) Options to purchase 28,000 ordinary shares with an exercise price of NIS 27.93 per share and with an expiration date of January 1, 2021. All such options have vested or will vest within 60 days of December 31, 2015.
(4) Consists of 8,585 ordinary shares and options to purchase 21,000 ordinary shares with an exercise price of NIS 42.69 per share and with an expiration date of October 13, 2016 and options to purchase 6,250 ordinary shares with an exercise price of NIS 56.35 per share and with an expiration date of August 26, 2019. All such options have vested or will vest within 60 days of December 31, 2015.
(5) Consists of options to purchase 10,751 ordinary shares with an exercise price of NIS 48.91 per share and with an expiration date of July 1, 2020. All such options have vested or will vest within 60 days of December 31, 2015.
(6) See footnotes (1) through (5).
(7) Consists of 576,933 ordinary shares. The ordinary shares are beneficially owned by various direct or indirect, majority or wholly-owned subsidiaries of the Phoenix Holding Ltd. The Phoenix Holding Ltd. is a majority-owned subsidiary of Delek Group Ltd. The majority of Delek Group Ltd.'s outstanding shares and voting rights are owned, directly and indirectly, by Itshak Sharon (Tshuva) through private companies wholly-owned by him, and the remainder is held by the public according to the following segmentation: 527,780 ordinary shares held by Phoenix Holdings Ltd. - Gemel and Pension, 2,700 ordinary shares held by Excellence Investments Ltd - mutual funds and 46,453 ordinary shares are held by Excellence Investments Ltd ETF.

None of our shareholders has different voting rights from other shareholders.

ITEM 7. Major Shareholders and Related Party Transactions.

A. Major Shareholders.

Except as set forth in "Item 6. Directors, Senior Management and Employees—E. Share Ownership", to the best of our knowledge, no other person who we know beneficially owns 5.0% or more of the Company's ordinary shares outstanding as of December 31, 2015. None of our shareholders has different voting rights from other shareholders. Other than as described herein, to the best of our knowledge, we are not owned or controlled, directly or indirectly, by another corporation, by any foreign government or by any natural person or legal persons, severally or jointly, and we are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

B. Related Party Transactions.

The following is a description of some of the transactions with related parties to which we are party and which were in effect within the past three fiscal years. The descriptions provided below are summaries of the terms of such agreements and do not purport to be complete and are qualified in their entirety by the complete agreements.

We believe that we have executed all of our transactions with related parties on terms no less favorable to us than those we could have obtained from unaffiliated third parties. See "Management — Approval of Related Party Transactions under Israeli Law."

Indemnification Agreements

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. See "Management — Exculpation, Insurance and Indemnification of Directors and Officers."

Registration Rights Agreement

The investors in our August 2013 financing round have piggyback registration rights for any ordinary shares purchased in the round or received pursuant to the exercise of warrants issued in the round. The subscription agreements with respect to such shares provided that because such shares were not included in the registration statement of our initial public offering in the United States, following the expiration or earlier waiver of the lock-up period for our initial public offering in the United States, the holders of up to 976,225 ordinary shares, consisting of (a) 522,681 ordinary shares, including 202,018 ordinary shares issued as a result of a previous Downside Protection event, (b) 198,812 ordinary shares underlying warrants issued as part of the August 2013 financial round, (c) an additional 80,166 ordinary shares underlying warrants that were issued as part of the August 2013 financing round because we did not complete certain obligations by September 30, 2014 and (d) 174,566 ordinary shares to investors in our August 2013 financing round as a result of the Downside Protection based on 192,398 ordinary shares held by investors in our August 2013 financing round as of August 3, 2015, would be entitled to request that we register such securities under the Securities Act, subject to cutback for marketing reasons and certain other conditions. In order to better define these registration rights, on July 8, 2015 we entered into a new registration rights agreement, which we refer to as the Registration Rights Agreement, with the investors who previously held such rights. The investors party to the Registration Rights Agreement have demand and piggyback registration rights with respect to the foregoing shares, subject to customary terms, conditions and limitations. As of the date hereof, 128,265 of the 320,663 ordinary shares originally issued in the August 2013 financing round have been sold on the TASE, thus we no longer have any registration rights with respect to such ordinary shares.

Employment and Consulting Agreements

We have or have had employment, consulting or related agreements with each member of our senior management. See "Management — Executive Officers and Directors — Employment and Consulting Agreements."

C. Interests of Experts and Counsel.

Not applicable.

ITEM 8. Financial Information.

A. Financial Statements and Other Financial Information.

See "Item 18. Financial Statements" for a list of all financial statements filed as part of this Annual Report on Form 20-F.

Legal Matters

We are neither party to any legal or arbitration proceedings, including those relating to bankruptcy, receivership or similar proceedings and those involving any third-party, nor any governmental proceedings pending or known to be contemplated, which may have, or have had in the recent past, significant effects on the company's financial position or profitability.

Dividend Policy

We have never declared or paid cash dividends to our shareholders. Currently we do not intend to pay cash dividends. 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, applicable Israeli law and other factors our board of directors may deem relevant. Accordingly, we have not appointed any paying agent.

In addition, the distribution of dividends is limited by the Companies Law, which permits the distribution of dividends only out of distributable profits. See "Description of Share Capital — Dividends." In addition, if we pay a dividend out of income attributed to our Benefited Enterprise during the tax exemption period, we may be subject to tax on the grossed-up amount of such income at the corporate tax rate which would have been applied to such Benefited Enterprise's income had we not enjoyed the exemption. See Item 10. Additional Information—E. Taxation—Certain Israeli Tax Considerations" for additional information.

B. Significant Changes.

No significant changes with respect to our financial statements have occurred since December 31, 2015.

ITEM 9. The Offer and Listing.

9.A.4 Offer and Listing Details

Our ordinary shares have been listed on the Nasdaq Capital Market under the symbol "NTEC" since August 4, 2015. Prior to that date, there was no public trading market for our ordinary shares in the United States. Our initial public offering was priced at $6.00 per share. The following table sets forth for the periods indicated the high and low sales prices per ordinary share as reported on the NASDAQ Capital Market:

	Low	High
Annual Information:		
2015	$ 5.25	$ 6.19
Quarterly Information		
Third Quarter 2015 (commencing August 4, 2015)	$ 5.26	$ 6.19
Fourth Quarter 2015	5.25	6.15
Monthly Information:		
August 2015	$ 5.26	$ 6.19
September 2015	5.38	6.19
October 2015	5.36	6.09
November 2015	5.30	6.15
December 2015	5.25	5.99

Our ordinary shares have been listed on the TASE under the symbol "INTP" since February 14, 2010. Prior to that date, there was no public trading market for our ordinary shares in Israel. Our initial public offering was priced at NIS 45.28 per share. The following table sets forth for the periods indicated the high and low sales prices per ordinary share as reported on the TASE:

	Low	High
Annual Information:		
2015	NIS 20.15	NIS 36.80
Quarterly Information		
First Quarter 2015	NIS 23.80	NIS 31.05
Second Quarter 2015	26.60	36.80
Third Quarter 2015	20.15	36.42
Fourth Quarter 2015	20.57	24.00
Monthly Information:		
July 2015	NIS 28.74	NIS 36.42
August 2015	20.15	33.80
September 2015	21.00	23.81
October 2015	20.57	22.98
November 2015	21.30	24.00
December 2015	20.66	23.00

9.B. Plan of distribution

Not applicable.

9.C. Market for Ordinary Shares

Our ordinary shares have been quoted on the NASDAQ Capital Market since August 4, 2015 under the symbol "NTEC" and on the TASE since 2010 under the symbol "INTP".

9.D. Selling shareholders

Not applicable.

9.E. Dilution

Not applicable.

9.F. Expenses of the issue

Not applicable.

ITEM 10. Additional Information.

A. Share Capital.

Not applicable.

B. Memorandum and Articles of Association.

The following are summaries of material provisions of our articles of association and the Companies Law insofar as they relate to the material terms of our ordinary shares.

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. Shareholders may vote at shareholder meetings either in person, by proxy or by written ballot. Israeli 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. Except as otherwise disclosed herein, 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 (or the consent in writing of all the holders of such class of shares). Our number with the Israeli Registrar of Companies is 513022780. Our purpose is set forth in Section 3 of our articles of association and includes every lawful purpose.

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.

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.

Our articles of association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Companies Law and must be approved by a resolution duly passed by our shareholders at a general 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 (ii) one or more shareholders holding, in the aggregate, 5% of the our issued share capital and 1% of our outstanding voting power or 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 of directors and appointment and dismissal of external directors;
- approval of acts and transactions requiring general meeting approval pursuant to the Companies Law;
- director compensation, indemnification and change of the principal executive officer;
- 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
- 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.

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. Consequently, our articles of association do not allow shareholders 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 25% 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, any number of our shareholders present in person or by proxy shall constitute a lawful quorum.

Resolutions

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

Israeli law provides that 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 provision allowing the vote by written ballot does not apply where the voting power of the controlling shareholder is sufficient to determine the vote.

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 registered 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 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, 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, articles of association, financial statements and any document it is required by law to file publicly with the Israeli Companies Registrar and the 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 shareholder 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 (6) 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 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, 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.

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 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, the ISA's 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, which do not provide for sufficient legal restrictions on obtaining control or an obligation to make a tender offer to the public, therefore the special tender offer requirements shall apply to such companies.

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 annual report, 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. In addition, the rules and regulations of the TASE also limit the terms permitted with respect to a new class of shares and prohibit any such new class of shares from having voting rights. Shareholders voting in such meeting will be subject to the restrictions provided in the Companies Law as described above.

C. Material Contracts

The following are summary descriptions of certain material agreements to which we are a party. The descriptions provided below do not purport to be complete and are qualified in their entirety by the complete agreements, which are attached as exhibits to this annual report on Form 20-F.

For a description of our material agreements relating to our strategic collaborations and research arrangements and other material agreements, please refer to "Item 4. Information on the Company."

Employment Agreements

See "Item 6. Directors, Senior Management and Employees—B. Compensation—Employment Agreements and Arrangements with Directors and Related Parties."

D. Exchange Controls.

There are no Israeli government laws, decrees or regulations that restrict or that affect our export or import of capital or the remittance of dividends, interest or other payments to non-resident holders of our securities, including the availability of cash and cash equivalents for use by us and our wholly-owned subsidiaries, except for ownership by nationals of certain countries that are, or have been, declared as enemies of Israel or otherwise as set forth under "Item 10. Additional Information—E. Taxation."

E. Taxation.

The following is a summary of the material Israeli tax laws applicable to us, and some Israeli Government programs benefiting us. This section also contains a discussion of some Israeli tax consequences to persons owning our ordinary shares. This summary does not discuss all the aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of this kind of investor include traders in securities or persons that own, directly or indirectly, 10% or more of our outstanding voting capital, all of whom are subject to special tax regimes not covered in this discussion. Some parts of this discussion are based on a new tax legislation which has not been subject to judicial or administrative interpretation. The discussion should not be construed as legal or professional tax advice and does not cover all possible tax considerations.

SHAREHOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS AS TO THE ISRAELI OR OTHER TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES, INCLUDING, IN PARTICULAR, THE EFFECT OF ANY FOREIGN, STATE OR LOCAL TAXES.

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax on their taxable income at the rate of 25% for the 2016 tax year. However, the effective tax rate payable by a company that derives income from an Approved Enterprise, a Benefited Enterprise or a Preferred Enterprise (as discussed below) may be considerably less. Capital gains derived by an Israeli company are subject to tax at the prevailing corporate tax rate.

Law for the Encouragement of Industry (Taxes), 1969

We believe that we qualify as an "Industrial Company" within the meaning of the Law for the Encouragement of Industry (Taxes), 1969, or the Industry Encouragement Law. The Industry Encouragement Law provides several tax benefits for "Industrial Companies."

The Industry Encouragement Law defines an "Industrial Company" as an Israeli resident company incorporated in Israel, of which 90% or more of its income in any tax year, other than income from defense loans, is derived from an "Industrial Enterprise" owned by it and located in Israel or in the "Area", in accordance with the definition in the section 3a of the Income Tax Ordinance, or the Ordinance. An "Industrial Enterprise" is defined as an enterprise which is held by an Industrial Enterprise whose principal activity in a given tax year is production activity.

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

- amortization over an eight-year period of the cost of patents and rights to use a patent and know-how that were purchased in good faith and are used for the development or advancement of the Industrial Enterprise, commencing from the tax year where the Industrial Enterprise began to use them;
- under certain conditions, an election to file consolidated tax returns with related Israeli Industrial Companies; and
- expenses related to a public offering are deductible in equal amounts over three years.

There can be no assurance that we will continue to qualify as an Industrial Company or that the benefits described above will be available to us in the future.

Tax Benefits under the Law for the Encouragement of Capital Investments, 1959

Tax benefits prior to the 2005 Amendment

The Law for the Encouragement of Capital Investments, 1959, generally referred to as the "Investments Law", provides that a capital investment in eligible facilities may, upon application to the Investment Center of the Ministry of Industry, Trade and Labor of the State of Israel the ("Investment Center"), be granted the status of an Approved Enterprise. Each certificate of approval for an Approved Enterprise relates to a specific investment program delineated both by its financial scope, including its capital sources, and by its physical characteristics, e.g., the equipment to be purchased and utilized pursuant to the program.

The tax benefits under the Investments Law also apply to income generated by a company from the grant of a usage right with respect to know-how developed pursuant to the Approved Enterprise, income generated from royalties, and income derived from a service which is auxiliary to such usage right or royalties, provided that such income is generated within the ordinary course of business of the company investing in the Approved Enterprise.

If a company has more than one approval or only a portion of its capital investments are approved, its effective tax rate is the result of a weighted average of the applicable rates. The Tax Benefits under the Investments Law are not, generally, available with respect to income derived from products manufactured outside of Israel. In addition, the Tax Benefits available to a company investing in an Approved Enterprise are contingent upon the fulfillment of conditions stipulated in the Investments Law and related regulations and the criteria set forth in the specific certificate of approval, as described above. In the event that a company does not meet these conditions, it would be required to refund the amount of tax benefits, plus a consumer price index linked adjustment and interest.

A company which qualifies as a foreign investment company (a "FIC") will be eligible for a three-year extension of tax benefits following the expiration of the seven-year period referenced above. In addition, in the event that the level of foreign ownership in an Approved Enterprise reaches 49% or higher, the corporate tax rate applicable to income earned from the Approved Enterprise is reduced as follows:

% of Foreign Ownership	Tax Rate
49% or more but less than 74%	20%
74% or more but less than 90%	15%
90% or more	10%

A company qualifies as a FIC if (i) it has received at least NIS 5 million in loans (for a minimum period of three years) or as investment in share capital from a foreign resident who is consequently entitled to at least 25% of the "rights" in the company (consisting of profit sharing rights, voting rights and appointment of directors), or (ii) if a foreign resident has purchased the company's shares from an existing shareholder, consequently entitling the foreign shareholder to at least 25% of such rights in the company provided that the company's outstanding and paid-up share capital exceeds NIS 5 million The determination as to whether a company qualifies as an FIC is made on an annual basis.

Amendment 68 to the Investments Law (the "2011 Amendment") eliminated the definition of a FIC. However, according to the 2011 Amendment's transitional provisions, the tax benefits of companies with Approved Enterprise or Benefited Enterprise plans that opt to remain under the Approved Enterprise or Benefited Enterprise regime in accordance with the Investments Law prior to the 2011 Amendment will be preserved. In circular no. 3/2012, (the "Circular") the Israeli Tax Authority addressed its position regarding the implementation of the aforementioned transitional provisions. According to the Circular, a company's foreign ownership percentage for purposes of Approved Enterprise or Benefited Enterprise benefits cannot exceed its percentage on December 31, 2010, the last day before the 2011 Amendment was implemented.

Additionally, a company owning an Approved Enterprise on or after April 1, 1986, may elect to forgo its entitlements to grants and tax benefits under the Grant Track and apply for alternative package of tax benefits for a benefit period of between seven and ten years (the "Alternative Track"). Under the Alternative Track, a company's undistributed income derived from the Approved Enterprise will be exempt from corporate tax for a period of between two and ten years, starting from the first year the company derives taxable income under the Approved Enterprise program. The length of time of this exemption will depend on the geographic location of the Approved Enterprise within Israel and the type of the approved enterprise. After the exemption period lapses, the company subject to tax at a tax rate of 25% (or a lower rate in the case of a FIC) for the remainder of the benefit period.

A company that has elected the Alternative Track and subsequently pays a dividend out of income derived from the Approved Enterprise during the tax exemption period will be subject to corporate tax on the amount which is determined by the distributed amount grossed up with the effective corporate tax rate which would have been applied had the company not elected the Alternative Track, which is at referred above ranged between 10%-25%. Under the Investments Law, the transfer of funds from the Company to shareholders and other related parties may be deemed to be regarded as a dividend distribution for this purpose in certain circumstances. Dividends paid out of income derived from an Approved Enterprise are generally subject to withholding tax at source at the reduced rate of 15%, if the dividend is distributed during the tax exemption period or within 12 years thereafter. In the event, however, which the company qualifies as a FIC, there is no such time limitation) or such lower rate as may be provided in an applicable tax treaty.

Under the Alternative Track, dividends paid by a company are considered to be attributable to income received from the entire company and the company's effective tax rate is the result of a weighted average of the various applicable tax rates, excluding any tax-exempt income. Under the Investments Law, a company that has elected the Alternative Track is not obliged to distribute retained profits, and may generally decide from which year's profits to declare dividends.

The Company is not entitled to an Approved Enterprise status.

Tax benefits under the 2005 Amendment

An amendment to the Investments Law, which effective as of April 1, 2005, has changed certain provisions of the Investments Law. An eligible investment program under the Amendment qualifies for benefits as a "Benefited Enterprise" (rather than as an Approved Enterprise which status is still applicable for investment programs approved prior to December 31, 2004 and/or investment programs under the Grant Track). According to the amendment, only Approved Enterprises receiving cash grants require the prior approval of the Investment Center.

The duration of the tax benefits described herein is limited to the earlier of seven or ten years (depending on the geographic location of the Approved Enterprise within Israel) from the Commencement Year (as described below) or 12 years from the first day of the Year of Election. Commencement Year is defined as the later of the first tax year in which a company had derived liable income for tax purposes from the Benefited Enterprise, or the year of election which is the year in which a company requested to have the tax benefits apply to the Benefited Enterprise. The tax benefits granted to a Benefited Enterprise are determined, depending on the geographic location of the Benefited Enterprise within Israel, according to one of the following, which may be applicable to us:

(i) Similar to the currently available Alternative Track, exemption from corporate tax may be available on undistributed income for a period of two to ten years, depending on the geographic location of the Benefited Enterprise within Israel, and a reduced corporate tax rate of 10% to 25% for the remainder of the benefit period, depending on the level of foreign investment in each year. Benefits may be granted for a term of seven to ten years, depending on the level of foreign investment in the company. If the company pays a dividend out of income derived from the Benefited Enterprise during the tax exemption period, such income will be subject to deferred corporate tax with respect to the amount distributed (grossed up with the effective corporate tax rate which would have applied had the company not enjoyed the exemption) at the rate which would have applied had such company had the status of a Benefited Enterprise. The company is required to withhold tax on such distribution at a rate of 15%, or such lower rate may be provided in an applicable tax treaty; or

(ii) A special track which enables companies owning facilities in certain geographical locations in Israel to pay corporate tax at a flat rate of 11.5% on income the Benefited Enterprise (the "Ireland Track"). The benefit period is for ten years. Upon payment of dividends, the company is required to withhold tax on such dividend at a rate of 15% for Israeli residents and at a rate of 4% for foreign residents.

Generally, a company that is Abundant in Foreign Investment (owned by at least 74% foreign shareholders and has undertaken to invest a minimum sum of $20 million in the Benefited Enterprise) is entitled to an extension of the benefit period by an additional five years, depending on the rate of its income that is derived in foreign currency.

Under the Investments Law, we may be entitled to tax benefits, by virtue of our status as a "Benefited Enterprise," which was awarded to us in October 2007. We received the status of a plant under establishment in Development Area A in a tax-exempt track, subject to compliance with the applicable requirements of the Investment Law. As of December 31, 2015, we had not yet generated operating income that will allow us to benefit from the tax benefits under the Investment Law. The tax benefits under the Investment 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.

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.

Tax benefits under the 2011 Amendment

On December 29, 2010, the Israeli Parliament approved the 2011 Amendment. The 2011 Amendment significantly revised the tax incentive regime in Israel and commenced on January, 1 2011.

The 2011 Amendment introduced a new status of "Preferred Enterprise", replacing the existed status of "Benefited Enterprise". Similarly to a "Beneficiary Company", a Preferred Company is an industrial company meeting certain conditions (including a minimum threshold of 25% export). However, under the 2011 Amendment the requirement for a minimum investment in productive assets in order to be eligible for the benefits granted under the Investments Law as with respect to "Benefited Enterprise" was cancelled.

A Preferred Company is entitled to a reduced flat tax rate with respect to the income attributed to the Preferred Enterprise, at the following rates:

Tax Year	Development Region "A"	Other Areas within Israel
2011-2012	10%	15%
2013	7%	12.5%
2014 onwards*	9%	16%

* In august 2013, the Israeli Parliament (the Knesset) approved an amendment to the Investments Law pursuant to which the previously scheduled gradual reduction in the tax rates applicable to Preferred Enterprises would be repealed as of 2014 to the tax rates reflected on the above table.

The classification of income generated from the provision of usage rights in know-how or software that were developed in the Preferred Enterprise, as well as royalty income received with respect to such usage, as Preferred Enterprise income is subject to the issuance if a pre-ruling from the Israeli Tax Authority stipulates that such income is associated with the productive activity of the Preferred Enterprise in Israel.

In addition, the 2011 Amendment introduced a new status of "Special Preferred Company", which is an Industrial company meeting, in addition to the conditions prescribed for "Preferred Company," certain additional conditions (including that the total Preferred Enterprise income is at least NIS 1.5 billion in the given tax year). The tax rate applicable for a period of 10 years to income generated by such an enterprise will be reduced to 5%, if located in Development Region "A", or to 8%, if located in other area within the State of Israel.

Dividends distributed from income which is attributed to a "Preferred Enterprise" or a "Special Preferred Enterprise" will be subject to withholding tax at source at the following rates: (i) Israeli resident corporations – 0%, (ii) Israeli resident individuals – 20% (iii) non-Israeli residents - 20%, subject to a reduced tax rate under the provisions of an applicable double tax treaty.

The 2011 Amendment also revised the Grant Track to apply only to the approved programs located in Development Region "A" and shall provide not only cash grants (as prior to the Amendment) but also the granting of loans. The rates for grants and loans shall not be fixed but up to 20% of the amount of the approved investment (may be increased with additional 4%). In addition, a company owning a Preferred Enterprise under the Grant Track may be entitled also to the tax benefits which are prescribed for a Preferred Company.

The provisions of the 2011 Amendment shall not apply to existing "Benefited Enterprises" or "Approved Enterprises", which will continue to be entitled to the tax benefits under the Investment Law, as has been in effect prior to the New Amendment, unless the company owning such enterprises had made an election to apply the provisions of the 2011 Amendment (such election cannot be later rescinded), which is to be filed with the Israeli Tax Authority, not later than the date prescribed for the filing of the company's annual tax return for the respective year.

We have examined the possible effect, if any, of the provisions of the 2011 Amendment on our financial statements and have decided, at this time, not to apply for the new benefits under the 2011 Amendment.

Taxation of the Company Shareholders

Capital Gains

Capital gain tax is imposed on the disposal of capital assets by an Israeli resident, and on the disposal of such assets by a non-Israel resident if those assets are either (i) located in Israel; (ii) are shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel. The Ordinance distinguishes between "Real Gain" and the "Inflationary Surplus". Real Gain is the excess of the total capital gain over Inflationary Surplus computed generally on the basis of the increase in the Israeli CPI between the date of purchase and the date of disposal.

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

The real capital gain derived by corporations will be generally subject to the ordinary corporate tax (25% in 2016).

Individual and corporate shareholder dealing in securities in Israel are taxed at the tax rates applicable to business income – 25% for corporations in 2016 and a marginal tax rate of up to 50% in 2016 for individuals, including a 2% excess tax for high earning individuals whose taxable income from Israeli sources exceeds a certain threshold (approximately NIS 811,000 in 2016). Notwithstanding the foregoing, capital gain derived from the sale of our ordinary shares by a non-Israeli shareholder may be exempt under the Ordinance from Israeli taxation provided that the following cumulative conditions are met: (i) the shares were purchased upon or after the registration of the securities on the stock exchange (this condition shall not apply to shares purchased on or after January 1, 2009), (ii) the seller does not have a permanent establishment in Israel to which the derived capital gain is attributed. Non-Israeli corporations will not be entitled to the foregoing exemptions if (i) an Israeli resident has a controlling interest, directly or indirectly, alone or together with another (i.e., together with a relative, or together with someone who is not a relative but with whom, according to an agreement, there is regular cooperation in material matters of the company, directly or indirectly), or together with another Israeli resident, exceed 25% in one or more of the means of control in such non-Israeli resident corporation or (ii) Israeli residents are the beneficiaries of, or are entitled to, 25% or more of the revenues or profits of such non-Israeli resident corporation, whether directly or indirectly.

In addition, the sale of shares may be exempt from Israeli capital gain tax under the provisions of an applicable tax treaty.

For example, the U.S.-Israel Double Tax Treaty exempts U.S. resident from Israeli capital gain tax in connection with such sale, provided (i) the U.S. resident owned, directly or indirectly, less than 10% of an Israeli resident company's voting power at any time within the 12 month period preceding such sale; (ii) the seller, being an individual, is present in Israel for a period or periods of less than 183 days at the taxable year; and (iii) the capital gain from the sale was not derived through a permanent establishment of the U.S. resident in Israel.

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

Either the purchaser, the Israeli stockbrokers or financial institution through which the shares are held is obliged, subject to the above mentioned exemptions, to withhold tax upon the sale of securities on the amount of the consideration paid upon the sale of the securities (or on the real capital gain realized on the sale, if known), at the rate of 25% in respect of a corporation and/or an individual.

At the sale of securities traded on a stock exchange a detailed return, including a computation of the tax due, must be filed and an advanced payment must be paid on January 31 and June 30 of every tax year in respect of sales of securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Ordinance and regulations promulgated thereunder the aforementioned return need not be filed and no advance payment must be paid. Capital gain is also reportable on the annual income tax return.

Dividends

As of January 1, 2014, any distribution of dividends from income attributed to a Preferred Enterprise is generally subject to a tax at a rate of 20%. However, if such dividends are distributed to an Israeli company, no tax is imposed. As of January 1, 2014, dividends distributed from income attributed to an Approved Enterprise and/or a Benefited Enterprise are subject to a tax rate of 20%. Notwithstanding the above, a reduced 15% tax rate will be applicable if the dividend was distributed out of income of: (i) Approved Enterprise activated prior to 2014; or (ii) Benefited Enterprise with a "Year of Election" prior to 2014.

Those rates may be further reduced under the provisions of any applicable double tax treaty.

If the dividend is attributable partly to income derived from an Approved Enterprise, Benefited Enterprise or Preferred Enterprise, and partly from other sources of income, the income tax rate will be a blended rate reflecting the relative portions of the types of income.

A distribution of dividends from income, which is not attributed to an Approved Enterprise/Benefited Enterprise/Preferred Enterprise to an Israeli resident individual, will generally be subject to income tax at a rate of 25%. However, a 30% tax rate will apply if the dividend recipient is a "Controlling Shareholder" (as defined above) at the time of distribution or at any time during the preceding 12 months period. If the recipient of the dividend is an Israeli resident corporation, such dividend will be exempt from income tax provided the income from which such dividend is distributed was derived or accrued within Israel. The Ordinance generally provides that a non-Israeli resident (either individual or corporation) is subject to an Israeli income tax on the receipt of dividends at the rate of 25% (30% if the dividends recipient is a "Controlling Shareholder" (as defined above), at the time of distribution or at any time during the preceding 12 months period); those rates are subject to a reduced tax rate under the provisions of an applicable double tax treaty.

Thus, under the U.S.-Israel Double Tax Treaty the following rates will apply in respect of dividends distributed by an Israeli resident company to a U.S. resident: (i) with regard to a dividend distributed from income which is not attributed to an Approved Enterprise/ Benefited Enterprise/ Preferred Enterprise, if the U.S. resident is a corporation which holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding shares of the voting stock of the Israeli resident paying corporation and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain type of interest or dividends – the maximum tax rate of withholding is 12.5% if a certificate for a reduced withholding tax rate would be provided in advance from the Israeli Tax Authority, (ii) with regard to a dividend distributed from income derived from an Approved Enterprise/ Benefited Enterprise/ Preferred Enterprise under the Investments Law, if the U.S. resident is a corporation which holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding shares of the voting stock of the Israeli resident paying corporation and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain type of interest or dividends, and given the fact that the text of the U.S.-Israel Double Tax Treaty has not been updated, the tax rate of withholding 15% will be applicable if a certificate for a reduced withholding tax rate would be provided in advance from the Israeli Tax Authority, and (iii) in all other cases, the tax rate is 25%, or the domestic rate (if such is lower). The aforementioned rates under the Israel U.S. Double Tax Treaty will not apply if the dividend income was derived through a permanent establishment of the U.S. resident in Israel.

A non-Israeli resident who receives dividend income derived from or accrued from Israel, from which the full amount of tax was withheld at source, is generally exempt from the obligation to file tax returns in Israel with respect to such income, provided that (i) such income was not generated from business conducted in Israel by the taxpayer, and (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed.

Payors of dividends on our shares, including the Israeli stockbroker effectuating the transaction, or the financial institution through which the securities are held, are generally required, subject to any of the foregoing exemption, reduced tax rates and the demonstration of a shareholder of his, her or its foreign residency, to withhold taxes upon the distribution of dividends at a rate of 25%, provided that the shares are registered with a Nominee Company (for corporations and individuals).

Excess Tax

Individuals who are subject to tax in Israel are also subject to an additional tax at a rate of 2% on annual income exceeding a certain threshold (approximately NIS 810,720 for 2016, which amount is linked to the annual change in the Israeli consumer price index), including, but not limited to income derived from dividends, interest and capital gains.

Foreign Exchange Regulations

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

Estate and gift tax

Israeli law presently does not impose estate or gift taxes.

U.S. Federal Income Tax Consequences

The following is a general summary of what we believe to be certain material U.S. federal income tax consequences relating to the purchase, ownership and disposition of our ordinary shares by U.S. Investors (as defined below) that hold such ordinary shares as capital assets. This summary is based on the Code, the regulations of the U.S. Department of the Treasury issued pursuant to the Code, or the Treasury Regulations, the income tax treaty between the United States and Israel (the "U.S.-Israel Tax Treaty"), and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect, or to different interpretation. No ruling has been sought from the IRS with respect to any U.S. federal income tax consequences described below, and there can be no assurance that the IRS or a court will not take a contrary position. This summary is for general information purposes only, it does not purport to be a complete analysis or listing of all potential U.S. federal income tax considerations that may apply to a U.S. Investor as a result of the purchase, ownership, and disposition of our ordinary shares, and it does not constitute tax advice. This summary does not address all of the tax considerations that may be relevant to specific U.S. Investors in light of their particular circumstances or to U.S. Investors subject to special treatment under U.S. federal income tax law (including, without limitation, banks, financial institutions, insurance companies, tax-exempt entities, retirement plans, tax-deferred accounts, regulated investment companies, "S corporations," grantor trusts, partnerships, dealers or traders in securities or currencies, brokers, real estate investment trusts, certain former citizens or residents of the United States, persons who acquire our ordinary shares as part of a straddle, hedge, conversion transaction or other integrated investment, persons subject to the alternative minimum tax, persons who acquire our ordinary shares through the exercise or cancellation of employee stock options or otherwise as compensation for their services, persons that have a "functional currency" other than the U.S. dollar, persons that own (or are deemed to own, indirectly or by attribution) 10% or more of our ordinary shares, or persons that mark their securities to market for U.S. federal income tax purposes). This summary does not address any U.S. state or local or non-U.S. tax considerations or any U.S. federal estate, gift, generation skipping or alternative minimum tax considerations or any U.S. federal tax consequences other than U.S. federal income tax consequences.

As used in this summary, the term "U.S. Investor" means a beneficial owner of our ordinary shares that is, for U.S. federal income tax purposes, (i) an individual citizen or resident of the United States, (ii) a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income tax regardless of its source or (iv) a trust with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions, or that has a valid election in effect under applicable Treasury Regulations to be treated as a "United States person."

If an entity treated as a partnership for U.S. federal income tax purposes holds our ordinary shares, the tax treatment of such partnership and each partner thereof will generally depend upon the status and activities of the partnership and such partner. A holder that is treated as a partnership for U.S. federal income tax purposes should consult its own tax advisor regarding the U.S. federal income tax considerations applicable to it and its partners of the purchase, ownership and disposition of its ordinary shares.

Prospective investors should be aware that this summary does not address the tax consequences to investors who are not U.S. Investors. Prospective investors should consult their own tax advisors as to the particular tax considerations applicable to them relating to the purchase, ownership and disposition of their ordinary shares, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Taxation of U.S. Investors

The discussions under "— Distributions" and under "— Sale, Exchange or Other Disposition of Ordinary Shares" below assumes that we will not be treated as a PFIC for U.S. federal income tax purposes. We believe that we were classified as a PFIC for 2015, but have not determined whether we will be a PFIC in 2016 or any subsequent year, and it is possible that we will be a PFIC in 2016 or in any subsequent year. For a discussion of the rules that would apply if we are treated as a PFIC, see the discussion under "— Passive Foreign Investment Company."

Distributions. We have no current plans to pay dividends. To the extent we pay any dividends, a U.S. Investor will be required to include in gross income as a taxable dividend (without reduction for any Israeli tax withheld from such distribution) the amount of any distributions made on the ordinary shares to the extent that those distributions are paid out of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes. Any distributions in excess of our earnings and profits will be applied against and will reduce (but not below zero) the U.S. Investor's tax basis in its ordinary shares (thereby increasing the amount of gain, or decreasing the amount of loss, to be recognized by the U.S. Investor on a subsequent disposition of the ordinary shares), and, to the extent they exceed that tax basis, will be treated as gain from the sale or exchange of those ordinary shares. We do not expect to maintain calculations of our earnings and profits under U.S. federal income tax principles. Therefore, a U.S. Investor should expect that the entire amount of any distribution generally may be treated as dividend income.

If we were to pay dividends, we expect to pay such dividends in NIS. A dividend paid in NIS, including the amount of any Israeli taxes withheld, will be includible in a U.S. Investor's income as a U.S. dollar amount calculated by reference to the exchange rate in effect on the date such dividend is received, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted to U.S. dollars on the date of receipt, a U.S. Investor generally will not recognize a foreign currency gain or loss. However, if the U.S. Investor converts the NIS into U.S. dollars on a later date, the U.S. Investor must include, in computing its income, any gain or loss resulting from any exchange rate fluctuations. The gain or loss will be equal to the difference between (i) the U.S. dollar value of the amount included in income when the dividend was received and (ii) the amount received on the conversion of the NIS into U.S. dollars. Such gain or loss will generally be ordinary income or loss and United States source for U.S. foreign tax credit purposes. U.S. Investors should consult their own tax advisors regarding the tax consequences to them if we pay dividends in NIS or any other non-U.S. currency.

Subject to certain significant conditions and limitations, including potential limitations under the U.S.-Israel Tax Treaty, any Israeli income taxes paid on or withheld from distributions from us and not refundable to a U.S. Investor may be credited against the investor's U.S. federal income tax liability or, alternatively, may be deducted from the investor's taxable income. The election to deduct, rather than credit, foreign taxes, is made on a year-by-year basis and applies to all foreign taxes paid by a U.S. Investor or withheld from a U.S. Investor that year. Dividends paid on the ordinary shares generally will constitute income from sources outside the United States, which may be relevant in calculating a U.S. Investor's foreign tax credit limitation. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends paid on our ordinary shares should generally be categorized as "passive category income" or, in the case of some U.S. Investors, as "general category income" for U.S. foreign tax credit purposes.

Because the rules governing foreign tax credits are complex, U.S. Investors should consult their own tax advisors regarding the availability of foreign tax credits in their particular circumstances.

Dividends paid on the ordinary shares will not be eligible for the "dividends-received" deduction generally allowed to corporate U.S. Investors with respect to dividends received from U.S. corporations.

Certain distributions treated as dividends that are received by an individual U.S. Investor from "qualified foreign corporations" generally qualify for a 20% reduced maximum tax rate so long as certain holding period and other requirements are met. A non-U.S. corporation (other than a corporation that is treated as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (i) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information program, or (ii) with respect to any dividend it pays on stock which is readily tradable on an established securities market in the United States. Dividends paid by us in a taxable year in which we are not a PFIC and with respect to which we were not a PFIC in the preceding taxable year are expected to be eligible for the 20% reduced maximum tax rate, although we can offer no assurances in this regard. However, any dividend paid by us in a taxable year in which we are a PFIC or were a PFIC in the preceding taxable year will be subject to tax at regular ordinary income rates (along with any applicable additional PFIC tax liability, as discussed below). As noted above, we believe that we were classified as a PFIC for 2015 but have not determined whether we will be a PFIC for any subsequent year. In addition, a non-corporate U.S. Investor will not be eligible for reduced U.S. federal income tax rate with respect to dividend distributions on ordinary shares if (a) such U.S. Investor has not held the ordinary shares for at least 61 days during the 121-day period starting on the date which is 60 days before, and ending 60 days after the ex-dividend date, (b) to the extent the U.S. Investor is under an obligation to make related payments on substantially similar or related property or (c) with respect to any portion of a dividend that is taken into account by the U.S. Investor as investment income under Section 163(d)(4)(B) of the Code. Any days during which the U.S. Investor has diminished its risk of loss with respect to ordinary shares (for example, by holding an option to sell the ordinary shares) are not counted towards meeting the 61-day holding period. Non-corporate U.S. Investors should consult their own tax advisors concerning whether dividends received by them qualify for the reduced rate of tax.

The additional 3.8% net investment income tax (described below) may apply to dividends received by certain U.S. Investors who meet the modified adjusted gross income thresholds.

Sale, Exchange or Other Disposition of Ordinary Shares. Subject to the discussion under "— Passive Foreign Investment Company" below, a U.S. Investor generally will recognize capital gain or loss upon the sale, exchange or other disposition of our ordinary shares in an amount equal to the difference between the amount realized on the sale, exchange or other disposition and the U.S. Investor's adjusted tax basis in such ordinary shares. The adjusted tax basis in an ordinary share generally will be equal to the cost basis of such ordinary share. This capital gain or loss will be long-term capital gain or loss if the U.S. Investor's holding period in our ordinary shares exceeds one year. Preferential tax rates for long-term capital gain (currently, with a maximum rate of 20%) will apply to individual U.S. Investors. The deductibility of capital losses is subject to limitations. The gain or loss will generally be income or loss from sources within the United States for U.S. foreign tax credit purposes, possibly subject to certain exceptions under the U.S.-Israel Tax Treaty. Additionally, certain losses may be treated as foreign source to the extent certain dividends were received by the U.S. Investor within the 24-month period preceding the date on which the U.S. Investor recognized the loss. The additional 3.8% net investment income tax (described below) may apply to gains recognized upon the sale, exchange or other taxable disposition of our ordinary shares by certain U.S. Investors who meet the modified adjusted gross income thresholds.

U.S. Investors should consult their own tax advisors regarding the U.S. federal income tax consequences of receiving currency other than U.S. dollars upon the disposition of their ordinary shares.

Passive Foreign Investment Company

In general, a corporation organized outside the United States will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (i) at least 75% of its gross income is "passive income" or (ii) on average at least 50% of its assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. Assets that produce or are held for the production of passive income include, among other things, cash, even if held as working capital or raised in a public offering, marketable securities and other assets that may produce passive income. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

A foreign corporation's PFIC status is an annual determination that is based on tests that are factual in nature and our status for any year will depend on our income, assets, and activities for such year, including, without limitation, how quickly we use the cash proceeds from our initial public offering in the United States in our business. In addition, because the value of our gross assets may be determined in part by reference to our market capitalization, a decline in the value of our ordinary shares may result in our becoming a PFIC. We expect to have been classified as a PFIC for 2015, but have not determined whether we will be a PFIC in 2016 or in future years. Because the PFIC determination is highly fact intensive, there can be no assurance that we will not be a PFIC in 2016 or any subsequent year.

U.S. Investors should be aware of certain tax consequences of investing directly or indirectly in us if we are a PFIC. A U.S. Investor is subject to different rules depending on whether the U.S. Investor makes an election to treat us as a "qualified electing fund," known as a QEF election, makes a "mark-to-market" election with respect to the ordinary shares, or makes neither election. An election to treat us as a QEF will not be available if we do not provide the information necessary to make such an election. It is not expected that a U.S. Investor will be able to make a QEF election because we do not intend to provide U.S. Investors with the information necessary to make a QEF election.

QEF Election. One way in which certain of the adverse consequences of PFIC status can be mitigated is for a U.S. Investor to make a QEF election. Generally, a shareholder making the QEF election is required for each taxable year to include in income a pro rata share of the ordinary earnings and net capital gain of the QEF, subject to a separate election to defer payment of taxes, which deferral is subject to an interest charge. An election to treat us as a QEF will not be available if we do not provide the information necessary to make such an election. It is not expected that a U.S. Investor will be able to make a QEF election because we do not intend to provide U.S. Investors with the information necessary to make a QEF election. As discussed below, however, a mark-to-market election that may alleviate some of the adverse consequences of PFIC status may be available to a U.S. Investor.

Mark-to-Market Election. Alternatively, if our ordinary shares are treated as "marketable stock," a U.S. Investor would be allowed to make a "mark-to-market" election with respect to our ordinary shares, provided the U.S. Investor completes and files IRS Form 8621 in accordance with the relevant instructions and related Treasury Regulations. If that election is made, the U.S. Investor generally would include as ordinary income in each taxable year the excess, if any, of the fair market value of our ordinary shares at the end of the taxable year over such holder's adjusted tax basis in such ordinary shares. Thus, the U.S. Investor may recognize taxable income without receiving any cash to pay its tax liability with respect to such income. The U.S. Investor would also be permitted an ordinary loss in respect of the excess, if any, of the U.S. Investor's adjusted tax basis in our ordinary shares over their fair market value at the end of the taxable year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. A U.S. Investor's tax basis in our ordinary shares would be adjusted to reflect any such income or loss amount. Gain realized on the sale, exchange or other disposition of our ordinary shares would be treated as ordinary income, and any loss realized on the sale, exchange or other disposition of our ordinary shares would be treated as ordinary loss to the extent that such loss does not exceed the net mark-to-market gains previously included in income by the U.S. Investor, and any loss in excess of such amount will be treated as capital loss. Amounts treated as ordinary income will not be eligible for the favorable tax rates applicable to qualified dividend income or long-term capital gains.

Generally, stock will be considered marketable stock if it is "regularly traded" on a "qualified exchange" within the meaning of applicable Treasury Regulations. A class of stock is regularly traded on an exchange during any calendar year during which such class of stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. To be marketable stock, our ordinary shares must be regularly traded on a qualifying exchange (i) in the United States that is registered with the SEC or a national market system established pursuant to the Exchange Act or (ii) outside the United States that is properly regulated and meets certain trading, listing, financial disclosure and other requirements. Our ordinary shares are expected to constitute "marketable stock" as long as they remain listed on the NASDAQ Capital Market and are regularly traded.

A mark-to-market election will not apply to our ordinary shares held by a U.S. Investor for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. The election will not remain in effect if the ordinary shares are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election. A mark-to-market election will not apply to any PFIC subsidiary that we own. Each U.S. Investor is encouraged to consult its own tax advisor with respect to the availability and tax consequences of a mark-to-market election with respect to our ordinary shares.

Each U.S. investor should consult its own tax adviser with respect to the applicability of the "net investment income tax" (discussed below) where a mark-to-market election is in effect.

Default PFIC Rules. A U.S. Investor who does not make a timely QEF election or a mark-to-market election, referred to in this disclosure as a "Non-Electing U.S. Investor," will be subject to special rules with respect to (i) any "excess distribution" (generally, the portion of any distributions received by the Non-Electing U.S. Investor on the ordinary shares in a taxable year in excess of 125% of the average annual distributions received by the Non-Electing U.S. Investor in the three preceding taxable years, or, if shorter, the Non-Electing U.S. Investor's holding period for the ordinary shares), and (ii) any gain realized on the sale or other disposition of such ordinary shares. Under these rules:

- the excess distribution or gain would be allocated ratably over the Non-Electing U.S. Investor's holding period for such ordinary shares;
- the amount allocated to the current taxable year and any year prior to us becoming a PFIC would be taxed as ordinary income; and
- the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year.

If a Non-Electing U.S. Investor who is an individual dies while owning our ordinary shares, the Non-Electing U.S. Investor's successor would be ineligible to receive a step-up in tax basis of such ordinary shares. Non-Electing U.S. Investors should consult their tax advisors regarding the application of the "net investment income tax" (described below) to their specific situation.

To the extent a distribution on our ordinary shares does not constitute an excess distribution to a Non-Electing U.S. Investor, such Non-Electing U.S. Investor generally will be required to include the amount of such distribution in gross income as a dividend to the extent of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) that are not allocated to excess distributions. The tax consequences of such distributions are discussed above under "— Taxation of U.S. Investors — Distributions." Each U.S. Investor is encouraged to consult its own tax advisor with respect to the appropriate U.S. federal income tax treatment of any distribution on our ordinary shares.

If we are treated as a PFIC for any taxable year during the holding period of a Non-Electing U.S. Investor, we will continue to be treated as a PFIC for all succeeding years during which the Non-Electing U.S. Investor is treated as a direct or indirect Non-Electing U.S. Investor even if we are not a PFIC for such years. A U.S. Investor is encouraged to consult its tax advisor with respect to any available elections that may be applicable in such a situation, including the "deemed sale" election of Section 1298(b)(1) of the Code (which will be taxed under the adverse tax rules described above).

We may invest in the equity of foreign corporations that are PFICs or may own subsidiaries that own PFICs. If we are classified as a PFIC, under attribution rules U.S. Investors will be subject to the PFIC rules with respect to their indirect ownership interests in such PFICs, such that a disposition of the ordinary shares of the PFIC or receipt by us of a distribution from the PFIC generally will be treated as a deemed disposition of such ordinary shares or the deemed receipt of such distribution by the U.S. Investor, subject to taxation under the PFIC rules. There can be no assurance that a U.S. Investor will be able to make a QEF election with respect to PFICs in which we invest, and a U.S. Investor may not make a mark-to-market election with respect to a PFIC in which we invest. Each U.S. Investor is encouraged to consult its own tax advisor with respect to tax consequences of an investment by us in a corporation that is a PFIC.

Under Section 1291(f) of the Code, the IRS has issued proposed Treasury regulations that, subject to certain exceptions, would cause a U.S. Investor that had not made a timely QEF election to recognize gain upon certain transfers of our ordinary shares that would otherwise not be subject to U.S. federal income tax (e.g., gifts and exchanges pursuant to corporate reorganizations).

The U.S. federal income tax rules relating to PFICs, QEF elections, and mark-to market elections are complex. U.S. Investors are urged to consult their own tax advisors with respect to the purchase, ownership and disposition of our ordinary shares, any elections available with respect to such ordinary shares and the IRS information reporting obligations with respect to the purchase, ownership and disposition of our ordinary shares.

Certain Reporting Requirements

Certain U.S. Investors are required to file IRS Form 926, Return by U.S. Transferor of Property to a Foreign Corporation, and certain U.S. Investors may be required to file IRS Form 5471, Information Return of U.S. Persons With Respect to Certain Foreign Corporations, reporting transfers of cash or other property to us and information relating to the U.S. Investor and us. Substantial penalties may be imposed upon a U.S. Investor that fails to comply.

In any year in which we are classified as a PFIC, a U.S. Investor will be required to file IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund).

In addition, recently enacted legislation requires certain U.S. Investors to report information on IRS Form 8938 with respect to their investments in certain "foreign financial assets," which would include an investment in our ordinary shares, to the IRS.

Investors who fail to report required information could become subject to substantial civil and criminal penalties. U.S. Investors should consult their tax advisors regarding the possible implications of these reporting requirements on their investment in our ordinary shares.

Disclosure of Reportable Transactions

If a U.S. Investor sells or disposes of the ordinary shares at a loss or otherwise incurs certain losses that meet certain thresholds, such U.S. Investor may be required to file a disclosure statement with the IRS. Failure to comply with these and other reporting requirements could result in the imposition of significant penalties.

Backup Withholding Tax and Information Reporting Requirements

Generally, information reporting requirements will apply to distributions on our ordinary shares or proceeds on the disposition of our ordinary shares paid within the United States (and, in certain cases, outside the United States) to U.S. Investors other than certain exempt recipients, such as corporations. Furthermore, backup withholding (currently at 28%) may apply to such amounts if the U.S. Investor fails to (i) provide a correct taxpayer identification number, (ii) report interest and dividends required to be shown on its U.S. federal income tax return, or (iii) make other appropriate certifications in the required manner. U.S. Investors who are required to establish their exempt status generally must provide such certification on IRS Form W-9.

Backup withholding is not an additional tax. Amounts withheld as backup withholding from a payment may be credited against a U.S. Investor's U.S. federal income tax liability and such U.S. Investor may obtain a refund of any excess amounts withheld by filing the appropriate claim for refund with the IRS and furnishing any required information in a timely manner.

Medicare Tax on Investment Income

Certain U.S. persons, including individuals, estates and trusts, will be subject to an additional 3.8% Medicare tax, or "net investment income tax," on unearned income. For individuals, the additional net investment income tax applies to the lesser of (i) "net investment income" or (ii) the excess of "modified adjusted gross income" over $200,000 ($250,000 if married and filing jointly or $125,000 if married and filing separately). "Net investment income" generally equals the taxpayer's gross investment income reduced by the deductions that are allocable to such income. Investment income generally includes passive income such as interest, dividends, annuities, royalties, rents, and capital gains. U.S. Investors are urged to consult their own tax advisors regarding the implications of the additional net investment income tax resulting from their ownership and disposition of our ordinary shares.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PROSPECTIVE INVESTOR. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF RELATING TO THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

F. Dividends and Paying Agents.

Not applicable.

G. Statements by Experts.

Not applicable.

H. Documents on Display.

You may read and copy this Annual Report on Form 20-F, including the related exhibits and schedules, and any document we file with the SEC without charge at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, DC 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains an Internet website that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are also available to the public through the SEC's website at http://www.sec.gov.

As a foreign private issuer, we will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. Furthermore, as a foreign private issuer, we are also not subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act. In addition, we will not be required under the Exchange Act to file annual or other reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. Instead, we will file with the SEC, within 120 days after the end of each fiscal year, or such other applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm. We also intend to furnish certain other material information to the SEC under cover of Form 6-K.

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

We maintain a corporate website at *www.intecpharma.com.* Information contained on, or that can be accessed through, our website does not constitute a part of this annual report on Form 20-F. We have included our website address in this annual report on Form 20-F solely as an inactive textual reference.

I. Subsidiary Information.

Not applicable.

ITEM 11. Quantitative and Qualitative Disclosures About Market Risk.

Quantitative and Qualitative Disclosure About Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position, results of operations or cash flows due to adverse changes in financial market prices and rates, including interest rates and foreign exchange rates, of financial instruments.

Foreign Currency Exchange Risk

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the U.S. dollar, our functional and reporting currency effective January 1, 2016, mainly against the NIS and the Euro. Our NIS and Euro expenses consist principally of payments made to employees, sub-contractors and consultants for clinical trials and other research and development activities. We anticipate that a portion of our expenses will continue to be denominated in currencies other than the U.S. dollar. If the U.S. dollar fluctuates significantly against the NIS it may have a negative impact on our results of operations. We manage our foreign exchange risk by aligning the currencies for holding short-term investments with the currencies of expected expenses, based on our expected cash flows.

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

Set forth below is a sensitivity test to possible changes in U.S. dollars / NIS exchange rate as of December 31, 2015:

Sensitive instrument	Income (loss) from change in exchange rate (U.S. dollars in thousands)		Value (U.S. dollars in thousands)	Income (loss) from change in exchange rate (U.S. dollars in thousands)	
	Down 2%	Down 5%		Up 5%	Up 2%
Cash and cash equivalents	50	124	2,485	(124)	(50)
Financial assets at fair value through profit or loss	40	101	2,024	(101)	(40)
Accounts receivable (except prepaid expenses and advances to suppliers)	16	39	780	(39)	(16)
Accounts payable and accrued expenses	(17)	(42)	(835)	42	17
Total loss	89	222		(222)	(89)

Interest Rate Risk

We have an exposure to interest income sensitivity, which is affected by changes in the general level of Israeli interest rates. We currently do not hedge against interest rate exposure. Because of the short-term maturities of our cash equivalents, short-term bank deposits and investment securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our investment securities. A 10% change in interest rates would not have a material effect on the fair value of our investment portfolio.

We do not anticipate undertaking any significant long-term borrowings. At present, our investments consist primarily of cash and cash equivalents, short-term bank deposits and financial assets at fair value. We may invest in investment-grade marketable securities with maturities of up to three years, including commercial paper, money market funds, and government/non-government debt securities. The primary objective of our investment activities is to preserve principal while maximizing the income that we receive from our investments without significantly increasing risk and loss.

ITEM 12. Description of Securities Other Than Equity Securities.

A. Debt Securities.

Not applicable.

B. Warrants and Rights.

Not applicable.

C. Other Securities.

Not applicable.

D. American Depositary Shares.

Not applicable.

PART II

ITEM 13. Defaults, Dividend Arrearages and Delinquencies.

Not applicable.

ITEM 14. Material Modifications to the Rights of Security Holders and Use of Proceeds.

A. Not applicable.

B. Not applicable.

C. Not applicable.

D. Not applicable.

E. Use of Proceeds.

On August 7, 2015, we completed our initial public offering of 5,025,000 ordinary shares at a public offering price of $6.00 per ordinary share. On September 18, 2015, the underwriters' exercised their underwriters' option in part to purchase an additional 638,750 ordinary shares to cover over-allotments, for aggregate gross offering proceeds of approximately $34.0 million. Maxim Group LLC and Roth Capital Partners acted as joint book-running managers of the offering. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form F-1, which was declared effective on August 3, 2015 (File No. 333-204836).

We received aggregate net proceeds from the offering of approximately $30.32 million, after deducting approximately $2.38 million of underwriting discounts and commissions and approximately $1.3 million of estimated offering expenses directly payable by us. None of the underwriting discounts and commissions or other offering expenses were incurred or paid to our directors or officers or their associates or to persons owning ten percent or more of our ordinary shares or to any of our affiliates.

As of December 31, 2015, the net proceeds from our initial public offering were held in cash and cash equivalents and short-term deposits. Since then, we have deployed approximately $30.7 million to fund our Phase III clinical trial for our current product candidate, AP-CDLD, and its continued development, and the balance for working capital, capital expenditures and other general corporate purposes, including a Phase I clinical trial that we initiated in December 2015 for one of our early stage pipeline products. We will need to raise additional capital in order to complete our Phase III clinical trial for AP-CDLD and its continued development. We have broad discretion in the use of the net proceeds from our initial public offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our ordinary shares.

We have no current understandings, commitments or agreements with respect to any material acquisition of or investment in any technologies, products or companies.

ITEM 15. Controls and Procedures.

Disclosure Controls and Procedures

We performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported timely within the time period specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act, is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving the desired control objectives. Based on our evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15(d) - 15(e) of the Exchange Act) as of the end of the period covered by this report are effective at such reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. Audit Committee Financial Expert.

Our board of directors affirmatively determined that Gil Bianco is an audit committee financial expert as defined by the SEC rules and has the requisite financial experience as defined by the NASDAQ Capital Market corporate governance rules. For information relating to Mr. Bianco's qualifications and experience, see "Item 6. Directors, Senior Management and Employees—A. Directors and Senior Management."

ITEM 16B. 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" as defined in Item 16B of Form 20-F promulgated by the SEC and as required by the Nasdaq Capital Market Listing Rules, which refers to Section 406(c) of the Sarbanes-Oxley Act. Section 406(c) of the Sarbanes-Oxley Act provides that a "code of ethics" means such standards as are reasonably necessary to promote (i) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; (ii) full, fair, accurate, timely and understandable disclosure in the periodic reports required to be filed by the issuer; and (iii) compliance with applicable governmental rules and regulation.

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 16C. Principal Accountant 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, 2015 and 2014, for which audited financial statements appear in this Annual Report on Form 20-F.

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 2014 and 2015.

	2015	2014
	(US$ in thousands)	(US$ in thousands)
Audit Fees (1)	219	133
Audit-Related Fees (2)	-	-
Tax Fees (3)	3	-
All Other Fees (4)	-	-
Total	222	133

(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 including audit services in connection with our initial public offering in the United States in August 2015.
(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 financial statements and are not reported under item (1).
(3) Tax fees relate to tax compliance, planning and advice.
(4) All other fees would be fees billed for products and services provided by the principal accountant, other than the services reported in items (1) through (3).

Audit Committee 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 & Kesselman during 2014 and 2015 and the fees paid for such services.

ITEM 16D. Exemptions from the Listing Standards for Audit Committees.

Not applicable.

ITEM 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

Not applicable.

ITEM 16F. Change in Registrant's Certifying Accountant.

Not applicable.

ITEM 16G. Corporate Governance.

Companies incorporated under the laws of the State of Israel whose shares are publicly traded, including companies with shares listed on the NASDAQ Capital Market, are considered public companies under Israeli law and are required to comply with various corporate governance requirements under Israeli law relating to such matters as external directors, the audit committee, the compensation committee and an internal auditor. These requirements are in addition to the corporate governance requirements imposed by the Listing Rules of the NASDAQ Capital Market and other applicable provisions of U.S. securities laws to which we became subject (as a foreign private issuer) upon the closing of our initial public offering in the United States and the listing of our ordinary shares on the NASDAQ Capital Market. Under the Listing Rules of the NASDAQ Capital Market, a foreign private issuer, such as us, may generally follow its home country rules of corporate governance in lieu of the comparable requirements of the Listing Rules of the NASDAQ Capital Market, except for certain matters including (among others) the composition and responsibilities of the audit committee and the independence of its members within the meaning of the rules and regulations of the SEC.

NASDAQ Capital Market Listing Rules and Home Country Practices

In accordance with Israeli law and practice, and subject to the exemption set forth in Rule 5615 of the Listing Rules of the NASDAQ Capital Market, if our ordinary shares are approved for listing on the NASDAQ Capital Market we intend to follow the provisions of the Companies Law, rather than the Listing Rules of the NASDAQ Capital Market, with respect to the following requirements:

- *Distribution of certain reports to shareholders.* As opposed to the Listing Rules of the NASDAQ Capital Market, which require listed issuers to make certain reports, such as annual reports, interim reports and quarterly reports, available to shareholders in one of a number of specific manners, Israeli law does not require us to distribute periodic reports directly to shareholders, and the generally accepted business practice in Israel is not to distribute such reports to shareholders, but to make such reports available through a public website. In addition to making such reports available on a public website, we plan to make our audited financial statements available to our shareholders at our offices and will only mail such reports to shareholders upon request. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules. See "Where You Can Find More Information" for a description of our Exchange Act reporting obligations.

- *Nomination of directors.* With the exception of our external directors and directors elected by our board of directors due to vacancy, our directors are elected by an annual meeting of our shareholders to hold office until the next annual meeting following his or her election. See "Management — Board Practices." The nominations for directors, which are presented to our shareholders by our board of directors, are generally made by the board of directors itself, in accordance with the provisions of our articles of association and the Companies Law. Nominations need not be made by a nominating committee of our board of directors consisting solely of independent directors or by independent directors constituting a majority of independent directors, as required under the Listing Rules of the NASDAQ Capital Market.

- *Compensation of officers.* We follow the provisions of the Companies Law with respect to matters in connection with the composition and responsibilities of our compensation committee, office holder compensation and any required approval by the shareholders of such compensation. Israeli law and our articles of association do not require that the independent members of our board of directors, or a compensation committee composed solely of independent members of our board of directors, determine an executive officer's compensation, as is generally required under the Listing Rules of the NASDAQ Capital Market with respect to the Chief Executive Officer and all other executive officers of a company. However, the Companies Law requires that each of our audit and compensation committees be comprised of at least three members, including all of our external directors, and that the external or independent directors must constitute a majority of the members of each committee. See "Management — Board Practices — External Directors." In addition, the Companies Law requires that additional members of the compensation committee and the external directors be compensated equally. Our compensation committee has been established and conducts itself in accordance with the provisions governing the composition of and the responsibilities of a compensation committee as set forth in the Companies Law. Furthermore, compensation of office holders is determined and approved by our compensation committee, and in general, by our board of directors as well, and in certain circumstances by our shareholders. Thus, we will seek shareholder approval for all corporate actions with respect to office holder compensation (including the compensation required to be approved for our chief executive officer) requiring such approval under the requirements of the Companies Law, including seeking prior approval of the shareholders for the compensation policy and for certain office holder compensation, rather than seeking approval for such corporate actions in accordance with Listing Rules of the NASDAQ Capital Market. For more information, see "Compensation Committee and Compensation Policy."

- *Compensation Committee.* According to the Companies Law, we established a compensation committee. Prior to the consummation of our initial public offering in the United States, our board of directors affirmatively determined that each member of our compensation committee qualifies as "independent" under applicable NASDAQ Capital Market and SEC rules.

- *Independent directors.* Israeli law does not require that a majority of the directors serving on our Board be "independent," as defined under NASDAQ Capital Market Listing Rule 5605(a)(2), but rather requires we have at least two external directors who meet the requirements of the Companies Law, as further described under "Management — Board Practices — External Directors." We are required, however, to ensure that all members of our audit committee are "independent" under the Companies Law and the applicable NASDAQ Capital Market and SEC criteria for independence and under Israeli law, the audit committee and compensation committee must each include all external directors then serving on our board of directors. We must also ensure that a majority of the members of our audit committee are "unaffiliated directors" as defined in the Companies Law as further described under the caption "— Audit Committee — Companies Law Requirements." Israeli law does not require that our independent directors conduct regularly scheduled meetings at which only such independent directors are present, as required by the NASDAQ Capital Market Listing Rules. Prior to the consummation of our initial public offering in the United States, our board of directors affirmatively determined that each of Gil Bianco, Amir Hayek, Hila Karah and Issac Silberman qualified as "independent" under the NASDAQ Capital Market independence standards.

- *Shareholder approval*. We will seek shareholder approval for all corporate actions requiring such approval under the requirements of the Companies Law, rather than seeking approval for corporate actions in accordance with NASDAQ Capital Market Listing Rule 5635. In particular, under this NASDAQ Capital Market rule, shareholder approval is generally required for: (i) an acquisition of shares or assets of another company that involves the issuance of 20% or more of the acquirer's shares or voting rights or if a director, officer or 5% shareholder has greater than a 5% interest in the target company or the consideration to be received; (ii) the issuance of shares leading to a change of control; (iii) adoption or amendment of equity compensation arrangements; and (iv) issuances of 20% or more of the shares or voting rights (including securities convertible into, or exercisable for, equity) of a listed company via a private placement (or via sales by directors, officers or 5% shareholders) if such equity is issued (or sold) at below the greater of the book or market value of shares. By contrast, under the Companies Law, shareholder approval is required for, among other things: (a) transactions with directors concerning the terms of their service or indemnification, exemption and insurance for their service (or for any other position that they may hold at a company), for which approvals of the compensation committee, board of directors and shareholders are all required, (b) extraordinary transactions with controlling shareholders of publicly held companies, which require the special approval further described under "Disclosure of personal interests of controlling shareholders and approval of certain transactions," (c) terms of office and employment or other engagement of our controlling shareholder, if any, or such controlling shareholder's relative, which require the special approval further described under "Disclosure of personal interests of controlling shareholders and approval of certain transactions," (d) approval of transactions with our Chief Executive Officer with respect to his or her compensation, whether in accordance with our approved compensation policy or not in accordance with our approved compensation policy, or transactions with our officers not in accordance with our approved compensation policy, and (e) approval of our compensation policy for office holders. In addition, under the Companies Law, a merger requires approval of the shareholders of each of the merging companies. See also "Additional Information — Memorandum and Articles of Association — Merger."

- *Quorum for shareholder meetings*. As permitted under the Companies Law, pursuant to our articles of association, the quorum required for an ordinary meeting of shareholders will consist of at least two shareholders present in person, by proxy or by other voting instrument in accordance with the Companies Law, who hold at least 25% of the voting power of our shares (and in an adjourned meeting, with some exceptions, any number of shareholders), instead of 33 ⅓% of the issued share capital required under the NASDAQ Capital Market corporate governance rules.

Other than the foregoing home country practices, we otherwise comply with the rules generally applicable to U.S. domestic companies listed on the NASDAQ Capital Market. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other NASDAQ Capital Market corporate governance rules. Following our home country corporate governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on the NASDAQ Capital Market may provide less protection to you than what is accorded to investors under the Listing Rules of the NASDAQ Capital Market applicable to domestic U.S. issuers.

ITEM 16H. Mine Safety Disclosure.

Not applicable.

PART III

ITEM 17. Financial Statements.

We have responded to Item 18 in lieu of responding to this item.

ITEM 18. Financial Statements.

Please refer to the financial statements beginning on page F-1. The following financial statements, financial statement schedules and related notes are filed as part of this Annual Report on Form 20-F, together with the report of the independent registered public accounting firm.

INTEC PHARMA LTD.
2015 ANNUAL REPORT

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the shareholders of
INTEC PHARMA LTD.

We have audited the accompanying statements of financial position of Intec Pharma Ltd. (the "Company") at December 31, 2014 and 2015 and the related statements of comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's Board of Directors and management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by the Company's Board of Directors and management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2014 and 2015 and the results of its operations, changes in equity and cash flows for each of the three years in the period ended December 31, 2015, in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB").

We draw your attention to note 1a(2) to the financial statements, which notes that the Company has not yet generated any revenues from its operations and has cumulative losses (as of December 31, 2015 the cumulative losses were approximately NIS 193 million). The Company's current cash resources are not sufficient to complete the research and development of all of its products. Management expects that the Company will continue to incur losses in the foreseeable future from its activities, which will result in negative cash flows from operating activities. If the Company is unsuccessful in funding its plans, it may need to make the necessary changes to its operations to reduce the level of expenditures in line with available resources.

Tel-Aviv, Israel
March 10, 2016

/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

INTEC PHARMA LTD.
STATEMENTS OF FINANCIAL POSITION

	Note	December 31		Convenience translation into USD (note 1b) December 31,
		2014	2015	2015
		NIS in thousands		In thousands
Assets				
CURRENT ASSETS:				
Cash and cash equivalents	5a	22,287	92,277	23,649
Short-term bank deposits	5b		19,510	5,000
Financial assets at fair value through profit or loss	6	7,820	7,897	2,024
Restricted bank deposits	11d, 11e	292	240	62
Other receivables	7	1,120	9,211	2,361
		31,519	129,135	33,096
NON-CURRENT ASSETS -				
Property and equipment	8	17,101	15,906	4,076
TOTAL ASSETS		48,620	145,041	37,172
Liabilities and equity				
CURRENT LIABILITIES -				
Accounts payable and accruals:				
Trade		716	2,394	614
Other	9	6,503	2,731	701
		7,219	5,125	1,315
NON-CURRENT LIABILITIES -				
Derivative financial instruments	10	4,528	1,277	327
COMMITMENTS AND CONTINGENT LIABILITIES	11			
TOTAL LIABILITIES		11,747	6,402	1,642
EQUITY:	13			
Ordinary shares		2,701	2,701	692
Share premium		198,566	328,985	84,312
Warrants		2,249	-	-
Accumulated deficit		(166,643)	(193,047)	(49,474)
TOTAL EQUITY		36,873	138,639	35,530
TOTAL LIABILITIES AND EQUITY		48,620	145,041	37,172

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

INTEC PHARMA LTD.
STATEMENTS OF COMPREHENSIVE LOSS

	Note	Year ended December 31			Convenience translation into USD (note 1b) December 31,
		2013	2014	2015	2015
		NIS in thousands			In thousands
RESEARCH AND DEVELOPMENT EXPENSES	14	(17,410)	(17,740)	(29,257)	(7,498)
LESS- PARTICIPATION IN RESEARCH AND DEVELOPMENT EXPENSES	11b, 11c	8,393	5,544	10,556	2,705
RESEARCH AND DEVELOPMENT EXPENSES, net		(9,017)	(12,196)	(18,701)	(4,793)
GENERAL AND ADMINISTRATIVE EXPENSES	15	(9,633)	(9,332)	(10,828)	(2,775)
OTHER GAINS, net	6, 11g	474	836	76	19
OPERATING LOSS		(18,176)	(20,692)	(29,453)	(7,549)
FINANCIAL INCOME	16	434	1,136	2,458	630
FINANCIAL EXPENSES	16	(648)	(812)	(889)	(228)
FINANCIAL INCOME (EXPENSES), net		(214)	324	1,569	402
LOSS AND COMPREHENSIVE LOSS		(18,390)	(20,368)	(27,884)	(7,147)
		NIS			USD
BASIC AND DILUTED LOSS PER ORDINARY SHARE	17	(4.25)	(4.22)	(3.58)	(0.92)

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

INTEC PHARMA LTD.
STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares					
	Number of shares	Issued and paid up share capital	Share Premium	Warrants	Accumulated deficit	Total
		NIS in thousands				
BALANCE AT JANUARY 1, 2013						
CHANGES DURING 2013:	3,984,445	1,992	146,357	7,877	(130,666)	25,560
Proceeds from issuance of shares and warrants, see note 13b(1)	231,000	116	13,561	1,338		15,015
Proceeds from issuance of shares as part of an investment agreement, see note 10	320,663	160	7,290			7,450
Exercise of warrants (Series 3)	4,181	2	262	(13)		251
Expiration of warrants (Series 3)			449	(449)		-
Exercise of options by employees and service providers	15,242	8	540			548
Share-based compensation					1,829	1,829
Comprehensive loss					(18,390)	(18,390)
BALANCE AT DECEMBER 31, 2013	4,555,531	2,278	168,459	8,753	(147,227)	32,263
CHANGES DURING 2014:						
Proceeds from issuance of shares and warrants net of NIS 742 thousand issuance costs, see note 13b(3)	577,795	289	15,392	911		16,592
Proceeds from issuance of shares as part of an addendum to an investment agreement, see note 10	202,018	101	6,499			6,600
Issuance of shares to former related party, see note11e	50,909	26	229		(255)	-
Expiration of warrants (Series 1)			5,197	(5,197)		-
Expiration of non-tradable warrants			2,218	(2,218)		-
Exercise of options by employees and service providers	14,214	7	572			579
Share-based compensation					1,207	1,207
Comprehensive loss					(20,368)	(20,368)
BALANCE AT DECEMBER 31, 2014	5,400,467	2,701	198,566	2,249	(166,643)	36,873
CHANGES DURING 2015:						
Expiration of non-tradable warrants, see note 13b(1)			1,338	(1,338)		-
Exercise of warrants (Series 7) , see note 13b(3)	208,843		7,639	(329)		7,310
Expiration of warrants (Series 7) , see note 13b(3)			582	(582)		-
Proceeds from issuance of shares through public offering, net of NIS 12,878 thousand issuance costs, see note 13b(5)	5,663,750		116,780			116,780
Shares issued as part of an anti-dilution right, see note 10	174,566		4,080			4,080
Exercise of options by employees and service providers	565		*			*
Share-based compensation					1,480	1,480
Comprehensive loss					(27,884)	(27,884)
BALANCE AT DECEMBER 31, 2015	11,448,191	2,701	328,985	-	(193,047)	138,639

* Represents an amount less than NIS 1,000 and USD 1,000

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

INTEC PHARMA LTD.
STATEMENTS OF CHANGES IN EQUITY

	Ordinary Shares					
	Number of shares	Issued and paid up share capital	Share Premium	Warrants	Accumulated deficit	Total
	Convenience translation into USD (note 1b) in thousands					
BALANCE AT JANUARY 1, 2015	5,400,467	692	50,888	576	(42,706)	**9,450**
CHANGES DURING 2015:						
Expiration of non-tradable warrants, see note 13b(1)			343	(343)		-
Exercise of warrants (Series 7), see note 13b(3)	208,843		1,958	(84)		1,874
Expiration of warrants (Series 7), see note 13b(3)			149	(149)		-
Proceeds from issuance of shares through an initial public offering, net of NIS 3,300 thousand issuance costs, see note 13b(5)	5,663,750		29,928			29,928
Shares issued as part of an anti-dilution right, see note 10	174,566		1,046			1,046
Exercise of options by employees and service providers	565		*			*
Share-based compensation					379	379
Comprehensive loss					(7,147)	(7,147)
BALANCE AT DECEMBER 31, 2015	11,448,191	692	84,312	-	(49,474)	35,530

* Represents an amount less than NIS 1,000 and USD 1,000

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

INTEC PHARMA LTD.
STATEMENTS OF CASH FLOWS

	Year ended December 31			Convenience translation into USD (note 1b)
	2013	2014	2015	December 31, 2015
	NIS in thousands			In thousands
CASH FLOWS FROM OPERATING ACTIVITIES:				
Loss for the year	(18,390)	(20,368)	(27,884)	(7,147)
Adjustments to reconcile comprehensive loss to net cash from operations (see appendix A)	6,172	3,371	(2,912)	(746)
Net cash used in operating activities	(12,218)	(16,997)	(30,796)	(7,893)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of property and equipment	(5,376)	(271)	(5,405)	(1,385)
Investments in short-term deposits	-	-	(19,425)	(4,978)
Proceeds from disposal (purchase) of financial assets at fair value through profit or loss, net	(5,955)	10,016	(1)	*
Changes in restricted bank deposits, net	76	(31)	49	12
Net cash provided by (used in) investing activities	(11,255)	9,714	(24,782)	(6,351)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Issuance of shares through public offering, net of issuance costs	-	-	116,780	29,928
Exercise of warrants (series 7)	-	-	7,310	1,874
Exercise of warrants (series 3)	251	-	-	-
Exercise of options by employees and service providers	548	579	*	*
Issuance of shares and warrants as part of an investment agreement, net of issuance costs, see note 10	17,692	-	-	-
Issuance of shares as part of an addendum to the investment agreement, see note 10	-	101	-	-
Issuance of shares and warrants, net of issuance costs	15,015	16,592	-	-
Net cash provided by financing activities	33,506	17,272	124,090	31,802
INCREASE IN CASH AND CASH EQUIVALENTS	10,033	9,989	68,512	17,558
CASH AND CASH EQUIVALENTS – BEGINNING OF YEAR	1,953	11,763	22,287	5,712
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(223)	535	1,478	379
CASH AND CASH EQUIVALENTS - END OF YEAR	11,763	22,287	92,277	23,649

* Represents an amount less than NIS 1,000 and USD 1,000

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

INTEC PHARMA LTD.
STATEMENTS OF CASH FLOWS

	Year ended December 31			Convenience translation into USD (note 1b) December 31,
	2013	2014	2015	2015
	NIS in thousands			In thousands
APPENDIX A				
Adjustments to reconcile loss and comprehensive loss to net cash provided from operations:				
Income and expenses not involving cash flows:				
Depreciation	2,176	2,092	2,898	743
Exchange differences on restricted deposits	(6)	(1)	3	*
Changes in the fair value of derivative financial instruments	(32)	729	829	212
Exchange differences on cash and cash equivalents	223	(535)	(1,478)	(379)
Exchange differences on short-term bank deposit			(85)	(22)
Losses (gains) on financial assets at fair value through profit or loss	(474)	51	(76)	(19)
Share-based compensation to investors, see note 10	88	-	-	-
Share-based compensation to employees and service providers	1,829	1,207	1,480	379
	3,804	3,543	3,571	914
Changes in operating asset and liability items:				
Decrease (increase) in other receivables	871	1,463	(8,091)	(2,073)
Increase (decrease) in accounts payable and accruals	1,497	(1,635)	1,608	413
	2,368	(172)	(6,483)	(1,660)
	6,172	3,371	(2,912)	(746)
APPENDIX B:				
Information regarding investment and financing activities not involving cash flows:				
Liability with respect to property purchase order, see note 11f		3,931		
Settlement of liability in respect to derivative financial instrument to equity, see note 10		6,499	4,080	1,046
Supplementary information to the statement of cash flows -				
Interest received	402	617	171	44

* Represents an amount less than USD 1,000

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

NOTE 1 - GENERAL INFORMATION:

a. General Information:

1) Intec Pharma Ltd. (the "Company") 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.

The Company is a limited liability public company incorporated and domiciled in Israel. The registered address of its offices is 12 Hartom St., Jerusalem, Israel.

The Company's ordinary shares are being traded on the Tel-Aviv Stock Exchange Ltd. ("TASE") Since August 4 2015, the Company's ordinary shares have also been traded on the NASDAQ Capital Market ("NASDAQ"), see note 13b(5).

2) The Company is engaged in research and development activities and has not yet generated revenues from its operations. There is no assurance that the Company's operations will generate positive cash flow. As of December 31, 2015 the cumulative losses of the Company were approximately NIS 193 million. Management expects that the Company will continue to incur losses from its operations in the foreseeable future, which will result in negative cash flows from operating activities.

The Company plans to fund its future operations through submission of applications for grants from governmental authorities and private funds and raising capital from the public and/or private investors and/or institutional investors. The Company's current cash resources are not sufficient to complete the research and development of all of its products.

The Company's management believes its cash and cash equivalents as of December 31, 2015 will allow the Company to fund its operating plan through at least 12 months from the date of this report. If the Company is unsuccessful in executing the abovementioned plans, it may need to make the necessary changes to its operations to reduce the level of expenditures in line with available resources.

3) On August 7, 2015, the Company completed its public offering of its ordinary shares on the NASDAQ. The Company raised, together with the exercise of part of the underwriters' over-allotment option, a total of approximately $30 million (NIS 117 million, net of commissions to the underwriters and offering expenses in the amount of NIS 12.9 million). For more details, see note 13b(5).

b. Convenience translation into US dollars ("dollars", "USD" or "$")

For the convenience of the reader, the reported New Israeli Shekel (NIS) amounts as of December 31, 2015 and for the year then ended have been translated into dollars at the Bank of Israel's representative rate of exchange for December 31, 2015 ($1 = NIS 3.902). The dollar amounts presented in these financial statements should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated.

c. Approval of financial statements

The financial statements were approved by the Company's Board of Directors on March 10, 2016.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a. Basis of presentation of the financial statements:

The Company's financial statements as of December 31, 2015 and December 31, 2014 and for each of the three years in the period ended December 31, 2015, have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB").

The significant accounting policies described below have been applied on a consistent basis for all years presented, unless noted otherwise.

The financial statements have been prepared on the basis of historical cost, subject to adjustments in respect of revaluation of financial assets and financial liabilities at fair value through profit or loss.

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Company's accounting policies. Areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the financial statements, are disclosed in note 3. Actual results may differ materially from estimates and assumptions used.

b. Foreign currency transaction:

1) Functional and presentation currency

Items included in the financial statements are measured using the currency of the primary economic environment in which the Company operates (the "functional currency"). The financial statements are presented in NIS, which has been the Company's functional and presentation currency since inception through December 31, 2015. Effective January 1, 2016, as a result of a number of factors, including a significant increase in expected expenses denominated in U.S. dollars relating to advanced clinical trials, the Company's functional and presentation currency will be the U.S. dollar.

2) Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the date of each transaction. Foreign exchange gains which derive from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recorded to the statement of comprehensive loss among financing income or expenses.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued):

c. Property and equipment

Property and equipment items are stated at cost less accumulated depreciation. Depreciation is computed by the straight-line method, over the estimated useful lives as follows:

	Years
Computer and peripheral equipment	3
Production and laboratory equipment	10
Office furniture and equipment	5-14
Automated production line	7

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

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Depreciation of property under construction begins when it is available for use, i.e. when it is in the location and condition necessary for it to be capable of operating in the manner intended by management.

d. Intangible assets

The Company applies the cost method of accounting for initial and subsequent measurements of intangible assets. Under this method of accounting, intangible assets are carried at cost less any accumulated amortization and any accumulated impairment losses.

Costs associated with research are recognized as an expense as incurred. Costs associated with development projects (which relate to the design and the testing of new products or improvements) are recognized as intangible assets when the following criteria are met:

- It is technically feasible to complete the intangible assets so that it will be available for use;
- Management intends to complete the intangible assets and use or sell it;
- There is an ability to use or sell the intangible assets;
- It can be demonstrated how the intangible assets will generate probable future economic benefits;
- Adequate technical, financial and other resources to complete the development and to use or sell the intangible assets are available; and costs associated with the intangible asset during development can be measured reliably.

Other development costs that do not meet the above criteria are recognized as expenses as incurred. Development costs previously recognized as an expense are not recognized as an asset in a subsequent period.

As of December 31, 2015, the Company has not yet capitalized development costs.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued):

e. Government grants and other grants:

1) The Company receives participation in research and development expenses from the State of Israel through the Office of the Chief Scientist of the Israeli Ministry of Economy ("OCS") in the form of grants which qualify as "forgivable loans", in accordance with IAS 20, "Accounting for Government Grants and Disclosure of Government Assistance," since the grants are repayable only if the Company generates revenues related to the project that is the subject of the grant.

The Company recognizes each forgivable loan as a grant receivable and a reduction of expenses on a systematic basis at the same time the Company records, as an expense, the related development costs for which the loan is received, provided that there is reasonable assurance that (a) the Company complies with the conditions attached to the loan and (b) the loan will be received. The amount of the forgivable loan is recognized based on the participation rate approved by the OCS.

Since the Company has reasonable grounds to believe it will meet the terms for forgiveness, the loan is accounted for as a government grant. Government grants relating to costs are deferred and recognized in the statement of comprehensive loss over the period necessary to match them with the costs that they are intended to compensate.

2) The Company receives other grants from certain funds. The grants are recorded to the comprehensive loss as a reduction of related research and development expenses over the period necessary to match these grants with the costs that they are intended to compensate.

f. Financial assets:

1) Classification

The Company classifies its financial assets in the following categories: (i) at fair value through profit or loss and (ii) loans and receivables. The classification depends on the purpose for which each financial asset was acquired. The Company's management determines the classification of financial assets at initial recognition.

a) Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. These assets are included in current assets, except for maturities greater than 12 months after the end of the reporting period, which are classified as non-current assets. The Company's loans and receivables are comprised of "other receivables", "cash and cash equivalents", "short term bank deposits" and "restricted bank deposits" in the statement of financial position (See note g below).

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued):

b) Financial assets at fair value through profit or loss

This category includes financial assets that are managed and their performance is evaluated on a fair value basis. Thus upon their initial recognition, these assets are designated by management at fair value through profit or loss. Assets in this category are classified as current assets if they are expected to be settled within 12 months.

2) Recognition and measurement

Regular purchases and sales of financial assets are recognized on the settlement date, which is the date on which the asset is delivered to the Company or delivered by the Company.

Investments are initially recognized at fair value plus transaction costs for all financial assets not carried at fair value through profit or loss. Financial assets carried at fair value through profit or loss are initially recognized at fair value, and transaction costs are expensed in profit or loss. Financial assets are derecognized when the rights to receive cash flows from the investments have expired or have been transferred and the Company has transferred substantially all risks and rewards of ownership. Financial assets at fair value through profit or loss are subsequently carried at fair value. Loans and receivables are subsequently recorded at amortized cost using the effective interest method.

Gains or losses arising from changes in the fair value of the "financial assets at fair value through profit or loss" are presented in the statement of comprehensive loss within "Other gains, net" in the period in which they arise.

g. Cash and cash equivalents

Cash and cash equivalents include cash on hand and short-term bank deposits (original maturities of three months or less) that are not restricted as to withdrawal or use and are therefore considered to be cash equivalents.

h. Restricted deposits

The Company has placed a lien on NIS deposits in banks to secure its liabilities and commitments to various parties. See notes 11d and 11e.

i. Share capital

The Company's ordinary shares are classified as equity. Incremental costs directly attributable to the issuance of new shares are shown in equity as a deduction from the issue proceeds.

j. Trade payables

Trade payables are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Accounts payable are classified as current liabilities if payment is due within one year or less (or in the normal operating cycle of the business if longer). Trade payables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued):

k. Provisions

Provisions are recognized when the Company has a present legal or constructive obligation as a result of past events, it is probable that an outflow of resources will be required to settle the obligation and the amount has been reliably estimated.

l. Derivative financial instruments

Derivatives are initially recognized at fair value on the date a derivative contract is entered into and are subsequently re-measured at their fair value. Changes in the fair value of derivative financial instruments are recognized in the statement of comprehensive loss within financing income or expenses.

Derivative financial instruments issued by the Company include the following:

- Derivative financial instrument - warrants ("Warrants")
- Derivative financial instrument - anti-dilution right ("Anti-dilution right")
- Derivative financial instrument - additional warrants, which were issued in November 2014 ("Additional warrants")

m. Employee benefits:

1) Retirement benefit obligations

The retirement benefit obligation of the Company is a defined contribution plan. A defined contribution plan is a post-employment benefit plan which is subject to section 14 of the Israeli severance pay law under which the Company pays fixed contributions into a separate and independent entity. The Company has no legal or constructive obligations to pay further 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 Company operates various pension plans that are generally funded through payments to insurance companies or trustee-administered funds. In accordance with their terms, the pension plans meet the definition of a defined contribution plan, as described above.

2) Vacation days and recreation pay

Labor laws in Israel entitle every employee to vacation days and recreation pay, both of which are computed annually. The entitlement with respect to each employee is based on the employee's length of service at the Company. The Company recognizes a liability and an expense in respect of vacation and recreation pay as earned by the employee based on his or her entitlement.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued):

n. Share-based payments

The Company operates an equity-settled, share-based compensation plan for employees, under which it receives services from employees as consideration for equity instruments (options) of the Company. The fair value of such services received in exchange for the grant of the options is recognized as an expense in the statement of comprehensive loss.

Non-market performance and service conditions are included in assumptions about the number of options that are expected to vest. The total amount of expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied. At the end of each reporting period, the Company revises its estimates of the number of options that are expected to vest based on the non-market vesting conditions.

The Company recognizes the impact of a revision in the original estimates, if any, in the statement of comprehensive loss, with a corresponding adjustment to equity.

When the options are exercised, the Company issues new shares. The proceeds received, net of any directly attributable transaction costs, are credited to share capital (at par value) and share premium when the options are exercised.

The fair value of the services received from service providers, other than labor services, are determined according to fair value of the services received, unless that value cannot be reliably measured, in which case the value of the benefit is determined based on the value of the instruments issued.

o. Leases

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases are charged to the statement of comprehensive loss on a straight-line basis over the period of the lease.

p. Loss per share

The computation of basic loss per share is based on the Company's loss divided by the weighted average number of ordinary shares outstanding during the period.

In calculating the diluted loss per share, the Company adds to the average number of shares outstanding that was used to calculate the basic loss per share the weighted average of the number of shares to be issued assuming all shares that have a potentially dilutive effect have been converted into shares. The potential shares, as described, are only taken into account in cases where their effect is dilutive (increasing the loss per share). Since the addition of potential shares reduces loss per share, these potential shares are not taken into account, and basic and diluted loss per share are identical.

q. Deferred taxes

Deferred income taxes are recognized, using the liability method, for temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued):

Deferred income taxes are determined using tax rates (and laws) that have been enacted or substantially enacted by the statement of financial position date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled. Deferred income tax assets are recognized only to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

Since the Company is unable to assess whether it will have taxable income in the foreseeable future, no deferred tax assets were recorded in these financial statements.

r. Standard that is not yet in effect and has not been early adopted by the Company for the financial year beginning 1 January 2015:

1) IFRS 9, Financial instruments ("IFRS 9")

IFRS 9, 'Financial instruments', addresses the classification, measurement and recognition of financial assets and financial liabilities. The complete version of IFRS 9 was issued in July 2014. It replaces the guidance in IAS 39 that relates to the classification and measurement of financial instruments. IFRS 9 retains but simplifies the mixed measurement model and establishes three primary measurement categories for financial assets: amortized cost, fair value through other comprehensive income and fair value through profit or loss. The basis of classification depends on the entity's business model and the contractual cash flow characteristics of the financial asset. Investments in equity instruments are required to be measured at fair value through profit or loss with the irrevocable option at inception to present changes in fair value in other comprehensive income. Further, the expected credit losses model replaces the incurred loss impairment model used in IAS 39. For financial liabilities, there were no changes to classification and measurement except for the recognition of changes in the Company's own credit risk in other comprehensive income for liabilities designated at fair value through profit or loss.

The standard is effective for accounting periods beginning on or after January 1, 2018. Early adoption is permitted. The Company has not yet assessed IFRS 9's full impact.

2) IFRS 16, Leases ("IFRS 16")

IFRS 16 defines a lease as a contract, or part of a contract, that conveys the right to use an asset (the underlying asset) for a period of time in exchange for consideration. Under IFRS 16 lessees have to recognize a lease liability reflecting future lease payments and a 'right-of-use asset' for almost all lease contracts.

The standard replaces the current guidance in IAS 17. The standard is effective for annual periods beginning on or after January 1, 2019. The Company has not yet assessed IFRS 16's full impact.

NOTE 3 - CRITICAL ACCOUNTING ESTIMATES

The accounting estimates are continually evaluated and adjusted based on historical experience and other factors, including expectation of future events that are believed to be reasonable under the circumstances. The Company makes estimates and assumptions concerning the future.

Such estimates, by nature, are subjective and complex and consequently may differ from actual results.

NOTE 3 - CRITICAL ACCOUNTING ESTIMATES (continued)**:**

The estimates for which there is significant risk of causing a material adjustment to the carrying amounts of liabilities within the next financial year are outlined below:

a. Share-based payments

For the purpose of the evaluation of the fair value and the manner of the recognition of share-based compensation, the Company's management is required to estimate, among other things, various parameters that are included in the calculation of the fair value of the option as well as the Company's results and the number of options that will vest. The actual results and the estimates that are made in the future may be significantly different from the current estimates.

b. Derivative financial instruments

As described in note 10, the Company has financial liabilities in respect to derivative financial instruments.

These liabilities historically were measured at fair value using a standard valuation technique for this type of instrument (Monte Carlo model) on the basis of observable inputs (such as the price of the Company's shares, risk-free interest and exercise price) and unobservable inputs (such as expected volatility, expected life and the probability of potential scenarios as described in the agreement).

Per the agreement described in note 10 and following the completion of the Company's public offering on the NASDAQ, see note 13b(5), the valuation technique of the derivative financial instruments was changed from the Monte Carlo model to the Black-Scholes model, a standard valuation technique for this type of instrument. At December 31, 2015 these liabilities were measured at fair value using the Black-Scholes model on the basis of various parameters (such as the price of the Company's shares, expected life, expected volatility, risk-free interest and exercise price).

Changes in the financial inputs underlying the model may cause significant changes in the fair value of the liability.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT:

a. Financial risk management:

1) Financial risk factors

The Company's activities expose it to a variety of financial risks: market risk (including foreign exchange risk and cash flow interest rate risk), credit risk and liquidity risk. The Company's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Company's financial performance. In the Company's opinion, the influence of market risk and credit risk is immaterial.

Risk management is carried out by the Company's management which identifies and evaluates the financial risks in close cooperation with the Company's management.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued):

a) Market risk

Foreign exchange risk – the Company's operations are exposed to foreign exchange risk derived from cash and cash equivalents, short term bank deposits, other receivables and other payables. In 2015 the gain on changes in foreign exchange rates was approximately NIS 2.3 million. These changes had no material effect on the Company's operations.

Set forth below is information on the linkage of monetary items:

	December 31, 2014			December 31, 2015		
	NIS	Dollar	Other currencies	NIS	Dollar	Other currencies
	NIS in thousands					
Assets:						
Current assets:						
Cash and cash equivalents	12,800	4,731	4,756	9,697	71,754	10,826
Short-term bank deposits	-	-	-	-	19,510	-
Financial assets at fair value through profit or loss	7,820	-	-	7,897	-	-
Restricted deposits	292	-	-	240	-	-
Other receivables	1,120	-	-	9,211	-	-
Total current assets	22,032	4,731	4,756	27,045	91,264	10,826
Total assets	22,032	4,731	4,756	27,045	91,264	10,826
Liabilities:						
Current liabilities -						
Accounts payable and accruals:						
Trade	399	317	-	731	1,589	74
Other	2,234	338	3,931	2,526	205	-
Total current liabilities	2,633	655	3,931	3,257	1,794	74
Non-current liabilities -						
Derivatives financial instruments	4,528	-	-	1,277	-	-
Total liabilities	7,161	655	3,931	4,534	1,794	74
Net asset value	14,871	4,076	825	22,511	89,470	10,752

b) Credit risks

Credit risks are handled by the Company's management. Credit risks arise from cash and cash equivalents, deposits in banks and receivable balances that have not yet been settled. The portfolio is well diversified (without a material investment in any single corporate bond) and, accordingly, minimal credit risk exists with respect to these investments.

The Company's cash and cash equivalents and financial assets at fair value through profit or loss at December 31, 2015 and 2014 were deposited with an A-rated Israeli bank. In the Company's opinion, the credit risk in respect of these balances is remote.

c) Liquidity risk

Prudent liquidity risk management implies maintaining sufficient cash and the availability of funding through an adequate amount of committed credit facilities.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued):

Management monitors rolling forecasts of the Company's liquidity reserve (comprising cash and cash equivalents, financial assets at fair value through profit or loss and deposits). This is generally carried out based on the expected cash flows in accordance with practice and limits set by the management of the Company.

The Company has not yet generated any revenue from the sale of drugs or royalties; the Company is therefore exposed to liquidity risk, taking into consideration the forecasts of cash flows required to finance its investments and other activities.

The table presented below classifies the Company's financial liabilities into relevant maturity groupings based on the remaining period to the contractual maturity date. The amounts presented in the table represent the contractual undiscounted cash flows.

	Less than one year
	NIS in thousands
Non-derivative financial liabilities:	
As of December 31, 2015 -	
Accounts payable and accruals	4,557
As of December 31, 2014 -	
Accounts payable and accruals	6,803

As of December 31, 2015, the cash and cash equivalents balance amounted to approximately NIS 92.3 million, short term bank deposits balance amounted to approximately NIS 19.5 million and the investment of bonds issued by the State of Israel and other bonds amounted to approximately NIS 7.9 million, which are expected to generate sufficient cash flow to the Company for liquidity risk management in the upcoming year.

2) Capital management

The Company's objectives when managing capital are to safeguard the Company's ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital. It should be indicated that the Company is in the development stage and has not yet generated revenue from the sale of drugs or from royalties.

3) Fair value estimations

The following is an analysis of the financial instruments measured at fair value through profit or loss, using valuation methods. The different levels have been defined as follows:

* Quoted prices (unadjusted) in active markets for identical assets or liabilities (Level 1).
* Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (that is, as prices) or indirectly (that is, derived from prices) (Level 2).
* Inputs for the asset or liability that are not based on observable market data (that is unobservable input) (Level 3).

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued):

The following table presents the Company's assets and liabilities that are measured at fair value at December 31, 2015 and December 31, 2014.

	2014		2015	
	Level 1	Level 3	Level 1	Level 3
	NIS in thousands			
Assets -				
financial assets at fair value through profit and loss	7,820		7,897	
Liabilities -				
derivative financial instruments		4,528		1,277

The following table presents the changes in Level 3 instruments for the three years ended December 31, 2015:

	Derivative financial instrument - warrants	Derivative financial instrument - anti dilution right	Derivative financial instrument - additional warrants	Total
	NIS in thousands			
Opening balance as of the date of issuance	4,781	4,384	1,165	10,330
Loss (gain) recognized in profit or loss during 2013	(1,408)	1,470	(94)	(32)
Closing balance as of December 31, 2013	3,373	5,854	1,071	10,298
Loss (gain) recognized in profit or loss during 2014	(2,141)	3,568	(698)	729
Settlement of liability in respect to derivative financial instrument to equity		(6,499)		(6,499)
Issuance of additional warrants (see note 10)	373		(373)	-
Closing balance as of December 31, 2014	1,605	2,923	-	4,528
Loss (gain) recognized in profit or loss during 2015	(328)	1,157		829
Settlement of liability in respect to derivative financial instrument to equity		(4,080)		(4,080)
Closing balance as of December 31, 2015	1,277	-	-	1,277

For more information about the assumptions used for measuring the fair value of the derivative financial instruments (level 3), see note 10.

b. Financial instruments:

Assets:

	December 31	
	2014	2015
	NIS in thousands	
1) Loans and receivables:		
Cash and cash equivalents	22,287	92,277
Short-term bank deposits	-	19,510
Restricted bank deposits	292	240
Other receivables	1,021	3,044
2) Financial assets at fair value through profit or loss	7,820	7,897

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued):

Liabilities:

	December 31	
	2014	2015
	NIS in thousands	
1) Financial liabilities at amortized cost - trade and other payables	6,803	4,557
2) Derivative financial instruments	4,528	1,227

NOTE 5 - CASH , CASH EQUIVALENTS AND SHORT TERM BANK DEPOSITS:

a. Cash and cash equivalents

As of December 31, 2015 and December 31, 2014, cash and cash equivalents include cash in hand. The carrying amount of cash and cash equivalents approximates their fair value, since the effect of discounting is immaterial.

b. Short-term bank deposits

The short-term bank deposit is linked to the Dollar and bears interest at an annual rate of 1%.

NOTE 6 - FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

The Company holds financial assets at fair value through profit or loss. Those assets include bonds issued by the State of Israel and corporate bonds with a minimum of A rating by Israeli rating agencies. As of December 31, 2015 and December 31, 2014, the amount of the financial assets at fair value through profit or loss is approximately NIS 7.9 million and NIS 7.8 million, respectively.

Changes in the fair value of the financial assets at fair value through profit or loss are recorded in the statement of comprehensive loss as "Other gains, net". The gain (loss), net from changes in fair value through profit or loss amounted to NIS 76 thousand, NIS (51) thousand and NIS 474 thousand in 2015, 2014 and 2013, respectively.

NOTE 7 - OTHER RECEIVABLES:

	December 31	
	2014	2015
	NIS in thousands	
Prepaid expenses	99	903
Advances to suppliers	-	5,264
Institutions	203	564
Grants receivable	818	2,480
	1,120	9,211

NOTE 8 - PROPERTY AND EQUIPMENT

Composition and movement grouped by major classifications:

	Cost			Accumulated depreciation			Net book value	
	Balance at beginning of year	Additions during year	Balance at end of year	Balance at beginning of year	Additions during year	Balance at end of year	Beginning of the year	End of the year
	NIS in thousands			NIS in thousands			NIS in thousands	
Composition in 2015:								
Computers and communications equipment	432	63	495	366	40	406	66	89
Production and laboratory equipment	13,090	993	14,083	7,384	1,172	8,556	5,706	5,527
Office furniture and equipment	501	47	548	350	36	386	151	162
Leasehold improvements	6,206	30	6,236	5,092	1,144	6,236	1,114	-
Automated production line, see note 11f	10,064	570	10,634		506	506	10,064	10,128
	30,293	1,703	31,996	13,192	2,898	16,090	17,101	15,906
Composition in 2014:								
Computers and communications equipment	385	47	432	331	35	366	54	66
Production and laboratory equipment	12,875	215	13,090	6,164	1,220	7,384	6,711	5,706
Office furniture and equipment	492	9	501	314	36	350	178	151
Leasehold improvements	6,206		6,206	4,291	801	5,092	1,915	1,114
	19,958	271	20,229	11,100	2,092	13,192	8,858	7,037
Automated production line, see note 11f	6,133	3,931	10,064				6,133	10,064
	26,091	4,202	30,293	11,100	2,092	13,192	14,991	17,101

NOTE 9 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	December 31	
	2014	2015
	NIS in thousands	
Expenses payable	1,363	1,108
Liability with respect to property, see note 11f	3,931	-
Salary and related expenses, including social security and other taxes	793	1,055
Accrual for vacation days and recreation pay for employees	363	514
Other	53	54
	6,503	2,731

The carrying amount of others accounts payables approximates their fair value, since effect of discounting is immaterial.

NOTE 10 - INVESTMENT AGREEMENT AND DERIVATIVE FINANCIAL INSTRUMENTS:

a. In August 2013, the Company signed an agreement with several investors in a total amount of US$5 million ("the Agreement"). According to the Agreement, the Company issued to the investors 320,663 ordinary shares with no par value and Warrants exercisable into 192,398 ordinary shares with no par value. These warrants are exercisable over a period of four years from the date of their issuance for an exercise price of NIS 64.14. Under the terms of these Warrants, the investors have the right to exercise them into shares through a net-settlement mechanism ("net settlement").

In addition, the Company undertook to issue Additional warrants exercisable into 80,166 ordinary shares with no par value, in the event in that, by September 30, 2014, the Company did not consummate an initial public offering of its ordinary shares on the NASDAQ in which it raised at least US$12 million or a merger with a company traded on the NASDAQ which immediately following the closure of such merger held free and unencumbered cash and/or publically raised, prior to September 30, 2014, a cumulative amount of at least US $12 million ("Dual Listing"). These Additional warrants were issued in November 2014 and are exercisable over a period of two years from the date of their issuance for an exercise price of NIS 64.14. See note 10e.

The investors were also entitled to anti-dilution protection until the occurrence of the earliest of one of the following events: (1) the Dual Listing, which was completed on August 7, 2015, (2) consummation of a merger or acquisition event (“M&A Event”) or (3) four years from the signing date of the Agreement. During this period, in case of the occurrence of an M&A Event or new investment in the Company at a price per share that is lower than NIS 66.93 (the “Protection Threshold Price”), an investor would have been entitled to an additional allotment of shares in accordance with a formula set forth in the Agreement, less the shares that were already issued following any previous anti-dilution right ("Downside Protection"). In the event of the activation of the Downside Protection mechanism, the exercise price of the Warrants which are still held by an investor would have been reduced by the same calculation.

b. As part of closing of the Agreement, 6,414 warrants were granted to third parties who assisted the Company with the investment process. These warrants have the same terms as the Warrants issued to the investors.

NOTE 10 - INVESTMENT AGREEMENT AND DERIVATIVE FINANCIAL INSTRUMENTS (continued):

c. Due to their terms, the Warrants and Additional warrants that were issued as part of this Agreement do not qualify for equity classification and are treated as a derivative financial liability. As of December 31, 2014 the Anti dilution right was also classified as a derivative financial liability and following the completion of the public offering on August 7, 2015, see note 13b(5), and the termination of the Downside Protection mechanism, the Anti dilution right was classified to equity.

d. On October 22, 2014, the Company and the investors signed an Addendum to the Agreement ("the Addendum") following the rights issuance that was completed on October 1, 2014 (see note 13b(3)). According to the Addendum, 202,018 additional ordinary shares were issued in consideration of approximately NIS 101 thousand. Due to the additional ordinary shares issuance, Anti dilution right in the amount of approximately NIS 6.5 million was settled to equity.

In addition, the exercise price of the Warrants which were issued to the investors, reduced from NIS 64.14 to NIS 35. Following the rights issuance, the conversion rate was adjusted so each warrant which was issued to the investors in 2013 is exercisable into 1.003 ordinary shares.

e. In November 2014, the Company issued to the investors Additional warrants since the Company failed to fulfill the Dual Listing goal. These Warrants are exercisable until October 22, 2016 for an exercise price of NIS 35 which was reduced from NIS 64.14 following the rights issuance. Under the terms of the Warrants, the investors have the right to exercise them into shares through a net-settlement.

f. According to the Agreement and following the completion of the public offering on August 7, 2015, the investors were entitled to an additional allotment of 174,566 ordinary shares and a reduction of the exercise price of the Warrants and Additional warrants from NIS 35 to NIS 21.7. Accordingly, the liability to issue additional shares, in the amount of approximately NIS 4.1 million was credited to equity, as shares were issued on October 8, 2015 and the Downside Protection terminated.

g. The financial derivatives are measured at fair value using standard valuation techniques for these types of instruments (Monte Carlo model for 2013 and 2014 and Black-Scholes model for 2015) on the basis of the following inputs:

	December 31	
Observable Inputs :	**2014**	**2015**
Share price (NIS)	23.55	20.8
Exercise price (NIS)	35	21.7
Volatility	48.7%-49.6%	45.81%-51.48%
Risk free rate	0.26%-0.67%	0.12%-0.31%
Expected term (years)	0.75-2.75	0.81-1.72

NOTE 10 - INVESTMENT AGREEMENT AND DERIVATIVE FINANCIAL INSTRUMENTS (continued):

Additional unobservable inputs for December 31, 2014:

Scenarios	Probability
Probability of occurrence of Qualifying Events only in 2015	15%-45.1%
Probability of occurrence of Qualifying Events only in 2016	2.5%
Probability of occurrence of Qualifying Events only in 2015 and 2016	2.4%
Probability of occurrence of Qualifying Events in 2015 and 2017	1.8%

Additional unobservable inputs for December 31, 2013:

Scenarios	Probability
Probability of occurrence of Qualifying Events only in 2014	5%-22.5%
Probability of occurrence of Qualifying Events only in 2015	6%
Probability of occurrence of Qualifying Events in 2014 and 2015	2.5%-17.5%
Probability of occurrence of Qualifying Events in 2014, 2015 and 2016	0.9%
Probability of occurrence of Qualifying Events in 2014, 2015 and 2017	0.9%

NOTE 11 - 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 ("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.

NOTE 11 - COMMITMENTS AND CONTINGENT LIABILITIES (continued)**:**

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

The parties are entitled to cancel the license agreement in the following cases: (a) the appointment of a liquidator or a receiver or the submission of an application for liquidation in relation to the other party, which is not cancelled within 180 days; (b) attachment proceedings, debt collecting agency proceedings and similar proceedings in connection with a significant portion of the other party's assets; (c) the liquidation or bankruptcy of the other party; (d) a significant breach that is not repaired within 30 days from the time warning 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.

In addition, as part of its development activities, the Company has engaged, from time to time, with Yissum in agreements for the provision of laboratory and research services for optimizing the technology that is being developed by the Company.

In January 2008, the Company engaged with Yissum in an agreement for the joint development of additional technology for the gastric retention of drugs. Among other things, pursuant to that agreement, intellectual property rights that may be created as a result of the joint research will be jointly owned and the Company will be granted a license to Yissum's share of those rights, in consideration for royalties at the rates detailed above. It was also clarified that the rights in intellectual property that may be developed by the Company independently and without Yissum's involvement, or that of employees of the Hebrew University, will belong entirely to the Company.

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 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 statement of comprehensive loss as a deduction from research and development expenses, as they are incurred.

NOTE 11 - COMMITMENTS AND CONTINGENT LIABILITIES (continued):

On April 15, 2015 an agreement was signed between the Company and Biogen MA Inc. ("Biogen") with respect to the execution of a research, option and licensing agreement. The agreement is for the development of a designated accordion pill with a marketed, proprietary drug of Biogen. Under the agreement, the Company will conduct activities for the development of the collaboration product, pursuant to an agreed upon research plan, which activities shall be funded by Biogen subject to achievement of certain research plan milestones.

The Company shall be entitled to consideration of $920 thousand for achievement of research plan milestones. In addition for the exercise of the option, achievement of additional milestones as described in the agreement and royalties based on sales, the Company shall be entitled to consideration of up to $147 million.

c. OCS grants program

In May and June 2015, in addition to previously approved programs, the Company received approval from the OCS for a participation in research and development activities performed by the Company ("Support Grant") from January 1, 2015 to December 31, 2015 in the amount of NIS 9.1 million. In October 2015, the Company submitted to the OCS a change request for the 2015 program and, consequently, the Support Grant was reduced to NIS 8 million.

The Company is obligated to pay 3% to 4.5% royalties to the government of Israel, computed based on the revenues from licensing the products that the Company is developing that are assisted by the governmental grants. Such commitment is up to the amount of grants received by the Company, linked to the U.S. dollar. Pursuant to reporting and royalty payment procedures of the OCS, such royalties will be paid at an annual interest rate equal to LIBOR. The Company is subject to the provisions of the Israeli Law for the Encouragement of Industrial Research and Development and related regulations (the "Encouragement Regulations"). Pursuant to the Encouragement Regulations there are restrictions regarding intellectual property and manufacturing, as defined in the Encouragement Regulations, outside of Israel, unless approval is received and additional payments are made to the OCS.

Since management's assessment is that it is reasonably assured that the Company will comply with the conditions for the forgiveness of the OCS loan, this loan is treated as a government grant and, accordingly, no liability has been recognized in the financial statements.

In 2015, 2014 and 2013, the participation in research and development expenses, amounts to approximately NIS 7.7 million, NIS 4.6 million and NIS 3.5 million, respectively.

In December 2015, in addition to previously approved programs, the Company submitted to the OCS a program of research and development activities as of January 1, 2016 to December 31, 2016. As of the date of approval of the financial statements, the Company has not yet received approval from the OCS for this program.

NOTE 11 - COMMITMENTS AND CONTINGENT LIABILITIES (continued)**:**

d. Operating long-term leases

The Company is a tenant under a lease agreement in respect of offices and operational spaces until June 30, 2018. Rent payments are linked to the CPI.

The lease payments amounted in 2015 to approximately NIS 1.7 million. The total forecast lease payments from January 1, 2016 through June 30, 2018 are approximately NIS 4.35 million.

To secure the Company's obligations to the lease agreement, the Company has granted a bank guarantee to the lessor, which amounted to approximately NIS 209 thousand as of December 31, 2015.

e. A lawsuit

On March 31, 2011, the Company received a statement of claim from a former related party, for an allocation of approximately 50,909 of the Company's ordinary shares.

The lawsuit was in respect of a performance target relating to a share-based compensation transaction with the plaintiff. The Company has recorded expenses in its 2006 financial statements (the year in which the service was rendered) with respect to the share-based compensation.

On September 8, 2013, the Israeli District Court ruled in favor of the plaintiff and ordered the Company to allocate to the plaintiff ordinary shares constituting approximately 0.89% of the Company's share capital at full dilution.

The Company filed an appeal to the Israeli Supreme Court and concurrently issued the shares to the plaintiff on April 22, 2014.

To secure the Company's obligations that may arise as part of the appeal proceedings, the Company has granted a bank guarantee to the plaintiff in the amount of approximately NIS 50 thousand.

On May 27, 2015, there was a court hearing relating to the Company's appeal. After the hearing, the Company decided to withdraw its appeal and because of this withdrawal, the Company is not required to pay costs to the plaintiff and the bank guarantee was returned to the Company.

NOTE 11 - COMMITMENTS AND CONTINGENT LIABILITIES (continued):

f. Automated Production Line

On August 30, 2011, the Company entered into an agreement with an international manufacturer for ordering an automated production line for Accordion Pills. The order covers engineering design and planning, and amounted to approximately NIS 1.3 million. In May 2013, the Company entered into a follow on order to manufacture and assemble the automated production line in the amount of approximately NIS 9.3 million. On September 1, 2015, the installation of the automated production line was completed. As of December 31, 2015 the Company paid the full amount of this order. The Company's management estimates that the useful life of the automated production line is 7 years and should be depreciated by the straight-line method.

g. Indemnification from insurance company

In 2014, the Company received indemnification from an insurance company for damage caused to the Company's offices and operational spaces in 2013, in the amount of NIS 887 thousand.

NOTE 12 - TAXES ON INCOME:

a. Corporate taxation in Israel:

1) Measurement of results for tax purposes

The results of the Company are measured for tax purposes in accordance with Generally Accepted Accounting Principles in Israel ("Israeli GAAP"). These financial statements are prepared in accordance with IFRS. The difference between IFRS and Israeli GAAP, both on an annual and a cumulative basis, causes a difference between taxable results and the results reflected in these financial statements.

2) Tax rates

Income not eligible for Approved Enterprise benefit is taxed at a regular rate,which was 26.5% in 2015. In January 2016, the regular tax rate in Israel was reduced to 25% from 2016 and thereafter.

In the absence of the expectation of taxable income in the future, no deferred tax asset is recorded in the financial statements.

Capital gains are taxed at the standard corporate tax rate.

NOTE 12 - TAXES ON INCOME (continued):

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

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

The Company 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, 2015, the Company has not yet generated operating income that will allow it to benefit from the tax benefits under the Law.

The tax benefits under the 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 loss carryforwards

As of December 31, 2015 the tax loss carryforwards of the Company were approximately NIS 193 million.

The Company has not created deferred tax assets in respect of these tax loss carryforwards since their utilization is not expected in the foreseeable future. There is no expiration date on these loss carry forwards.

d. Tax assessments

Final tax assessments have been received by the Company through the year ended December 31, 2011.

e. Value-added tax (VAT)

The Company is registered as an authorized business for VAT purposes.

NOTE 13 – EQUITY:

a. Share capital:

1) Composition

Share capital is composed of ordinary shares with no par value, as follows:

	Number of ordinary shares	
	December 31	
	2014	2015
Authorized share capital	8,000,000	16,000,000
Issued and paid up share capital	5,400,467	11,448,191

2) The ordinary shares confer upon their holders participating and voting rights in shareholders meetings (where the holder of an ordinary share has one vote), a right to receive a share of earnings and the right to receive assets of the Company upon its liquidation.

NOTE 13 – EQUITY (continued):

b. Changes in share capital:

1) On February 13, 2013, the Company entered into agreements for a private placement with two institutional investors, in accordance with which the Company allocated the offerees an overall quantity of 231,000 ordinary shares and 92,400 non-tradable and unlinked warrants (at a ratio of 2.5 shares to one warrant). Each warrant was exercisable into one ordinary share, each for an exercise price of NIS 80 (unlinked). Issuance proceeds amounted to approximately NIS 15 million. In respect of this issuance, there were no issuance costs.

   The warrants were exercisable until February 13, 2015 and all expired on that date.

2) Based on the investment agreement signed on August 6, 2013 and the Addendum to the investment agreement signed on October 22, 2014, (as described in note 10), the Company issued to several investors during 2013, 320,663 ordinary shares and 198,812 warrants and, in November 2014, 202,018 ordinary shares and 80,166 warrants. For more details, see note 10.

3) On May 27, 2014, the Company issued on the TASE a shelf prospectus for the issue of 4,000,000 ordinary share sand of up to 10 series of warrants (Series 7 to 16), each of which may include no more than 4,000,000 warrants, which are exercisable such that each warrant from each of the series 7 to 16 will be exercisable into one ordinary share.

   On October 1, 2014, the Company issued 577,795 ordinary shares and 577,795 unlinked warrants (Series 7) through a rights issuance. Each warrant (Series 7) was exercisable into one ordinary share, each for an exercise price of NIS 35 (unlinked). The shares and warrants were offered through a rights issuance to the Company's shareholders at the trading day on the TASE on September 15, 2014, such that each shareholder holding 15 ordinary shares was entitled to two ordinary shares and two warrants (Series 7) for an overall price of NIS 60. Issuance proceeds, net of issuance costs, amounted to NIS 16.6 million.

   Until April 26, 2015, 208,843 unlinked warrants (Series 7) were exercised to purchase 208,843 ordinary shares for consideration of approximately NIS 7.3 million. The remaining 368,952 unexercised and unlinked warrants (Series 7) expired on that date.

4) On March 29, 2015, further to an approval of the General Meeting on March 18, 2015, the Company executed a 50-to-1 reverse share split of the Company's ordinary shares and eliminated their par value. Upon the effectiveness of the reverse share split, (i) the number of ordinary shares was proportionally decreased and their par value was eliminated, (ii) the number of ordinary shares into which each outstanding option and outstanding warrant to purchase ordinary shares is exercisable was proportionally decreased, and (iii) the exercise price of each outstanding option and outstanding warrant to purchase ordinary shares was proportionally increased. In addition, the general meeting approved an increase of the Company's authorized share capital to include, after the reverse share split, 16,000,000 ordinary shares with no par value. Unless otherwise indicated, all of the shares numbers, the options and warrants numbers, loss per share amounts, share prices, warrant exercise prices and option exercise prices in these financial statements have been adjusted, on a retroactive basis, to reflect this 50-to-1 reverse share split.

NOTE 13 – EQUITY (continued):

5) On August 7, 2015, the Company completed its public offering of its ordinary shares on the NASDAQ, pursuant to which the Company issued 5,025,000 ordinary shares with no par value, at a price of $6.00 per ordinary share, raising a total of approximately $26.5 million (net of commissions to the underwriters and offering expenses). In addition, on September 17, 2015, the underwriters exercised in part their over-allotment option and purchased an additional 638,750 ordinary shares at a price of $6 per share. The proceeds from the exercise of the option, net of underwriters' commission and offering expenses, were approximately $3.5 million, bringing the total net proceeds from the initial public offering to approximately $30 million.

c. Share-based payment to employees and service providers:

1) On May 26, 2013, the Board of Directors approved a grant of 15,000 options to Company employees, where each option will be exercisable into one ordinary share, each for an exercise price of NIS 60.42. The options will vest over a four-year period, with half of the options vesting at the end of a two-year period from the date of grant, and the second half vesting in eight equal quarterly tranches, subsequent to the two-year period from the grant date, subject to the employees' continued employment with the Company at the time that each tranche vests. The options will expire six years after the date of grant. The value of the benefit in respect of said options, as calculated on the grant date, is approximately NIS 530 thousand. See note 13c(10)(a) regarding the assumptions in respect of this calculation.

2) In August 2013, the Company's officers were granted options. Each option will be exercisable into one ordinary share. See section 3 and section 4 of this note 13 below for options granted to the VP R&D and Operations and the Company's former Chief Financial Officer ("former CFO"), respectively. See note 19 regarding the options granted to the Chairman of the Company's Board of Directors, CEO and former Co-CEO.

3) On October 21, 2013, the Company's General Meeting approved, further to a resolution adopted by the Board of Directors on August 26, 2013 and the recommendation of the Compensation Committee on August 21, 2013, the amendment to the employment agreement with the Company's Vice President R&D and Operations. As part of the updates, the Company's Vice President R&D and Operations was granted options to purchase 57,200 ordinary shares, each for an exercise price of NIS 56.35. These options will be exercisable only in the event that a material agreement, as defined in his agreement, is signed between the Company and a third party, and subject to his continued employment with the Company. These options will expire after six years from the date of grant. The value of the benefit of these options is approximately NIS 2 million and will be recognized in the financial statements of the Company only if a material agreement is signed. In addition, the Company's Vice President R&D and Operations was granted options to purchase 10,000 ordinary shares, each for an exercise price of NIS 56.35.

NOTE 13 – EQUITY (continued):

These options will vest over a four-year period, with half of the options vesting at the end of a two-year period from the date of grant, and the second half of the options vesting in eight equal quarterly tranches subsequent to the two-year period from the grant date, subject to his continued employment at the time that each tranche vests. The value of the benefit of those options, as calculated at the date of grant, is approximately NIS 300 thousand. See note 13c(10)(d) regarding the assumptions in respect of this calculation.

4) On October 21, 2013, the Company's General Meeting approved, further to a resolution adopted by the Board of Directors on August 26, 2013 and recommendation of the compensation committee on August 21, 2013, the amendment to the employment agreement with the Company's financial manager, who served as CFO until December 31, 2014. As part of the updates to the agreement the Company's former CFO will be granted options to purchase 35,000 ordinary shares, each for an exercise price of NIS 56.35. These options will be exercisable only in the event that a material agreement, as defined in his agreement, is signed between the Company and a third party, subject to his continued employment with the Company. These options will expire after six years from the date of grant. The value of the benefit of those options is approximately NIS 1.25 million and will be recognized in the financial statements of the Company only if a material agreement is signed. In addition, the Company's former CFO was granted options to purchase 15,000 ordinary shares, each for an exercise price of NIS 56.35. These options will vest over a four-year period, with half of the options vesting at the end of a two-year period from the date of grant, and the second half of the options will vest in eight equal quarterly tranches subsequent to the two-year period from the grant date, subject to his continued employment at the time that each tranche vests. The value of the benefit of these options, as calculated at the date of grant, is approximately NIS 500 thousand. See note 13c(10)(d) regarding the assumptions in respect of this calculation.

5) See note 11e regarding the issuance of shares to former related party in April 2014.

6) On August 28, 2014, the Board of Directors approved a grant of 10,000 options to Company employees, where each option will be exercisable into one ordinary share, each for an exercise price of NIS 39.55. The options will vest over a four-year period, with half of the options vesting at the end of a two-year period from the date of grant, and the second half vesting in eight equal quarterly tranches, subsequent to the two-year period from the grant date, subject to the employees' continued employment with the Company at the time that each tranche vests. The options will expire six years after the date of grant. The value of the benefit in respect of the said options, as calculated at the date of grant, is approximately NIS 175 thousand. See note 13c(10)(e) regarding the assumptions in respect of this calculation.

NOTE 13 - EQUITY (continued)**:**

7) On August 28, 2014, the Board of Directors approved, further to a recommendation of the Compensation Committee, a grant of 24,000 options to the Company's VP Business Development and Clinical Affairs, where each option will be exercisable into one ordinary share, each for an exercise price of NIS 39.55. The options will vest over a four-year period, with half of the options vesting at the end of a two-year period from the date of grant, and the second half vesting in eight equal quarterly tranches, subsequent to the two-year period from the grant date, subject to the employees' continued employment with the Company at the time that each tranche vests. The options will expire six years after the date of grant. The value of the benefit in respect of the said options, as calculated at the date of grant, is approximately NIS 400 thousand. In addition, the Company's VP Business Development and Clinical Affairs will be granted options to purchase 36,000 ordinary shares, each for an exercise price of NIS 39.55. These options will be exercisable only in the event that a material agreement, as defined in the Company's compensation policy, is signed between the Company and a third party, subject to her continued employment with the Company. These options will expire after six years from the date of grant. The value of the benefit of those options is approximately NIS 620 thousand and will be recognized in the financial statements of the Company only if a material agreement is signed. See note 13c(10)(e) regarding the assumptions in respect of this calculation.

8) On October 6, 2014, the Board of Directors approved a grant of 61,200 options to Company employees, where each option will be exercisable into one ordinary share, each for an exercise price of NIS 32.47. The options will vest over a four-year period, with half of the options vesting at the end of a two-year period from the date of grant, and the second half vesting in eight equal quarterly tranches, subsequent to the two-year period from the grant date, subject to the employees' continued employment with the Company at the time that each tranche vests. The options will expire six years after the date of grant. The value of the benefit in respect of the said options, as calculated at the date of grant, is approximately NIS 810 thousand. See note 13c(10)(f) regarding the assumptions in respect of this calculation.

9) On December 31, 2014, the Board of Directors approved, further to a recommendation of the Compensation Committee, effective January 1, 2015, the appointment of the Company's Chief Financial Officer ("CFO"). As part of his employment agreement, a grant of 20,000 options was approved. Each option will be exercisable into one ordinary share, each for an exercise price of NIS 27.93. The options will vest over a four-year period, with half of the options vesting at the end of a two-year period from the date of grant, and the second half vesting in eight equal quarterly tranches, subsequent to the two-year period from the grant date, subject to the CFO's continued employment with the Company at the time that each tranche vests. These options will expire after six years from the date of grant. The value of the benefit in respect of the said options, as calculated at the date of grant, is approximately NIS 200 thousand. In addition, a grant of 40,000 options was approved of which 12,000 options to purchase 12,000 ordinary shares, each for an exercise price of NIS 27.93 will be exercisable only in the event that a material agreement, as defined in the Company's compensation policy, is signed between the Company and a third party, subject to the CFO's continued employment with the Company. These options will expire after six years from the date of grant. The value of the benefit of those options is approximately NIS 120 thousand and will be recognized in the financial statements of the Company only if a material agreement is signed. The remaining 28,000 options to purchase 28,000 ordinary shares were to become exercisable upon completion of an issuance of the Company's ordinary shares in a foreign stock exchange, subject to the CFO's continued employment with the Company.

NOTE 13 - EQUITY (continued)**:**

The exercise price of these options will be NIS 27.93, and in the event that a material agreement has been signed, the higher of NIS 27.93 and the average of the share price for the 30 trading days after the signing of a material agreement. These options will expire after six years from the date of grant. See note 13c(10)(g) regarding the assumptions in respect of this calculation.

In August 2015, following the completion of the public offering, see note 13b(5), 28,000 options, that were exercisable upon completion of an issuance of the Company's ordinary shares in a foreign stock exchange, as described above, were vested and the value of the benefit of those options in the amount of approximately NIS 280 thousand was recognized in the financial statements of the Company.

10) Assumptions used in calculating options' fair value:

The fair value of the options at the date of grant was calculated on the basis of the Black-Scholes model. The assumptions used in calculating the fair value of the options granted are as follows:

Date of grant	The Company's ordinary share price	Expected annual volatility *	Risk-free interest rate **	Expected life to exercise
	NIS	%	%	In years
(a) May 2013	57	68	3	6
(b) August 2013	60	45.07	1.9	3
(c) August 2013	60	51.61	2.6	4.5
(d) August 2013	60	59.95	3.2	6
(e) August 2014	38.5	46.24	1.9	6
(f) October 2014	30	46.64	1.9	6
(g) January 2015	27.93	48.07	1.9	6

* Until the end of third quarter 2013 the Company's expected volatility was derived from an average of historical volatilities of certain companies that are similar to the Company (same market cap, clinical stage, etc.). In the following periods the Company used its volatility in the calculation of expected 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.

NOTE 13 - EQUITY (continued)**:**

11) The following table contains additional information concerning options granted to employees and service providers:

	Year ended December 31		
	2013	**2014**	**2015**
	Number of options		
(a) Options with an exercise price of NIS 0.5:			
Outstanding at beginning of year	145,565	140,195	137,951
Granted	-	-	-
Exercised	(5,370)	(2,244)	(565)
Forfeited	-	-	-
Expired	-	-	-
Outstanding at end of year	140,195	137,951	137,386
Exercisable at end of year	11,800	9,556	8,991
Weighted average remaining contractual life (years)	2.5	2.15	1.72
(b) Options with an exercise price of NIS 32.47 – NIS 81.1:			
Outstanding at beginning of year	327,586	519,740	630,089
Granted	207,200	131,200	60,000
Exercised	(9,872)	(11,970)	-
Forfeited	(5,174)	(8,881)	(3,343)
Expired	-	-	-
Outstanding at end of year	519,740	630,089	686,746
Exercisable at end of year	223,334	257,714	292,562
Weighted average remaining contractual life (years)	2.5	2.41	1.83

Each option that is exercisable affords the right to acquire one ordinary share of the Company.

The options granted to the Company's employees are governed by principles of section 102 of the Israeli Income Tax Ordinance. Under the tax classification elected by the Company and in accordance with those principles, the Company is not entitled to deduct the share-based payment as a salary expense in the Company's accounting records.

NOTE 14 - RESEARCH AND DEVELOPMENT EXPENSES:

	Year ended December 31		
	2013	2014	2015
	NIS in thousands		
Payroll and related expenses	6,530	7,505	8,864
Materials and subcontractors	1,013	1,707	2,021
Professional services	2,246	1,674	1,817
Research and clinical trials	2,356	1,597	9,974
Rent and maintenance	2,460	2,329	2,489
Depreciation	2,097	2,021	2,822
Share-based compensation	359	384	591
Others	349	523	679
	17,410	17,740	29,257

NOTE 15 - GENERAL AND ADMINISTRATIVE EXPENSES:

	Year ended December 31		
	2013	2014	2015
	NIS in thousands		
Payroll and related expenses	2,778	2,826	3,224
Rent and maintenance	665	736	686
Professional services	3,990	4,165	4,577
Overseas travel and trade shows	151	89	256
Depreciation	79	71	76
Share-based compensation	1,470	823	889
Insurance, fees and others	500	622	1,120
	9,633	9,332	10,828

NOTE 16 - FINANCIAL INCOME (EXPENSES):

	Year ended December 31		
	2013	2014	2015
	NIS in thousands		
Financial income:			
Interest on cash equivalents and short term bank deposits	402	617	174
Changes in fair value of derivative financial instruments, see note 10	32		
Gain on changes in exchange rates		519	2,284
	434	1,136	2,458
Financial expenses:			
Bank fees	85	83	60
Changes in fair value of derivative financial instruments, see note 10		729	829
Loss on changes in exchange rates	239		
Transaction costs for investment agreement	324		
	648	812	889
Total financial income (expenses), net	(214)	324	1,569

NOTE 17 - LOSS PER SHARE

The basic loss per share is computed by dividing the Company's loss attributable to the holders of shares by the weighted average number of ordinary shares outstanding during the period.

	Year ended December 31		
	2013	2014	2015
	NIS in thousands (except per share amounts)		
Loss per year as reported in the statements of comprehensive loss	18,390	20,368	27,482
Weighted average of ordinary shares outstanding during the period	4,322	4,825	7,791
Basic and diluted loss per share	(4.25)	(4.22)	(3.53)

The diluted loss per share does not include 824,132, 768,040 and 659,935 options granted to employees and service providers for the years ended December 31, 2015, 2014 and 2013, respectively, 313,588 warrants (Series 1) which were issued in 2010 and expired in 2014, 577,795 warrants (Series 7) which were issued in 2014 and expired in 2015, 103,673 warrants which were issued to institutional investors in 2010 and expired in 2014, 92,400 warrants which were issued to institutional investors in 2013 and expired in 2015 and 198,812 and 80,166 warrants which were issued to several investors in 2013 and in 2014, respectively, as part of an investment agreement, because the effect of their inclusion in the calculation would be anti-dilutive.

NOTE 18 - EXPENSES RELATING TO EMPLOYEE BENEFITS:

	Year ended December 31		
	2013	2014	2015
	NIS in thousands		
Payroll and other benefits	8,734	9,667	10,968
Social security	405	456	557
Share-based compensation	1,707	1,207	1,480
Post-employment benefits –defined contribution plan	910	1,038	1,178
	11,756	12,368	14,183
Average number of employees to which these benefits are related	41	43	47

NOTE 19 - TRANSACTIONS AND BALANCES WITH RELATED PARTIES

"Related party" – has the meaning set forth in IAS 24R.

The Company's key management personnel (who are included, together with other persons, within the definition of "related parties" as defined in IAS 24R) in 2013 and 2014 include the members of the Board of Directors, the CEO and the former Co-CEO and in 2015 include the members of the Board of Directors and the CEO.

a. Transactions with related parties:

	Year ended December 31		
	2013	2014	2015
	NIS in thousands		
Key management compensation expenses:			
Salaries and short-term employee benefits	2,312	2,239	1,672
Long term employment benefits	169	165	116
Share-based compensation expenses	1,359	605	326
	3,840	3,009	2,114

1) Employment agreement with the Chairman of the Board (the "Chairman")

On October 21, 2013, the Company's General Meeting approved, further to a resolution adopted by the Board of Directors on August 26, 2013 and recommendation of the Compensation Committee on August 21, 2013, the amendment to the employment agreement with the Chairman.

The following are the main updates to the agreement:

a) Continued service in that position for an additional three years beginning on the date of the approval of the agreement by the General Meeting.

b) The Chairman was granted options to purchase 26,000 ordinary shares, each for an exercise price of NIS 56.35. 6,000 options were fully vested immediately following the approval of the general meeting and 20,000 options will vest in three equal annual tranches over a three-year period, subject to his continued employment at the time that each tranche vests. These options will expire after six years from the grant date. The value of the benefit of these options, as calculated at the date of grant, is approximately NIS 500 thousand. See note 13c(10)(b) regarding the assumptions in respect of this calculation.

c) The Chairman was granted options to purchase 14,000 ordinary shares, each for an exercise price of NIS 56.35. These options will be exercisable only in the event that a material agreement, as defined in the employment agreement, is signed between the Company and a third party, during the course of the period of the employment agreement or within 18 months from the termination of employment. These options will expire after six years from the grant date.

NOTE 19 - TRANSACTIONS AND BALANCES WITH RELATED PARTIES (continued)**:**

The value of the benefit of those options, as calculated at the date of grant, is approximately NIS 200 thousand. In addition, options to purchase 35,463 ordinary shares at an exercise price of NIS 0.5 and options to purchase 41,654 ordinary shares at an exercise price of NIS 81.1 were granted under previous amendments of his employment agreement from October 2009 and May 2011, respectively, and will be exercisable only if a material agreement is signed between the Company and a third party, during the course of the period of the employment agreement or within 18 months from the termination of the employment. The value of the benefit of the extension period, as calculated at the date of change, is approximately NIS 300 thousand. See note 13c(10)(c) regarding the assumptions in respect of this calculation.

d) The Company and the Chairman will be entitled to terminate the engagement between them upon six months prior written notice.

In addition, on May 2011 the Chairman was granted options to purchase 20,827 ordinary shares at an exercise price of NIS 81.1. These options will expire after six years from grant date.

As of the date of approval of these financial statements these options had vested but were not yet exercised.

2) Employment agreement with CEO

On October 21, 2013, the Company's General Meeting approved, further to a resolution adopted by the Board of Directors on August 26, 2013 and recommendation of the Compensation Committee on August 21, 2013, the amendment to the employment agreement with the CEO Mr. Zeev Weiss, who was appointed as Co-CEO by the Board of Directors on November 7, 2013 and who was appointed as CEO by the Board of Directors on October 7, 2014 after the former Co-CEO, Mr. Giora Carni, stepped down.

The following are the main updates to the agreement:

a) A grant of up to $300 thousand, to which the CEO was entitled subject to the signing of a material agreement as defined in the employment agreement, will be cancelled.

b) The CEO was granted options to purchase 15,000 ordinary shares with an exercise price of NIS 56.35. These options will be exercisable only in the event that a material agreement, as defined within his employment agreement, is signed between the Company and a third party, subject to his continued employment in the Company. These options will expire after six years from grant date. The value of the benefit in those options as calculated at the date of grant is approximately NIS 500 thousand and will be recognized in the financial statements of the Company only if the material agreement is signed.

NOTE 19 - TRANSACTIONS AND BALANCES WITH RELATED PARTIES (continued)**:**

c) The Company and the CEO will be entitled to terminate the engagement after six months' prior written notice.

On June 9, 2009, the CEO was granted options to purchase 42,023 ordinary shares at an exercise price of NIS 0.5. These options are exercisable only in the event that a material agreement, as defined within his employment agreement, is signed between the Company and a third party. These options will expire after ten years from the date of grant.

In addition, on May 2012, the CEO was granted options to purchase 40,000 ordinary shares at an exercise price of NIS 47.6. The options will vest over a four-year period, with half of the options vesting at the end of a two-year period from the date of grant, and the second half of the options vesting in eight equal quarterly tranches subsequent to the two-year period from the grant date, subject to his continued employment at the time that each tranche vests. These options will expire after six years from the date of grant.

3) Employment agreement with the former Co-CEO

On October 21, 2013, the Company's General Meeting approved, further to a resolution adopted by the Board of Directors on August 26, 2013 and recommendation of the Compensation Committee on August 21, 2013, the amendment to the employment agreement with the Company's former Co-CEO, Mr. Giora Carni, who was appointed as Co-CEO on November 7, 2013, and who ceased to be Co-CEO and a related party on October 7, 2014.

The following are the main updates to the agreement:

a) The former Co-CEO was granted options to purchase 20,000 ordinary shares at an exercise price of NIS 56.35. These options will be exercisable only in the event that a material agreement, as defined in his agreement, is signed between the Company and a third party, subject to his continued employment with the Company. These options will expire after six years from the date of grant. The value of the benefit of those options is approximately NIS 700 thousand and will be recognized in the financial statements of the Company only if a material agreement is signed.

b) Options to purchase 50,909 ordinary shares with an exercise price of NIS 0.5 were granted under the employment agreement dated September 2008. Such options will be exercisable only if a material agreement is signed between the Company and a third party, during the course of the period of the employment agreement.

In addition, in August 2010, the former Co-CEO was granted options to purchase 80,631 ordinary shares at an exercise price of NIS 47.6. As of the date of approval of the financial statements, these options were vested but were not yet exercised.

NOTE 19 - TRANSACTIONS AND BALANCES WITH RELATED PARTIES (continued)**:**

3) On June 27, 2010, at a General Meeting of the Company's shareholders, further to a decision by the Company's Audit Committee and its Board of Directors, the Company's shareholders approved the grant of 10,751 options to each of the three executive members of the Company's Board of Directors and to the two external directors. Each option will be exercisable into one ordinary share at an exercise price of NIS 48.91. These options will expire after ten years from the date of grant. As of the date of approval of the financial statement all these options were vested. On March 2014, one of the directors, who ceased to serve as a director in January 2014, exercised 10,751 options that were granted to him in 2010 into 10,751 ordinary shares and 904 options that were granted to him in 2006 into 904 ordinary shares for consideration of approximately NIS 526 thousand.

b. Balances with related parties:

	December 31	
	2014	**2015**
	NIS in thousands	
Statement of financial position items -		
current liabilities - Accounts payable and accruals - other	181	145

ITEM 19. Exhibits.

Exhibit No.	Exhibit Description
1.1*	Certificate of Incorporation of Orly Guy Ltd., dated October 23, 2000
1.2*	Certificate of Name Change of Orly Guy Ltd. to Intec Pharmaceutical (2000) Ltd., dated February 7, 2001
1.3*	Certificate of Name Change of Intec Pharmaceutical (2000) Ltd. to Intec Pharma Ltd., dated March 15, 2004
1.4*	Articles of Association of Intec Pharma Ltd.
2.1***	Specimen share certificate
4.1+*	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.
4.2+*	Notice of Extension Letter, dated October 5, 2004, from Intec Pharma Ltd. to Yissum Research Development Company of the Hebrew University of Jerusalem
4.3*	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
4.4*	Research Agreement, dated January 15, 2008, by and between Yissum Research Development Company of the Hebrew University of Jerusalem and Intec Pharma Ltd.
4.5*	Form of Indemnification Letter
4.6*	Intec Pharma Ltd. 2005 Share Option Plan
4.7*****	Intec Pharma Ltd. 2015 Equity Incentive Plan
4.8*	Subscription Agreement between Intec Pharma Ltd. and the investors listed on Schedules A and C thereto, dated August 6, 2013, including forms of Certificates of Warrants
4.9*	Addendum & Amendment to that certain Subscription Agreement of August 6, 2013, dated October 20, 2014, by and between Intec Pharma Ltd. and Gabriel Capital Management (GP) Ltd.
4.10*	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 and January 18, 2011
4.11	Lease Agreement – Appendix between Intec Pharma Ltd. and R.M.P.A. Assets Ltd., dated October 28, 2015
4.12*	Employment Agreement, dated August 1, 2008, between Intec Pharma Ltd. and Giora Carni as amended by the Agreement, dated October 12, 2010, and the Addendum to Agreement, dated October 21, 2013

4.13*	Employment Agreement, dated June 1, 2009, between Intec Pharma Ltd. and Zeev Weiss as amended by Amendment to Agreement, dated 2012 and Addendum to Agreement, dated November 11, 2013
4.14*	Employment Agreement, dated November 25, 2013, between Intec Pharma Ltd. and Liat Flaishon
4.15*	Employment Agreement, dated January 15, 2006, between Intec Pharma Ltd. and Nadav Navon, as amended by Annex to Employment Agreement, dated May 29, 2011, Addendum to Agreement, dated March 2012 and Amendment to Agreement, dated October 21, 2013
4.16*	Employment Agreement, dated December 31, 2014, between Intec Pharma Ltd. and Oren Mohar
4.17*	Employment Agreement, dated November 1, 2004, between Intec Pharma Ltd. and Zvika Joseph, as amended by Addendum to Employment Agreement, dated October 20, 2009, Amendment to Agreement, dated July 28, 2011 and Addendum to Agreement, dated October 21, 2013
4.18+**	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.
4.19+**	Research, Option and License Agreement, dated April 15, 2015, between Intec Pharma Ltd. and Biogen MA Inc.
4.20**	Registration Rights Agreement, dated as of July 8, 2015, by and among Intec Pharma Ltd., Gabriel Capital Management (GP) Ltd. and the other persons identified on Schedule A thereto
4.21***	Form of Indemnification Agreement
4.22***	Form of Exemption from Liability
12.1	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
12.2	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
13.1	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1	Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), independent registered public accounting firm, a member of PricewaterhouseCoopers International Limited

* Incorporated herein by reference to the Company's Registration Statement on Form F-1 filed with the SEC on June 9, 2015.
** Incorporated herein by reference to Amendment No. 1 to the Company's Registration Statement on Form F-1 filed with the SEC on July 16, 2015.
*** Incorporated herein by reference to Amendment No. 2 to the Company's Registration Statement on Form F-1 filed with the SEC on July 28, 2015.
**** Incorporated herein by reference to Post-Effective Amendment No. 1 to the Company's Registration Statement on Form F-1 filed with the SEC on August 4, 2015.
***** Incorporated herein by reference to the Company's Registration Statement on Form S-8 filed with the SEC on February 25, 2016.
\+ 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.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

INTEC PHARMA LTD.

By: /s/ Zeev Weiss
Zeev Weiss
Chief Executive Officer

Date: March 14, 2016

Exhibit 4.11

Lease Agreement - Appendix
Signed by and between the parties on June 2, 2003

Made and entered into in Jerusalem on October 28, 2015

Between: **R.M.P.A. assets ltd.**
Company number 51-1808008
Which address is 12 Hartom St., Mount Hozvim, Jerusalem
(Hereinafter referred to for the sake of brevity as "the Lessor")

On the one hand

And: **Intec Pharma Ltd.** (formerly Intec Pharmaceuticals (2000) Ltd)
Corporation number 513022780
Which address is 12 Hartom St., Mount Hozvim, Jerusalem
(Hereinafter referred to for the sake of brevity as "the Lessee")

On the other hand

Whereas the parties have signed a lease agreement ("Lease Agreement**"**) on date June 2, 2003, pursuant to which the lessee rented rental spaces located on the 1st floor and 2nd floor of the building built on the plot known as " R.M.P.A. building" (to be called hereinafter: **"The building"**), a warehouse and parking spaces, all as set forth in the Lease Agreement and its appendices;

Whereas the lessee is interested to extend the lease period and furthermore rent additional space on the second floor of the building;

Whereas the lessor has agreed to extend the lease period and to lease additional space to the lessee in accordance with the terms set out specifically in this appendix;

Therefore, it was agreed, declared and stipulated between the parties as follows: -

1. The lease period will be extended by an additional 30 months period, commencing from January 1, 2016 and until June 30, 2018.

2. The Lessee is granted an option to extend the Lease Period by a further 12 months period, commencing on July 1, 2018 and until June 30. 2019 (hereinafter: "the "option period "). The option will be exercised automatically unless the lessee notified the lessor that he does not intend to exercise the option, at least 150 days prior to the expiry of the lease period.

3. All payments in respect of the leased property, as defined in the Lease Agreement, the appendices and addenda thereto, shall remain unchanged during the additional lease period. The rental fee, management fees, parking spaces and the warehouse will increase by 5% over the increase in the index during the option period as it would be exercised.

4. As from January 1, 2016, an additional space (hereinafter: the "**additional space**") on the second floor of the building, consisting of an area of approximately 78 square meters (m^2) gross, will be added to the leased property , in accordance with the attached sketch. This space will be added to the currently leased space of 1,814 m^2 gross, 10 m^2 warehouse and 19 parking spaces. There may be a possibility of advancing the delivery date of the additional space, by a written notice to the lessor, 30 days in advance.

5. After the signing of the parties to this Appendix and after the delivery of the additional space on the 2nd floor, the property will be deemed as inclusive of the additional space, as if it was included in the Lease Agreement from the outset.

6. The additional space shall be leased to the lessee in its AS-IS condition, and all the adjustments that the lessee requires, will be carried out by the lessee and at his expense. The separation of the additional space from the rest of the office space will be carried out by the lessee and at his expense.

7. The lessee states that he is aware that the additional space is installed with central air conditioning system which is not connected to the chillers' system of the building. Should the lessee chooses to connect the additional space to the air chillers' system, he will have to carry out the change himself and at his own expense, as well as submit work plans for the lessor's approval, prior to the execution of the work.

8. The rental fees, their Linkage, the management fees and the remaining provisions of the Lease Agreement shall apply in their entirety to this Appendix and nothing in this appendix shall derogate and / or modify the provisions of the Lease Agreement, with the exception regarding the extension of the period and the addition of the supplement space leased by the lessee from the lessor.

/s/ Yair Hadar	/s/ Oren Mohar
The Lessor	**The Lessee**

Exhibit 12.1

CERTIFICATIONS

I, Zeev Weiss, certify that:

1. I have reviewed this annual report on Form 20-F of Intec Pharma Ltd.;

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 company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent 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 company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 14, 2016

By: /s/ Zeev Weiss
Zeev Weiss
Chief Executive Officer
(Principal Executive Officer)

Exhibit 12.2

CERTIFICATIONS

I, Oren Mohar, certify that:

1. I have reviewed this annual report on Form 20-F of Intec Pharma Ltd.;

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 company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent 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 company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 14, 2016

By: /s/ Oren Mohar
Oren Mohar
Chief Financial Officer
(Principal Financial Officer)

Exhibit 13.1

Certification Pursuant to 18 U.S.C Section 1350
(Adopted by Section 906 of the Sarbanes-Oxley Act of 2002)

In connection with the Annual Report of Intec Pharma Ltd. on Form 20-F for the year ended December 31, 2015 (the "Report"), each of the undersigned hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that (i) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Intec Pharma Ltd.

A signed original of this written statement required by Section 906 has been provided to Intec Pharma Ltd. and will be retained by Intec Pharma Ltd. and furnished to the Securities and Exchange Commission or its staff upon request.

March 14, 2016

By: /s/ Zeev Weiss
Zeev Weiss
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Oren Mohar
Oren Mohar
Chief Financial Officer
(Principal Financial Officer)

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-209700) of Intec Pharma Ltd. of our report dated March 10, 2016 relating to the financial statements, which appears in this Form 20-F.

Tel-Aviv, Israel
March 14, 2016

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